

**2021 HOUSE HUMAN SERVICES**

**HB 1307**

# 2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee  
Pioneer Room, State Capitol

HB 1307  
1/19/2021

To prohibit public accommodations from refusing services to an individual because the individual has not been vaccinated; and to provide a penalty
--

**Chairman Weisz** opened the hearing at 2:05 p.m.

<b>Representatives</b>	<b>Attendance</b>
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

## Discussion Topics:

- Public accommodation
- Civil penalty

**Rep. Ben Koppelman, District 16 (2:05)** introduced the bill, testified in favor, and submitted testimony #1779.

**Carel Two-Eagle (2:10)** testified in favor.

**Thea Lee (2:14)** testified in favor.

**Steve Nagel, Owner/DC 18 Health Solutions (2:16)** testified in favor and submitted testimony #1669, #1670, #1671, #1672

**Kolette Kramer (2:31)** testified in favor.

**Edward Fogarty MD, Bismarck North Dakota (2:36)** testified in favor and submitted testimony #1624.

**Alexis Wangler, Co-Founder & President Health Freedom North Dakota (2:43)** testified in favor and submitted testimony #1452.

**Travis Zabloutney, Minot (2:46)** testified in favor and submitted testimony #1751.

**Kari Roller (3:03)** testified in favor.

**Rep. Jeff Hoverson, District 3 (3:04)** testified in favor.

**Matt Gardner, Greater North Dakota Chamber (3:05)** testified in opposition.

**Courtney Koebele, Executive Director North Dakota Medical Association (3:07)** testified in opposition.

**Paul Carson, Center of Immunization Research and Education – North Dakota State University (3:09)** testified as neutral.

**Additional written testimony:** #1068, #1213, #1328, #1381, #1424, #1428, #1438, #1439, #1440, #1441, #1447, #1471, #1512, #1523, #1530, #1533, #1540, #1541, #1545, #1550, #1557, #1576, #1597, #1614, #1618, #1630, #1639, #1681, #1682,

**Chairman Weisz** adjourned at 3:18 p.m.

*Tamara Krause, Committee Clerk*

1/19/2021

HB 1307

Rep. Ben Koppelman- Testimony

Mr. Chairman and Members of the Committee, thank you for the opportunity to introduce HB 1307. I introduced this bill to ensure that all consumers maintain access to essential goods and services in the marketplace.

The response to COVID-19 has caused many changes in behavior within the businesses community in an effort to curb liability and respond to new government regulations and overreach. There has also been many discussions of required vaccinations on the national level, such as denying ones right to board an airplane if they choose not to get the COVID-19 vaccine. As of now, I am not aware of many North Dakota businesses that plan to require vaccinations, and if that is correct, then there is little or no burden placed on businesses to change their practices if this bill passes.

As many of you are aware, I am a pro-business and pro-industry legislator that is typically in favor of reducing regulation and removing government red-tape. However, I believe there is a time when some government regulation makes sense, and that is when its purpose is to protect individual freedom. Now you might look at this bill and say that it appears to take a small amount of freedom away from businesses to choose who to provide good or services to, and there is some truth in that. Some may also look at this bill and say it protects individual freedom by not allowing businesses to refuse service based on your private medical history, that is also true.

The key is that there are two fundamental conflicting freedoms here: an individual's ability to choose where to shop and what medical treatment to seek, and the business' freedom to set sales policy. Government has had to wrestle with how to balance overlapping or conflicting interests before. A few examples are ADA accessibility, not refusing service based on race or religion, or businesses having the right to refuse service to individuals who are behaving poorly. In each of these examples, the attempt is to balance fair access to services without being too overbearing on businesses.

I am supportive of the need for liability protection for businesses from communicable diseases and I believe that there are several bills like HB 1301 that do just that. I also am supportive of businesses ability to refuse entry to sick individuals that threaten to spread disease. However, I think the line is crossed when businesses refuse service based on medical history.

I am not anti-vaccine. In fact, I just received numerous vaccinations to prepare for upcoming international travel. Notably though, not a single vaccine was required, and they all had a long track record of success. Based on this information, I made the choice to proceed. I believe that it should always be a personal choice as to whether to have a procedure performed or to receive a vaccination.

Some might say that consumers should just shop elsewhere if they don't like a business' vaccination policy, and for now, this strategy might work in Fargo or Bismarck. In many small towns however, there is only one grocery store, gas station, café, or bar. If those businesses choose to have such a policy and if the consumer was lacking protection, there is not another alternative, especially if the individual does not have reliable transportation to another city. Therefore, you have a bill before you that protects consumer access and choice in the marketplace, while protecting medical privacy. It achieves this without unreasonable government regulation on businesses.

I respectfully request a Do-Pass from the Committee and would be happy to answer any questions.

*Grant Final Report*

---

Grant ID: R18 HS 017045

**Electronic Support for Public Health–Vaccine Adverse  
Event Reporting System (ESP:VAERS)**

**Inclusive dates:** 12/01/07 - 09/30/10

**Principal Investigator:**

Lazarus, Ross, MBBS, MPH, MMed, GDCompSci

**Team members:**

Michael Klompas, MD, MPH

**Performing Organization:**

Harvard Pilgrim Health Care, Inc.

**Project Officer:**

Steve Bernstein

**Submitted to:**

**The Agency for Healthcare Research and Quality (AHRQ)**

**U.S. Department of Health and Human Services**

**540 Gaither Road**

**Rockville, MD 20850**

**[www.ahrq.gov](http://www.ahrq.gov)**

# Abstract

**Purpose:** To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

**Scope:** To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

**Methods:** Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

**Results:** Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

**Key Words:** electronic health records, vaccinations, adverse event reporting

The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services of a particular drug, device, test, treatment, or other clinical service.

# Final Report

## Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

**Aim 1.** Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

**Aim 2.** Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

**Aim 3.** Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

**Aim 4.** Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

## Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values

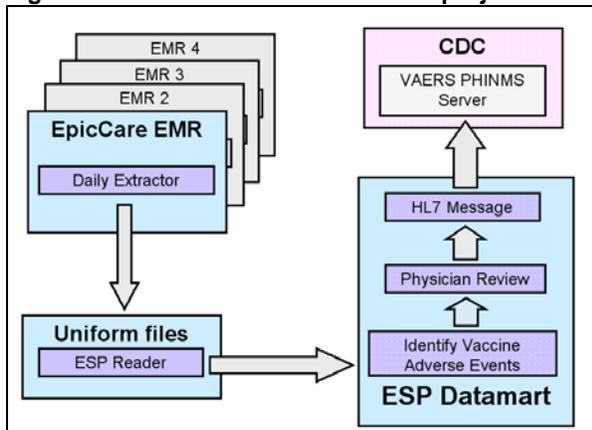
suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

## Methods

The goal of Aim 1: *Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration*, and Aim 2: *Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS)*, was to construct the below flow of data in order to support the first two Aims:

**Figure 1. Overview of the ESP:VAERS project**



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect*. A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS*. The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to *Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data*.

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 *Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems* has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center <http://esphealth.org>, specifically, the Subversion repository available at: <http://esphealth.org/trac/ESP/wiki/ESPVAERS>.

## Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of “problem” drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians’ usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

### Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atruis currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atruis physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atruis was included in our adverse event surveillance system (ESP:VAERS). Atruis serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atruis is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atruis population is under age 18.

## List of Publications and Products

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: <http://esphealth.org>.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

Lazarus R, Klompas M Automated vaccine adverse event detection and reporting from electronic medical records. CDC Public Health Informatics Network (PHIN) Conference August 27, 2008.

Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

#1670

**Vaccines and Related Biological Products Advisory Committee Meeting  
December 10, 2020**

**FDA Briefing Document**

**Pfizer-BioNTech COVID-19 Vaccine**

**Sponsor:  
Pfizer and BioNTech**

## Table of Contents

List of Tables .....	3
List of Figures .....	4
Glossary.....	5
1. Executive Summary .....	6
2. Background.....	7
2.1. SARS-CoV-2 Pandemic .....	7
2.2. EUA Request for the Pfizer and BioNTech COVID-19 Vaccine BNT162b2.....	8
2.3. U.S. Requirements to Support Issuance of an EUA for a Biological Product.....	8
2.4. Applicable Guidance for Industry .....	9
2.5. Safety and Effectiveness Information Needed to Support an EUA.....	9
2.6. Continuation of clinical trials following issuance of an EUA for a COVID-19 vaccine .....	10
2.7. Previous Meetings of the VRBPAC to Discuss Vaccines to Prevent COVID-19.....	10
3. Topics for VRBPAC Discussion.....	11
4. Pfizer-BioNTech COVID-19 Vaccine (BNT162b2).....	11
4.1. Vaccine Composition, Dosing Regimen.....	11
4.2. Proposed Use Under EUA.....	12
5. FDA Review of Clinical Safety and Effectiveness Data .....	12
5.1. Overview of Clinical Studies .....	12
5.2. Study C4591001.....	12
5.2.1. Design .....	12
5.2.2. FDA Assessment of Phase 2/3 Follow-Up Duration .....	17
5.2.3. Subject Disposition and Inclusion in Analysis Populations .....	17
5.2.4. Demographics and Other Baseline Characteristics .....	19
5.2.5. Vaccine Efficacy.....	24
5.2.6. Safety .....	33
6. Sponsor's Plans for Continuing Blinded, Placebo-Controlled Follow-Up.....	44
7. Pharmacovigilance Activities .....	44
8. Benefit/Risk Assessment in the Context of Proposed Indication and Use Under EUA .....	46
8.1. Known Benefits .....	46
8.2. Unknown Benefits/Data Gaps.....	46
8.3. Known Risks .....	48
8.4. Unknown Risks/Data Gaps.....	49

9. References .....	49
10. Appendix A. Study BNT162-01.....	51
11. Appendix B. Charlson Comorbidity Index .....	52
12. Appendix C. Guidance for Industry: Emergency Use Authorization for Vaccines to Prevent COVID-19.....	53

## List of Tables

Table 1: Clinical Trials Submitted in Support of Efficacy and Safety Determinations of the Pfizer-BioNTech COVID-19 Vaccine .....	12
Table 2. Efficacy Populations, Treatment Groups as Randomized.....	18
Table 3. Disposition of All Randomized Participants, Phase 2/3 Safety Population .....	19
Table 4. Demographic Characteristics, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy (7 Days) Population .....	20
Table 5. Demographics and Other Baseline Characteristics, Phase 2/3 Safety Population .....	21
Table 6. Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection - Evaluable Efficacy Population .....	24
Table 7. Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants With And Without Evidence of Prior SARS-CoV-2 Infection, Evaluable Efficacy Population.....	25
Table 8: Subgroup Analyses of Second Primary Endpoint: First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup, Participants With and Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy (7 Days) Population .....	26
Table 9. Demographic Characteristics, Participants With Protocol Defined Case (Without Evidence of Infection Prior to 7 Days After Dose 2).....	28
Table 10. Vaccine Efficacy: First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status, Among Participants Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy (7 Days) Population .....	29
Table 11. First Severe COVID-19 Occurrence from 7 Days after Dose 2 - Evaluable Efficacy Population.....	31
Table 12. First Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population.....	31
Table 13. Primary Efficacy Endpoint –All-Available Efficacy Population .....	32
Table 14. Study C4591001 Safety Overview- Ages 16 years and older .....	33
Table 15. Frequency of Solicited Local Reactions Within 7 Days After Each Vaccination, Reactogenicity Subset of the Phase 2/3 Safety Population*, 18 to 55 Years of Age.....	34
Table 16. Frequency of Solicited Local Reactions Within 7 Days After Each Vaccination, Reactogenicity Subset of the Phase 2/3 Safety Population*, >55 Years of Age and Older 35	
Table 17. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Vaccination- Reactogenicity Subset of the Phase 2/3 Safety Population*, 18 to 55 Years of Age .....	35

Table 18. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Vaccination- Reactogenicity Subset of the Phase 2/3 Safety Population\*, >55 Years of Age and Older .....37

Table 19. Frequency of Unsolicited AEs with Occurrence in  $\geq 1\%$  of Participants in any Treatment Group from Dose 1 to 1-month After Dose 2, Phase 2/3 Safety Population\*, 16 Years of Age and Older.....39

Table 20. Frequency of Unsolicited AEs with Occurrence in  $\geq 1\%$  of Participants in any Treatment Group from Dose 1 to 1 Month After Dose 2, Phase 2/3 Safety Population\*, 16 and 17 Years of Age .....39

Table 21. Frequency of Unsolicited AEs with Occurrence in  $\geq 1\%$  of Participants in any Treatment Group from Dose 1 to 1 Month After Dose 2, Phase 2/3 Safety Population\*, 65 Years and Older.....40

**List of Figures**

Figure 1. Safety Monitoring Plan, Study C4591001 .....15

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Dose 1 All-Available Efficacy Population .....30

## Glossary

AE	adverse event
AIDS	acquired immunodeficiency syndrome
ARDS	acute respiratory distress syndrome
BNT162b2	Pfizer-BioNTech COVID-19 Vaccine
CBRN	chemical, biological, radiological, or nuclear
CDC	Centers for Disease Control and Prevention
CMC	Che
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
hACE2	human angiotensin converting enzyme 2
HHS	Health and Human Services
HIV	human immunodeficiency virus
IM	intramuscular
LNP	lipid nanoparticle
MERS-CoV	Middle Eastern respiratory syndrome
modRNA	nucleoside-modified messenger RNA
NAAT	nucleic acid amplification-based test
PVP	Pharmacovigilance Plan
RBD	receptor binding domain
RT-PCR	reverse transcription-polymerase chain reaction
SAE	serious adverse event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
VE	vaccine efficacy
VRBPAC	Vaccines and Related Biological Products Advisory Committee

## 1. Executive Summary

On November 20, 2020, Pfizer and BioNTech (the Sponsor) submitted an Emergency Use Authorization (EUA) request to FDA for an investigational COVID-19 vaccine (BNT162b2) intended to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The vaccine is based on the SARS-CoV-2 spike glycoprotein (S) antigen encoded by RNA and formulated in lipid nanoparticles (LNPs). The proposed use under an EUA is “for active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.” The proposed dosing regimen is 2 doses, 30 µg each, administered 21 days apart.

The EUA request includes safety and efficacy data from an ongoing phase 3 randomized, double-blinded and placebo-controlled trial of BNT162b2 in approximately 44,000 participants. The primary efficacy endpoint is incidence of COVID-19 among participants without evidence of SARS-CoV-2 infection before or during the 2-dose vaccination regimen. In a mid-November analysis of 36,621 participants randomized 1:1 to vaccine or placebo who were included in the per-protocol efficacy analysis population of participants without evidence of SARS-CoV-2 infection prior to 7 days after completion of the vaccination regimen, efficacy in preventing confirmed COVID-19 occurring at least 7 days after the second dose of vaccine was 95.0%, with 8 COVID-19 cases in the vaccine group and 162 COVID-19 cases in the placebo group. Subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19. Secondary efficacy analyses suggested benefit of the vaccine in preventing severe COVID-19, in preventing COVID-19 following the first dose, and in preventing COVID-19 in individuals with prior SARS-CoV-2 infection, although available data for these outcomes did not allow for firm conclusions.

Safety data from approximately 38,000 participants  $\geq 16$  years of age randomized 1:1 to vaccine or placebo with a median of 2 months of follow up after the second dose suggest a favorable safety profile, with no specific safety concerns identified that would preclude issuance of an EUA. Available safety data from all participants enrolled through the November 14, 2020 data cut-off (N=43,252, which includes late enrollment of additional adolescent and adult participants), was consistent with the safety profile for the approximately 38,000 participants with median follow-up of 2 months and also did not raise specific safety concerns. The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%); severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after Dose 2 than after Dose 1, and were generally less frequent in participants  $\geq 55$  years of age ( $\leq 2.8\%$ ) as compared to younger participants ( $\leq 4.6\%$ ). The frequency of serious adverse events was low ( $<0.5\%$ ), without meaningful imbalances between study arms. Among non-serious unsolicited adverse events, there was a numerical imbalance of four cases of Bell’s palsy in the vaccine group compared with no cases in the placebo group, though the four cases in the vaccine group do not represent a frequency above that expected in the general population. Otherwise, there were no notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to BNT162b2 vaccine. With the exception of more frequent, generally mild to moderate reactogenicity in participants  $<55$  years of age, the safety profile of BNT162b2 was generally similar across age groups, genders, ethnic and racial groups, participants with or without medical comorbidities, and participants with or without evidence of prior SARS-CoV-2 infection at enrollment.

This meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) is being convened to discuss and provide recommendations on whether:

- based on the totality of scientific evidence available, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 in individuals 16 years of age and older, and
- the known and potential benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its known and potential risks for use in individuals 16 years of age and older.

The committee will also discuss what additional studies should be conducted by the vaccine manufacturer following issuance of the EUA to gather further data on the safety and effectiveness of this vaccine.

## **2. Background**

### **2.1. SARS-CoV-2 Pandemic**

The SARS-CoV-2 pandemic presents an extraordinary challenge to global health and, as of November 30, 2020, has caused more than 60 million cases of COVID-19 and claimed the lives of 1.5 million people worldwide. In the United States, over 13 million cases have been reported to the Centers for Disease Control and Prevention (CDC), with over 260,000 deaths. Confirmed cases and mortality continue to rise globally. On January 31, 2020, the U.S. Secretary of Health and Human Services (HHS) declared a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. Following the World Health Organization's declaration of the novel coronavirus pandemic on March 11, 2020, the U.S. President declared a national emergency in response to COVID-19 on March 13, 2020. Vaccines to protect against COVID-19 are critical to mitigate the current SARS-CoV-2 pandemic and to prevent future disease outbreaks.

SARS-CoV-2 is a novel, zoonotic coronavirus that emerged in late 2019 in patients with pneumonia of unknown cause.<sup>1</sup> The virus was named SARS-CoV-2 because of its similarity to the coronavirus responsible for severe acute respiratory syndrome (SARS-CoV, a lineage B betacoronavirus).<sup>2</sup> SARS-CoV-2 is an enveloped, positive sense, single stranded RNA virus sharing more than 70% of its sequence with SARS-CoV, and ~50% with the coronavirus responsible for Middle Eastern respiratory syndrome (MERS-CoV).<sup>3</sup> The SARS-CoV-2 spike glycoprotein (S), which is a main target for neutralizing antibody, binds to its receptor human angiotensin converting enzyme 2 (hACE2) to initiate infection.<sup>4</sup> SARS-CoV-2 is the cause of COVID-19, an infectious disease with respiratory and systemic manifestations. Disease symptoms vary, with many persons presenting with asymptomatic or mild disease and some progressing to severe respiratory tract disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multiorgan failure and death.

In an attempt to prevent the spread of disease and to control the pandemic, numerous COVID-19 vaccine candidates are in development. These vaccines are based on different platforms including mRNA and DNA technologies and include viral vectored, subunit, inactivated, and live attenuated vaccines. Most COVID-19 candidate vaccines express the spike protein or parts of the spike protein, i.e., the receptor binding domain (RBD), as the immunogenic determinant.

## **2.2. EUA Request for the Pfizer and BioNTech COVID-19 Vaccine BNT162b2**

Pfizer, in partnership with BioNTech Manufacturing GmbH, is developing a vaccine to prevent COVID-19 which is based on the SARS-CoV-2 spike glycoprotein (S) antigen encoded by RNA and formulated in lipid nanoparticles (LNP). The Pfizer-BioNTech COVID-19 Vaccine (also referred to as BNT162b2) is administered intramuscularly as a 2-dose series spaced 21 days apart at a dose of 30 µg each. The vaccine is supplied as a multi-dose vial (5 doses) containing a frozen suspension (-80°C to -60°C) of BNT162b2 that must be thawed and diluted with 1.8 mL of sterile 0.9% sodium chloride, allowing for five 0.3 mL doses. The vaccine is preservative free.

A phase 3 randomized and placebo-controlled trial using BNT162b2 in approximately 44,000 participants is currently ongoing to evaluate the vaccine's safety and efficacy. Vaccine efficacy for the primary endpoint against confirmed COVID-19 occurring at least 7 days after the second dose was 95.0% with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group. Data from about 38,000 participants randomized 1:1 with a median of 2 months of follow-up after the second dose of vaccine showed a favorable safety profile at a dose of 30 µg in participants 16 years of age and older. On November 20, 2020, Pfizer and BioNTech submitted an EUA request to FDA for its investigational COVID-19 vaccine (BNT162b2) intended to prevent COVID-19 caused by SARS-CoV-2.

## **2.3. U.S. Requirements to Support Issuance of an EUA for a Biological Product**

Based on the declaration by the Secretary of HHS that the COVID-19 pandemic constitutes a public health emergency with a significant potential to affect national security or the health and security of United States citizens living abroad, FDA may issue an EUA after determining that certain statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3)).<sup>5</sup>

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition.
- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2, or to mitigate a serious or life-threatening disease or condition caused by an FDA-regulated product used to diagnose, treat, or prevent a disease or condition caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

If these criteria are met, under an EUA, FDA can allow unapproved medical products (or unapproved uses of approved medical products) to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents. FDA has been providing regulatory advice to COVID-19 vaccine manufacturers regarding the data needed to determine that a vaccine's benefit outweighs its risks. This includes demonstrating that manufacturing information ensures product quality and consistency along with data from at least one phase 3 clinical trial demonstrating a vaccine's safety and efficacy in a clear and compelling manner.

In the event an EUA is issued for this product, it would still be considered unapproved and it would be under further investigation (under an Investigational New Drug Application) until it is licensed under a Biologics License Application (BLA). Licensure of a COVID-19 vaccine will be based on review of additional manufacturing, efficacy, and safety data, providing greater assurance of the comparability of licensed product to product tested in the clinical trials, greater assurance of safety based on larger numbers of vaccine recipients who have been followed for a longer period of time, and additional information about efficacy that addresses, among other questions, the potential for waning of protection over time.

## **2.4. Applicable Guidance for Industry**

Risk and benefit considerations are unique for COVID-19 vaccines, given that an EUA may be requested to allow for a vaccine's rapid and widespread deployment for administration to millions of individuals, including healthy people. FDA published in October 2020 guidance for industry entitled "[Emergency Use Authorization for Vaccines to Prevent COVID-19](#)" (Appendix C, page 53) describing FDA's current recommendations regarding the manufacturing, nonclinical, and clinical data and information needed under section 564 of the FD&C Act to support the issuance of an EUA for an investigational vaccine to prevent COVID-19, including a discussion of FDA's current thinking regarding the circumstances under which an EUA for a COVID-19 vaccine would be appropriate.

## **2.5. Safety and Effectiveness Information Needed to Support an EUA**

### **Effectiveness data**

Issuance of an EUA requires a determination that the known and potential benefits of the vaccine outweigh the known and potential risks. For a preventive COVID-19 vaccine to be potentially administered to millions of individuals, including healthy individuals, data adequate to inform an assessment of the vaccine's benefits and risks and support issuance of an EUA would include meeting the prespecified success criteria for the study's primary efficacy endpoint, as described in the guidance for industry entitled "[Development and Licensure of Vaccines to Prevent COVID-19](#)" (i.e., a point estimate for a placebo-controlled efficacy trial of at least 50%, with a lower bound of the appropriately alpha-adjusted confidence interval around the primary efficacy endpoint point estimate of >30%).<sup>6</sup>

### **Safety data**

An EUA request for a COVID-19 vaccine should include all safety data accumulated from studies conducted with the vaccine, with data from phase 1 and 2 focused on serious adverse events, adverse events of special interest, and cases of severe COVID-19 among study participants. Phase 3 safety data should include characterization of reactogenicity (common and expected adverse reactions shortly following vaccination) in a sufficient number of participants from relevant age groups and should include a high proportion of enrolled participants (numbering well over 3,000) followed for serious adverse events and adverse events of special interest for at least one month after completion of the full vaccination regimen. The phase 1 and 2 safety data likely will be of a longer duration than the available safety data from the phase 3 trial at the time of submission of an EUA request and thus, are intended to complement the available data from safety follow-up from ongoing phase 3 studies.

### **Phase 3 Follow-up**

Data from phase 3 studies should include a median follow-up duration of at least 2 months after completion of the full vaccination regimen to help provide adequate information to assess a vaccine's benefit-risk profile. From a safety perspective, a 2-month median follow-up following completion of the full vaccination regimen will allow identification of potential adverse events that were not apparent in the immediate postvaccination period. Adverse events considered plausibly linked to vaccination generally start within 6 weeks of vaccine receipt.<sup>7</sup> Therefore, a 2-month follow-up period may allow for identification of potential immune-mediated adverse events that began within 6 weeks of vaccination. From the perspective of vaccine efficacy, it is important to assess whether protection mediated by early responses has not started to wane. A 2-month median follow-up is the shortest follow-up period to achieve some confidence that any protection against COVID-19 is likely to be more than short-lived. The EUA request should include a plan for active follow-up for safety (including deaths, hospitalizations, and other serious or clinically significant adverse events) among individuals administered the vaccine under an EUA in order to inform ongoing benefit-risk determinations to support continuation of the EUA.

#### **2.6. Continuation of clinical trials following issuance of an EUA for a COVID-19 vaccine**

FDA does not consider availability of a COVID-19 vaccine under EUA, in and of itself, as grounds for immediately stopping blinded follow-up in an ongoing clinical trial or grounds for offering vaccine to all placebo recipients. To minimize the risk that use of an unapproved vaccine under EUA will interfere with long-term assessment of safety and efficacy in ongoing trials, it is critical to continue to gather data about the vaccine even after it is made available under EUA. An EUA request should therefore include strategies that will be implemented to ensure that ongoing clinical trials of the vaccine are able to assess long-term safety and efficacy (including evaluating for vaccine-associated enhanced respiratory disease and decreased effectiveness as immunity wanes over time) in sufficient numbers of participants to support vaccine licensure. These strategies should address how ongoing trial(s) will handle loss of follow-up information for study participants who choose to withdraw from the study in order to receive the vaccine under an EUA.

FDA is aware that some COVID-19 vaccine developers may wish to immediately unblind their trials upon issuance of an EUA in order to rapidly provide vaccine to trial participants who received placebo. Some developers have proposed maintaining blinding in a crossover design that provides vaccine to previous placebo recipients and placebo to previous vaccine recipients. Such strategies would impact collection of longer-term placebo-controlled safety data and evaluation of the duration of vaccine efficacy. Ethical and scientific issues associated with offering vaccination to placebo recipients have been discussed in recent statements and articles.<sup>8-10</sup>

#### **2.7. Previous Meetings of the VRBPAC to Discuss Vaccines to Prevent COVID-19**

On [October 22, 2020](#), the VRBPAC met in open session, to discuss, in general, the development, authorization and/or licensure of vaccines to prevent COVID-19. No specific application was discussed at this meeting. Topics discussed at the meeting included:

- FDA's approach to safety and effectiveness, and chemistry, manufacturing and control (CMC) data as outlined in the respective guidance documents

- Considerations for continuation of blinded Phase 3 clinical trials if an EUA has been issued for an investigational COVID-19 vaccine
- Studies following licensure and/or issuance of an EUA for COVID-19 vaccines to:
  - Further evaluate safety, effectiveness and immune markers of protection
  - Evaluate the safety and effectiveness in specific populations.

### **3. Topics for VRBPAC Discussion**

The Vaccines and Related Biological Products Advisory Committee will convene on December 10, 2020, to discuss and provide recommendations on whether:

- based on the totality of scientific evidence available, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 in individuals 16 years of age and older, and
- the known and potential benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its known and potential risks for use in individuals 16 years of age and older.

The committee will also discuss what additional studies should be conducted by the vaccine manufacturer following issuance of the EUA to gather further data on the safety and effectiveness of this vaccine.

### **4. Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)**

#### **4.1. Vaccine Composition, Dosing Regimen**

The Pfizer-BioNTech COVID-19 Vaccine is a white to off-white, sterile, preservative-free, frozen suspension for intramuscular injection. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2. The vaccine also includes the following ingredients: lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen [between -80°C to -60°C (-112°F to -76°F)] multi-dose (5-dose) vial. The vaccine must be thawed and diluted in its original vial with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to administration. After dilution, the vial contains 5 doses of 0.3 mL per dose. After dilution, the multiple-dose vials must be stored between 2°C to 25°C (35°F to 77°F) and used within 6 hours from the time of dilution.

The Pfizer-BioNTech COVID-19 Vaccine, BNT162b2 (30 µg), is administered intramuscularly (IM) as a series of two 30 µg doses (0.3 mL each) 21 days apart.

FDA has reviewed the CMC data submitted to date for this vaccine and has determined that the CMC information is consistent with the recommendations set forth in FDA's Guidance on Emergency Use Authorization for Vaccines to Prevent COVID-19. As such, FDA has determined that the Sponsor has provided adequate information to ensure the vaccine's quality and consistency for authorization of the product under an EUA.

## 4.2. Proposed Use Under EUA

The proposed indication and use of the vaccine under an EUA is “for active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.”

## 5. FDA Review of Clinical Safety and Effectiveness Data

### 5.1. Overview of Clinical Studies

Data from two ongoing clinical studies were included in the EUA request, which are summarized in [Table 1](#) below. Study C4591001 is a multi-center, multi-national Phase 1,2,3 randomized, blinded, placebo-controlled safety, immunogenicity, and efficacy study that is the focus of the EUA review. Study BNT162-01 is a Phase 1 study that explored various vaccine candidates and dose levels and will not be discussed in detail. A brief summary of the BNT162-01 study design and results to date is found in Appendix A, page [51](#).

**Table 1: Clinical Trials Submitted in Support of Efficacy and Safety Determinations of the Pfizer-BioNTech COVID-19 Vaccine**

Study Number/ Country	Description	BNT162b2 (30 µg)* participants (N)	Placebo participants (N)	Study Status
<b>C4591001</b> USA, Argentina, Brazil, Germany, S. Africa, Turkey	Phase 1,2,3 randomized, placebo-controlled, observer- blind; to evaluate safety, immunogenicity and efficacy of COVID-19 vaccine	Phase 1: 24 Phase 2/3: 21823	Phase 1: 6 Phase 2/3: 21828	Ongoing
<b>BNT162-01</b> Germany	Phase 1/2 randomized, open- label; to evaluate safety and immunogenicity, dose escalation	12	0	Ongoing

N= total number of randomized participants as of November 14, 2020. Placebo: saline.

\*Phase 1 studies included additional participants vaccinated with other dose levels and other mRNA vaccine candidates. Studies C4591001 and BNT162-01 started in April 2020 (first participant, first visit).

### 5.2. Study C4591001

#### 5.2.1. Design

Study C4591001 is an ongoing, randomized, placebo-controlled, phase 1/2/3 study being conducted in the US, Argentina, Brazil, Germany, South Africa and Turkey. Initially the study was designed as a phase 1/2 study in healthy adults in the US for vaccine candidate and dosage selection, immunogenicity and preliminary efficacy, but the protocol was revised to expand the study design for inclusion of a phase 2/3 portion to evaluate clinical disease endpoint efficacy in individuals 12 years of age and older in the US and additional sites outside of the US.

In phase 1, two age groups were evaluated in separate cohorts, younger participants 18 through 55 years of age (N=45) and older participants 65 through 85 years of age (N=45). The study population included healthy men and women and excluded participants at high risk of SARS-CoV-2 infection or with serological evidence of prior or current SARS-CoV-2 infection. Two different vaccine candidates were evaluated, and younger participants received escalating dose levels with progression to subsequent dose levels and evaluation of escalating dose levels in the older age group (65 through 85 years), based on recommendations from an internal review committee that reviewed safety and immunogenicity data. For each vaccine candidate and dose

level, participants were randomized 4:1, such that 12 participants received the vaccine candidate and 3 participants received placebo. Review of the safety and immunogenicity from phase 1, in combination with data from Study BNT162-01 (See Section 10), supported the final vaccine candidate and dose level (BNT162b2 at 30 µg, given 21 days apart) to proceed into phase 2/3.

In phase 2/3, participants were enrolled with stratification by age (younger adults: 18 through 55 years of age; older adults: over 55 years of age) and a goal of 40% enrollment in the older adult age group. Adolescents were added to the protocol, based on review of safety data in younger adults enrolled in the ongoing study, so the age strata were revised as follows: 12 through 15 years of age, 16 through 54 years of age, and 55 years of age and older. The study population for phase 2/3 includes participants at higher risk for acquiring COVID-19 and at higher risk of severe COVID-19 disease, such as participants working in the healthcare field, participants with autoimmune disease, and participants with chronic but stable medical conditions such as hypertension, asthma, diabetes, and infection with HIV, hepatitis B or hepatitis C. Participants were randomized 1:1 to receive 2 doses of either BNT162b2 or placebo, 21 days apart. The phase 2 portion of the study evaluated reactogenicity and immunogenicity for 360 participants enrolled early-on, and these participants also contribute to the overall efficacy and safety data in the phase 3 portion. The ongoing phase 3 portion of the study is evaluating the safety and efficacy of BNT162b2 for the prevention of COVID-19 disease occurring at least 7 days after the second dose of vaccine. Efficacy is being assessed throughout a participant's follow-up in the study through surveillance for potential cases of COVID-19. If, at any time, a participant develops acute respiratory illness, an illness visit occurs. Assessments for illness visits include a nasal (midturbinate) swab, which is tested at a central laboratory using a reverse transcription-polymerase chain reaction (RT-PCR) test (e.g., Cepheid; FDA authorized under EUA), or other sufficiently validated nucleic acid amplification-based test (NAAT), to detect SARS-CoV-2. The central laboratory NAAT result is used for the case definition, unless it is not possible to test the sample at the central laboratory. In that case, the following NAAT results are acceptable: Cepheid Xpert Xpress SARS-CoV-2 Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001) Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001).

The study design includes planned interim analyses of the first primary efficacy endpoint at pre-specified numbers of COVID-19 cases (at least 62, 92, and 120 cases), and all primary and secondary efficacy endpoints were analyzed in the final efficacy analysis after at least 164 COVID-19 cases were accrued (see Statistical Analysis section, below). Participants are expected to participate for a maximum of approximately 26 months.

### Primary Efficacy Endpoints

Study C4591001 has two primary endpoints:

**First primary endpoint:** COVID-19 incidence per 1000 person-years of follow-up in participants without serological or virological evidence of past SARS-CoV-2 infection before and during vaccination regimen – cases confirmed ≥7 days after Dose 2

**Second primary endpoint:** COVID-19 incidence per 1000 person-years of follow-up in participants with and without evidence of past SARS-CoV-2 infection before and during vaccination regimen – cases confirmed ≥7 days after Dose 2

### Secondary Efficacy Endpoints

Study C4591001 has secondary endpoints based on different approaches to COVID-19 case evaluation criteria as follows:

**COVID-19 confirmed at least 14 days after Dose 2:** COVID-19 incidence per 1000 person-years of follow up in participants either (1) without or (2) with and without serological or virological evidence of past SARS-CoV-2 infection before and during vaccination regimen – cases confirmed  $\geq 14$  days after Dose 2

**Severe COVID-19:** incidence per 1000 person-years of follow-up in participants either (1) without or (2) with and without evidence of past SARS-CoV-2 infection before and during vaccination regimen – cases confirmed either (1)  $\geq 7$  days after Dose 2 or (2)  $\geq 14$  days after Dose 2

**CDC-defined COVID-19:** incidence per 1000 person-years of follow-up in participants either (1) without or (2) with and without evidence of past SARS-CoV-2 infection before and during vaccination regimen – cases confirmed either (1)  $\geq 7$  days after Dose 2 or (2)  $\geq 14$  days after Dose 2.

For the primary efficacy endpoint, the case definition for a confirmed COVID-19 case was the presence of at least one of the following symptoms and a positive SARS-CoV-2 NAAT within 4 days of the symptomatic period:

- Fever;
- New or increased cough;
- New or increased shortness of breath;
- Chills;
- New or increased muscle pain;
- New loss of taste or smell;
- Sore throat;
- Diarrhea;
- Vomiting.

For a secondary efficacy endpoint, a second definition, which may be updated as more is learned about COVID-19, included the following additional symptoms defined by CDC (listed at <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>):

- Fatigue;
- Headache;
- Nasal congestion or runny nose;
- Nausea.

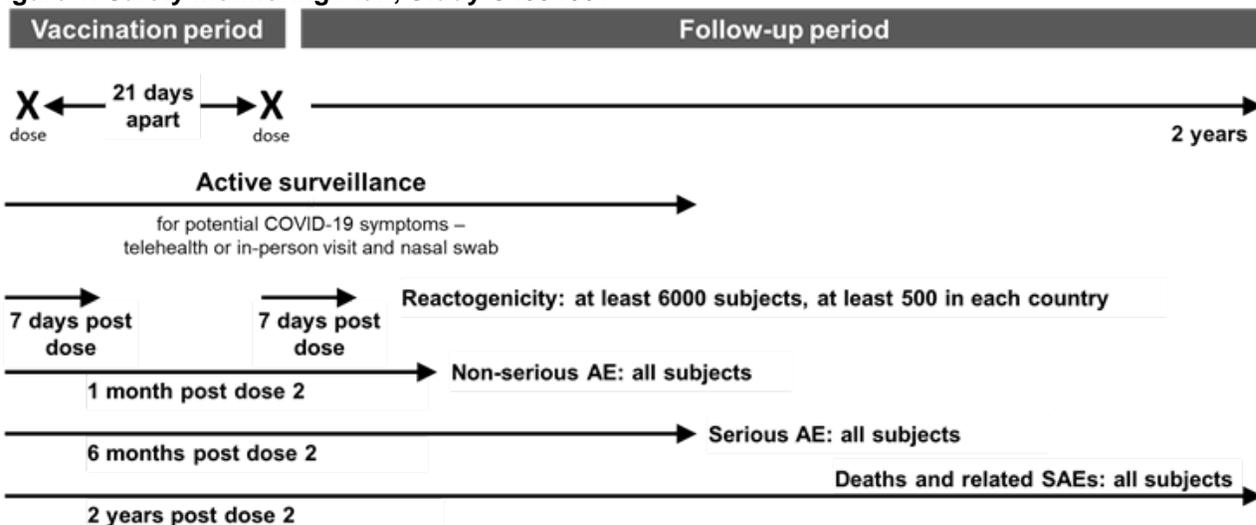
For another secondary endpoint, the case definition for a severe COVID-19 case was a confirmed COVID-19 case with at least one of the following:

- Clinical signs at rest indicative of severe systemic illness (RR  $\geq 30$  breaths per minute, HR  $\geq 125$  beats per minute, SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level, or PaO<sub>2</sub>/FiO<sub>2</sub>  $< 300$  mm Hg);
- Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO);
- Evidence of shock (SBP  $< 90$  mm Hg, DBP  $< 60$  mm Hg, or requiring vasopressors)
- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an ICU;
- Death.

## Evaluation of Safety

The primary safety objective for all phases was to describe the safety of BNT162 vaccine(s) in healthy adults after 1 or 2 doses. All phase 1 participants (n=30), and then 6653 U.S. participants (360 phase 2, 6293 phase 3) and the first ~500 phase 3 participants/per country with enrollment through October 9, 2020 (Argentina, Brazil and South Africa) recorded local reactions, systemic events, and antipyretic/pain medication usage from Day 1 through Day 7 after each dose. Unsolicited adverse events (AEs) are collected from Dose 1 to 1 month after the last dose and serious AEs (SAEs) from Dose 1 to 6 months after the last dose. [Figure 1](#) below shows the study safety monitoring plan.

**Figure 1. Safety Monitoring Plan, Study C4591001**



Reactogenicity assessments included solicited injection site reactions (pain, redness, swelling) and systemic AEs (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain), and antipyretic/pain medication use were recorded in an e-diary. At the data cutoff date for the EUA, reactogenicity events were not collected from adolescents 16 to 17 years of age (enrolled prior to the implementation of Protocol Amendment 9, finalized on 29 October 2020) using an e-diary but were detected and reported as unsolicited AEs. For any phase 3 participants who were not in the reactogenicity subset, local reactions and systemic events consistent with reactogenicity were detected and reported as unsolicited AEs. HIV-positive participants and adolescents 12 through 15 years of age were included in the reactogenicity subset with implementation of protocol amendment 6 (finalized on September 8, 2020) and amendment 7 (finalized on October 6, 2020), respectively. Solicited reactogenicity data in adolescents 16-17 years of age are not available for the reporting period. Reactogenicity data from a total of 100 adolescents 12 through 15 years of age enrolled in C4591001 phase 2/3 were provided in the EUA submission. However, the Sponsor did not request inclusion of this age group in the EUA because the available data, including number of participants and follow-up duration, were insufficient to support favorable a benefit-risk determination at this time. Therefore, the reactogenicity data for participants 12 through 15 years of age are not presented in this document.

Clinical laboratory tests were assessed in phase 1 at 1-week postvaccination. The planned safety follow-up for currently enrolled adolescents and adults is through 24 months after vaccination #2.

Potential COVID-19 illnesses and their sequelae were not to be reported as AEs, with the exception of illnesses that met regulatory criteria for seriousness and were not confirmed to be COVID-19. These illnesses were evaluated and reported as SAEs.

In phase 2/3, monitoring for risk of vaccine-enhanced disease was performed by an unblinded team supporting the Data Monitoring Committee that reviewed cases of severe COVID-19 as they were received and reviewed AEs at least weekly for additional potential cases of severe COVID-19. The stopping rule was triggered when the 1-sided probability of observing the same or a more extreme case split was 5% or less when the true incidence of severe disease was the same for vaccine and placebo participants, and alert criteria were triggered when this probability was less than 11%.

### Analysis Populations

For the purposes of analysis, the following populations are defined:

Population	Description
Enrolled	All participants who have a signed informed consent document.
Randomized	All participants who are assigned a randomization number.
Evaluable efficacy	All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window and have no other important protocol deviations as determined by the clinician.
All-available efficacy	1. All randomized participants who receive at least 1 vaccination. 2. All randomized participants who complete 2 vaccination doses.

Phase 2/3 safety analysis populations were as follows:

- Phase 2/3 all-enrolled population: composed of a total of 43,448 (21720 vaccine, 21728 placebo) participants  $\geq 16$  years of age, regardless of duration of follow-up, for whom written informed consent was obtained. Initial enrollment included individuals 18 years and older, then included individuals as young as 16 years of age and individuals with known HIV (protocol amendment 6; finalized on September 8, 2020). As of November 14, 2020, 43.9% and 79.5% of vaccine recipients completed at least 2 months ( $\geq 8$  weeks) and at least 1 month ( $\geq 4$  weeks), respectively, of safety follow-up after Dose 2. The percentages of placebo recipients completing at least 2 months ( $\geq 8$  weeks) and at least 1 month ( $\geq 4$  weeks) were similar to the vaccine group.
- Phase 2/3 safety population (median follow-up time of 2 months after vaccination #2): comprised of a total of 37586 (18801 vaccine, 18785 placebo) participants  $> 16$  years of age enrolled by October 9, 2020 and received at least 1 dose of study vaccine or placebo; overall, 98.1% of participants completed the 2-dose series. As of November 14, 2020, 50.6% and 91.6% of vaccine recipients completed at least 2 months ( $> 8$  weeks) and at least 1 month ( $> 4$  weeks), respectively, of safety follow-up after Dose 2. The percentages of placebo recipients completing at least 2 months ( $> 8$  weeks) and at least 1 month ( $> 4$  weeks) were similar to the vaccine group. A total of 283 (138 vaccine, 145 placebo) individuals were 16 to  $< 18$  years of age. HIV-positive individuals were included in the all-enrolled population, but not the phase 2/3 safety population because the number of participants enrolled by October 9, 2020 was small ( $n=120$ ) and the median duration of safety follow-up was short.

### 5.2.2. FDA Assessment of Phase 2/3 Follow-Up Duration

Study C4591001 initially enrolled approximately 30,000 participants and then several months later began enrollment of approximately 14,000 additional participants, including adolescents and participants with chronic, stable HIV, hepatitis B, or hepatitis C infections. Because of the gap in enrollment, the entire enrolled study population had a median follow-up of less than 2 months as of the EUA submission data cut-off date of November 14, 2020. However, the analyses submitted to support this EUA request meet the expectation for median duration of follow-up time, as follows:

- Submitted safety analyses for participants enrolled through October 9, 2020, and followed through November 14, 2020 (referred to by Pfizer and in this document as the phase 2/3 safety population and including a total of 37,586 participants), represent a median follow-up of 2 months. Additionally, this safety database is larger than for the initial planned enrollment of approximately 30,000 participants.
- The date for data cut-off for the first interim analysis for efficacy was November 4, 2020, when a total of 94 confirmed COVID-19 cases were accrued. All of the participants included in the first interim efficacy analysis had at least 7 days of follow-up after Dose 2, and thus were enrolled no later than October 7, 2020. All participants in the first interim efficacy analysis were therefore included in the phase 2/3 safety population defined above. Although the median follow-up duration for participants included in the first interim efficacy analysis was slightly less than 2 months as of November 4, 2020, these participants were also included in the final efficacy analyses with data cut-off of November 14, 2020, which extended the median follow-up for these participants to greater than 2 months. The results of the final efficacy analysis on data to November 14, 2020, indicate that the conclusions from the first interim efficacy analysis would not change when including additional follow-up to November 14, 2020.

The date for data cut-off for the final efficacy analysis was November 14, 2020, when a total of 170 confirmed COVID-19 cases were accrued. As noted above, the median follow-up duration after completion of the full vaccination regimen for all participants enrolled at that time was less than 2 months for both safety and efficacy populations, due to a gap in enrollment. Because the data for the final efficacy analysis could be submitted in support of the EUA request and could provide data from a greater number of participants than from the interim analysis, FDA has focused its review on the efficacy data from the final efficacy analyses. Additional safety analyses from this larger database of all enrolled participants were also reviewed to evaluate for differences compared with the smaller phase 2/3 safety population.

### 5.2.3. Subject Disposition and Inclusion in Analysis Populations

Disposition tables are presented below in [Table 2](#) (efficacy analysis populations) and [Table 3](#) (phase 2/3 safety population). Overall, few participants were discontinued or lost to follow-up, and these and other analysis population exclusions were generally balanced between treatment groups. Of 43,448 participants in the phase 2/3 all-enrolled population, 94.2% of vaccine recipients and 94.1% of placebo recipients completed 2 doses (data not shown).

**Table 2. Efficacy Populations, Treatment Groups as Randomized**

	<b>BNT162b2 (30 µg) n<sup>a</sup> (%)</b>	<b>Placebo n<sup>a</sup> (%)</b>	<b>Total n<sup>a</sup> (%)</b>
Randomized <sup>b</sup>	21823 (100.0)	21828 (100.0)	43651 (100.0)
Dose 1 all-available efficacy population	21768 (99.7)	21783 (99.8)	43551 (99.8)
Participants without evidence of infection before Dose 1	20314 (93.1)	20296 (93.0)	40610 (93.0)
Participants excluded from Dose 1 all-available efficacy population	55 (0.3)	45 (0.2)	100 (0.2)
Reason for exclusion <sup>c</sup>			
Did not receive at least 1 vaccination	54 (0.2)	45 (0.2)	99 (0.2)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Dose 2 all-available efficacy population	20566 (94.2)	20536 (94.1)	41102 (94.2)
Participants without evidence of infection prior to 7 days after Dose 2	18701 (85.7)	18627 (85.3)	37328 (85.5)
Participants without evidence of infection prior to 14 days after Dose 2	18678 (85.6)	18563 (85.0)	37241 (85.3)
Participants excluded from Dose 2 all-available efficacy population	1257 (5.8)	1292 (5.9)	2549 (5.8)
Reason for exclusion <sup>c</sup>			
Did not receive 2 vaccinations	1256 (5.8)	1292 (5.9)	2548 (5.8)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Evaluable efficacy (7 days) population	20033 (91.8)	20244 (92.7)	40277 (92.3)
Evaluable efficacy (14 days) population	20033 (91.8)	20243 (92.7)	40276 (92.3)
Participants excluded from evaluable efficacy (7 days) population	1790 (8.2)	1584 (7.3)	3374 (7.7)
Participants excluded from evaluable efficacy (14 days) population	1790 (8.2)	1585 (7.3)	3375 (7.7)
Reason for exclusion <sup>c</sup>			
Randomized but did not meet all eligibility criteria	36 (0.2)	26 (0.1)	62 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	1550 (7.1)	1561 (7.2)	3111 (7.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	311 (1.4)	60 (0.3)	371 (0.8)
Had other important protocol deviations on or prior to 14 days after Dose 2	311 (1.4)	61 (0.3)	372 (0.9)

<sup>a</sup>n = Number of participants with the specified characteristic.

<sup>b</sup>These values are the denominators for the percentage calculations.

<sup>c</sup>Participants may have been excluded for more than 1 reason.

Note: 100 participants 12 through 15 years of age with limited follow-up are included in the randomized population (49 in the vaccine group and 51 in the placebo group). Some of these subjects were included in the denominators of efficacy analyses, depending on the population analyzed, but did not contribute primary endpoint cases and do not affect efficacy conclusions for ages 16 years and above.

**Table 3. Disposition of All Randomized Participants, Phase 2/3 Safety Population**

<b>Treatment Group</b>	<b>BNT162b2 N=18904 n (%)</b>	<b>Placebo N=18892 n (%)</b>	<b>Total N=37796 n (%)</b>
Randomized	18904 (100.0)	18892 (100.0)	37796 (100.0)
Vaccinated			
Completed 1 dose	18858 (99.8)	18849 (99.8)	37707 (99.8)
Completed 2 doses	18555 (98.2)	18533 (98.1)	37088 (98.1)
Withdrawn from Study	180 (1.0)	259 (1.4)	439 (1.2)
Reason for Withdrawal			
Adverse Event	8 (0.0)	5 (0.0)	13 (0.0)
Death	2 (0.0)	4 (0.0)	6 (0.0)
Withdrawal by Subject	84 (0.4)	157 (0.8)	241 (0.6)
Lost to Follow-up	80 (0.4)	86 (0.5)	166 (0.4)
No longer meets eligibility criteria	1 (0.0)	2 (0.0)	3 (0.0)
Refused further study procedures	0	1 (0.0)	1 (0.0)

Source: EUA 27036, amendment 3, Table 2; c4591001-safety-tables-cos-reacto.pdf, page 43.

Note: One participant was randomized but did not sign informed consent and therefore not included in any analysis population.

Note: 120 HIV-positive participants included in this table. HIV population analyses were summarized separately from analyses based on the phase 2/3 safety population, but included in the all-enrolled population analyses presented in this briefing document.

%;n/N. n = number of subjects with the specified characteristic. N = number of participants  $\geq 16$  years of age enrolled by October 9, 2020, including 120 HIV-positive participants, and received at least 1 dose of study vaccine or placebo. N is the denominator used for the percentage calculations.

Data analysis cutoff date: November 14, 2020

The numbers of randomized participants contributing to efficacy analyses presented in this document include 100 participants 12 through 15 years of age (49 in the vaccine group and 51 in the placebo group) who had limited follow-up at the time of the November 14, 2020 data cut-off. However, the sponsor did not include this age group in the EUA request. The numbers of participants presented and used as denominators for efficacy calculations were not adjusted to remove participants 12 through 15 years of age. Because the number of participants 12 through 15 years of age is very small relative to the overall efficacy analysis populations, and no primary endpoint COVID-19 cases occurred in this age group, the vaccine efficacy conclusions are not impacted. No participants 12 through 15 years of age are included in the safety analyses. However, the safety disposition table includes 120 HIV-positive participants who were not included in the phase 2/3 safety population analyses.

#### **5.2.4. Demographics and Other Baseline Characteristics**

Overall, the phase 2/3 evaluable efficacy population included 49.4% females, 81.9% White, 9.8% African American, 4.4% Asian participants, and <3% from other racial groups; 26.2% of participants were Hispanic/Latino; 21.4% of participants were  $\geq 65$  years of age. The median age was 51 years. The most frequently reported comorbidities were obesity (35.1%), diabetes (with and without chronic complications, 8.4%) and pulmonary disease (7.8%). Geographically, 76.7% of participants were from the US, 15.3% from Argentina, 6.1% from Brazil, and 2% from South Africa.

The demographic characteristics among vaccine and placebo participants in the all-available efficacy population were similar to the evaluable efficacy population. Please refer to the table below.

**Table 4. Demographic Characteristics, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy (7 Days) Population**

<b>Characteristic</b>	<b>BNT162b2 (N<sup>a</sup>=20033) N<sup>b</sup> (%)</b>	<b>Placebo (N<sup>a</sup>=20244) N<sup>b</sup> (%)</b>	<b>Total (N<sup>a</sup>=40277) N<sup>b</sup> (%)</b>
Sex: Female	9794 (48.9)	10107 (49.9)	19901 (49.4)
Sex: Male	10239 (51.1)	10137 (50.1)	20376 (50.6)
Age at Vaccination: Mean years (SD)	50.3 (15.73)	50.1 (15.78)	50.2 (15.76)
Age at Vaccination: Median (years)	51.0	51.0	51.0
Age at Vaccination: Min, max (years)	(12, 89)	(12, 91)	(12, 91)
Age Group: 16 to <18 years	77 (0.4)	76 (0.4)	153 (0.4)
Age Group: 16 to 55 years	11589 (57.8)	11743 (58.0)	23332 (57.9)
Age Group: >55 years	8396 (41.9)	8454 (41.8)	16850 (41.8)
Age Group: ≥65 years	4294 (21.4)	4319 (21.3)	8613 (21.38)
Age Group: ≥75 years	860 (4.3)	852 (4.2)	1712 (4.3)
Race: American Indian or Alaska Native	131 (0.7)	122 (0.6)	253 (0.6)
Race: Asian	880 (4.4)	883 (4.4)	1763 (4.4)
Race: Black or African American	1957 (9.8)	1972 (9.7)	3929 (9.8)
Race: Native Hawaiian or Other Pacific Islander	54 (0.3)	29 (0.1)	83 (0.2)
Race: White	16387 (81.8)	16619 (82.1)	33006 (81.9)
Race: Multiracial	523 (2.6)	493 (2.4)	1016 (2.5)
Race: Not reported	101 (0.5)	126 (0.6)	227 (0.6)
Ethnicity: Hispanic or Latino	5272 (26.3)	5281 (26.1)	10553 (26.2)
Ethnicity: Not Hispanic or Latino	14652 (73.1)	14847 (73.3)	29499 (73.2)
Ethnicity: Not reported	109 (0.5)	116 (0.6)	225 (0.6)
Comorbidities <sup>c</sup> : Yes	9278 (46.3)	9314 (46.0)	18592 (46.2)
Comorbidities: No	10755 (53.7)	10930 (54.0)	21685 (53.8)
Comorbidity: Obesity	6934 (34.6)	7093 (35.0)	14027 (34.8)

<sup>a</sup>. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.

<sup>b</sup>. n = number of participants with the specified characteristic.

<sup>c</sup>. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index (Appendix B, page 52) category or obesity only (BMI ≥30 kg/m<sup>2</sup>).

Overall, the phase 2/3 safety population included 83.1% White, 9.1% African American, 4.3% Asian participants, and <3% from other racial groups; 28.0% of participants were Hispanic/Latino; 21.6% of participants were >65 years of age. The median age was 52 years, and safety data from a total of 103 participants 16 and 17 years of age were included in this submission. The most frequently reported comorbidities were obesity (35.1%), diabetes (without chronic complications, 7.8%) and chronic pulmonary disease (7.8%). Geographically, 76.7% of participants were from the US, 15.3% from Argentina, 6.1% from Brazil, and 2.0% from South Africa.

The demographic characteristics among vaccine and placebo participants in the all-enrolled population were similar and were also enrolled from sites in Germany (1%) and Turkey (1%). There were no significant imbalances in demographic and other baseline characteristics between the all-enrolled population and phase 2/3 safety population with median 2-month follow-up.

**Table 5. Demographics and Other Baseline Characteristics, Phase 2/3 Safety Population**

Characteristic	BNT162b2				Placebo				Total N=37586 n (%)
	N=18801 n (%)	BNT162b2 n (%)	BNT162b2 n (%)	BNT162b2 n (%)	N=18785 n (%)	Placebo n (%)	Placebo n (%)	Placebo n (%)	
Age (years)	16 to <18	18 to <65	65 to <75	>75	16 to <18	18 to <65	65 to <75	>75	
<b>Age (years)</b>									
Mean	16.40	44.99	68.84	78.07	16.36	44.78	68.84	78.10	50.38
[SD]	[0.49]	[12.66]	[2.80]	[2.78]	[0.48]	[12.72]	[2.78]	[2.81]	[15.70]
Median	16	46	68	77	16	46	69	77	52
Min, max	16-17	18-64	65-74	75-89	16-17	18-64	65-74	75-91	16-91
<b>Sex</b>									
Male	33 (0.2)	7385 (39.3)	1714 (9.1)	470 (2.5)	24 (0.1)	7153 (38.1)	1724 (9.2)	498 (2.7)	19001 (50.6)
Female	20 (0.1)	7305 (38.9)	1513 (8.0)	361 (1.9)	26 (0.1)	7539 (40.1)	1511 (8.0)	310 (1.7)	18585 (49.4)
<b>Race</b>									
White	37 (0.2)	11895 (63.3)	2908 (15.5)	775 (4.1)	38 (0.2)	11891 (63.3)	2930 (15.6)	756 (4.0)	31230 (83.1)
African American	11 (0.1)	1477 (7.9)	186 (1.0)	20 (0.1)	7 (0.0)	1505 (8.0)	189 (1.0)	21 (0.1)	3416 (9.1)
Asian	0 (0.0)	693 (3.7)	81 (0.4)	26 (0.1)	0 (0.0)	715 (3.8)	72 (0.4)	19 (0.1)	1606 (4.3)
Multiracial	3 (0.0)	417 (2.2)	21 (0.1)	7 (0.0)	3 (0.0)	379 (2.0)	18 (0.1)	5 (0.0)	853 (2.3)
Not reported	0 (0.0)	82 (0.4)	11 (0.1)	0 (0.0)	1 (0.0)	98 (0.5)	10 (0.1)	5 (0.0)	207 (0.6)
American Indian or Alaska native	0 (0.0)	84 (0.4)	15 (0.1)	2 (0.0)	1 (0.0)	83 (0.4)	11 (0.1)	2 (0.0)	198 (0.5)
Nat. HI or other Pac. Isl.	2 (0.0)	42 (0.2)	5 (0.0)	1 (0.0)	0 (0.0)	21 (0.1)	5 (0.0)	0 (0.0)	76 (0.2)
<b>Ethnicity</b>									
Hispanic or Latino	6 (0.0)	4595 (24.4)	549 (2.9)	103 (0.5)	5 (0.0)	4616 (24.6)	558 (3.0)	90 (0.5)	10522 (28.0)
Non-Hispanic/non-Latino	47 (0.2)	10009 (53.2)	2658 (14.1)	722 (3.8)	44 (0.2)	10004 (53.3)	2652 (14.1)	707 (3.8)	26843 (71.4)
Not reported	0 (0.0)	86 (0.5)	20 (0.1)	6 (0.0)	1 (0.0)	72 (0.4)	25 (0.1)	11 (0.1)	221 (0.6)
<b>Baseline Body Mass Index (BMI)</b>									
Obese	3 (0.0)	5200 (27.7)	1079 (5.7)	248 (1.3)	14 (0.1)	5242 (27.9)	1147 (6.1)	235 (1.3)	13168 (35.0)
Overweight	14 (0.1)	4901 (26.1)	1278 (6.8)	368 (2.0)	9 (0.0)	4857 (25.9)	1255 (6.7)	340 (1.8)	13022 (34.6)

Pfizer-BioNTech COVID-19 Vaccine  
VRBPAC Briefing Document

Characteristic	BNT162b2				Placebo				Total
	N=18801	BNT162b2	BNT162b2	BNT162b2	N=18785	Placebo	Placebo	Placebo	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
<b>Age (years)</b>	<b>16 to &lt;18</b>	<b>18 to &lt;65</b>	<b>65 to &lt;75</b>	<b>≥75</b>	<b>16 to &lt;18</b>	<b>18 to &lt;65</b>	<b>65 to &lt;75</b>	<b>≥75</b>	
Baseline Evidence of Prior SARS-CoV-2 Infection									
Negative	48 (0.3)	13879 (73.8%)	3109 (16.5)	805 (4.3)	47 (0.3%)	13858 (73.8%)	3115 (16.6%)	788 (4.2%)	35649 (94.8%)
Positive	3 (0.0)	473 (2.5%)	53 (0.3)	16 (0.1)	3 (0.0%)	520 (2.8%)	52 (0.3%)	5 (0.0%)	1125 (3.0%)
Missing	2 (0.0)	338 (1.8%)	65 (0.3)	10 (0.1)	0 (0.0%)	314 (1.7%)	68 (0.4%)	15 (0.1%)	812 (2.2%)
Comorbidities									
No	48 (0.3)	12353 (65.7%)	2081 (11.1)	444 (2.4)	37 (0.2%)	12412 (66.1%)	2118 (11.3%)	470 (2.5%)	29963 (79.7%)
Yes	5 (0.0)	2337 (12.4%)	1146 (6.1)	387 (2.1)	13 (0.1%)	2280 (12.1%)	1117 (5.9%)	338 (1.8%)	7623 (20.3%)
Diabetes Without Chronic Complication	0 (0.0)	814 (4.3%)	497 (2.6)	156 (0.8)	1 (0.0%)	849 (4.5%)	491 (2.6%)	132 (0.7%)	2940 (7.8%)
Chronic Pulmonary Disease	5 (0.0)	1093 (5.8%)	286 (1.5)	89 (0.5)	12 (0.1%)	1060 (5.6%)	309 (1.6%)	66 (0.4%)	2920 (7.8%)
Myocardial Infarction	0 (0.0)	82 (0.4%)	71 (0.4)	41 (0.2)	0 (0.0%)	73 (0.4%)	83 (0.4%)	31 (0.2%)	381 (1.0%)
Peripheral Vascular Disease	0 (0.0)	26 (0.1%)	67 (0.4)	31 (0.2)	0 (0.0%)	29 (0.2%)	52 (0.3%)	33 (0.2%)	238 (0.6%)
Liver Disease (mild, moderate or severe)	0 (0.0)	83 (0.4%)	34 (0.2)	7 (0.0)	0 (0.0%)	67 (0.4%)	17 (0.1%)	6 (0.0%)	214 (0.6%)
Diabetes With Chronic Complication	0 (0.0)	47 (0.2%)	36 (0.2)	15 (0.1)	0 (0.0%)	47 (0.3%)	47 (0.3%)	18 (0.1%)	210 (0.6%)
Congestive Heart Failure	0 (0.0)	44 (0.2%)	26 (0.1)	17 (0.1)	0 (0.0%)	36 (0.2%)	30 (0.2%)	16 (0.1%)	169 (0.4%)
AIDS/HIV	0 (0.0)	0 (0.0%)	0 (0.0)	0 (0.0)	0 (0.0%)	1 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.0%)

Pfizer-BioNTech COVID-19 Vaccine  
VRBPAC Briefing Document

Characteristic	BNT162b2				Placebo				Total
	N=18801 n (%)	BNT162b2 n (%)	BNT162b2 n (%)	BNT162b2 n (%)	N=18785 n (%)	Placebo n (%)	Placebo n (%)	Placebo n (%)	N=37586 n (%)
<b>Age (years)</b>	<b>16 to &lt;18</b>	<b>18 to &lt;65</b>	<b>65 to &lt;75</b>	<b>≥75</b>	<b>16 to &lt;18</b>	<b>18 to &lt;65</b>	<b>65 to &lt;75</b>	<b>≥75</b>	
Hypertension only	0 (0.0)	2569 (13.7%)	1528 (8.1)	488 (2.6)	1 (0.0%)	2621 (14.0%)	1569 (8.4%)	432 (2.3%)	9208 (24.5%)

Source: FDA-generated table.

Abbreviations: n = number of participants with the specified characteristic; N = number of participants ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo, N is denominator for the percentage calculations; SD = standard deviation; min, max = minimum, maximum; Nat. HI = Native Hawaiian; Pac. Isl. = Pacific Islander  
Data analysis cutoff date: November 14, 2020.

## 5.2.5. Vaccine Efficacy

### Primary Efficacy Analyses

#### Efficacy Results – Primary Endpoint (Evaluable Efficacy Population)

For the first primary efficacy endpoint, vaccine efficacy (VE) for BNT162b2 against confirmed COVID-19 was evaluated in participants without evidence of prior SARS-CoV-2 infection prior to 7 days after Dose 2. For the second primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants with and without evidence of prior SARS-CoV-2 infection prior to 7 days after Dose 2. Cases were counted from 7 days after Dose 2 for both endpoints. The criterion for success was met if the posterior probability that true vaccine efficacy >30% conditioning on the available data was >99.5% at the final analysis.

For participants without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0%. The case split was 8 COVID-19 cases in the BNT162b2 group compared to 162 COVID-19 cases in the placebo group ([Table 6](#)). The 95% credible interval for the vaccine efficacy was 90.3% to 97.6%, indicating that the true VE is at least 90.3% with a 97.5% probability, which met the pre-specified success criterion.

**Table 6. Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection - Evaluable Efficacy Population**

<b>Pre-specified Age Group</b>	<b>BNT162b2 N<sup>a</sup> = 18198 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup> =18325 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>	<b>Met Predefined Success Criterion*</b>
All participants	8 2.214 (17411)	162 2.222 (17511)	95.0 (90.3, 97.6) <sup>e</sup>	Yes
16 to 55 years	5 1.234 (9897)	114 1.239 (9955)	95.6 (89.4, 98.6) <sup>f</sup>	NA
> 55 years and older	3 0.980 (7500)	48 0.983 (7543)	93.7 (80.6, 98.8) <sup>f</sup>	NA

\*Success criterion: the posterior probability that true vaccine efficacy > 30% conditioning on the available data is >99.5% at the final analysis

<sup>a</sup> N = number of participants in the specified group.

<sup>b</sup> n1 = Number of participants meeting the endpoint definition.

<sup>c</sup> Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

<sup>d</sup> n2 = Number of participants at risk for the endpoint.

<sup>e</sup> Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.

<sup>f</sup> Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

For participants with and without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively ([Table 7](#)). The posterior probability was >99.99% for the true VE being greater than 30%. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%, indicating that the true VE is at least 89.9% with a 97.5% probability given the available data.

**Table 7. Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants With And Without Evidence of Prior SARS-CoV-2 Infection, Evaluable Efficacy Population**

<b>Pre-specified Age Group</b>	<b>BNT162b2 N<sup>a</sup> = 19965 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup> =20172 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>	<b>Met Predefined Success Criterion*</b>
All participants	9 2.332 (18559)	169 2.345 (18708)	94.6 (89.9, 97.3) <sup>e</sup>	Yes
16 to 55 years	6 1.309 (10653)	120 1.317 (10738)	95.0 (88.7, 98.2) <sup>f</sup>	NA
>55 years and older	3 1.022 (7892)	49 1.028 (7956)	93.8 (80.9, 98.8) <sup>f</sup>	NA

\*Success criterion: the posterior probability that true vaccine efficacy >30% conditioning on the available data is >99.5% at the final analysis

<sup>a</sup> N = number of participants in the specified group.

<sup>b</sup> n1 = Number of participants meeting the endpoint definition.

<sup>c</sup> Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

<sup>d</sup> n2 = Number of participants at risk for the endpoint.

<sup>e</sup> Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.

<sup>f</sup> Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

### Subgroup Analyses of Vaccine Efficacy

Subgroup analyses of the second primary efficacy endpoint provide additional information about the VE for participants with and without evidence of infection prior to vaccination in specific populations enrolled, which is the endpoint considered to represent the general population who may receive the vaccine, as baseline evidence of prior infection may not be known by all people who might receive the vaccine. The results are displayed below in [Table 8](#). The VE point estimates for the subgroup analyses were comparable to results for the first primary efficacy endpoint.

VE point estimates were uniformly high across the subgroups examined with the exception of participants identifying as multiracial and participants with evidence of prior SARS-CoV-2 infection at enrollment, for which too few COVID-19 cases occurred to interpret efficacy data for these subgroups. Additionally, the numbers of participants and cases in some other specific subgroups, such as the adolescent age group and racial subgroups, limits the interpretability of the VE results because of the wide credible intervals, but are displayed for completeness.

**Table 8: Subgroup Analyses of Second Primary Endpoint: First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup, Participants With and Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy (7 Days) Population**

<b>Efficacy Endpoint Subgroup</b>	<b>BNT162b2 N<sup>a</sup>=19965 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=20172 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)<sup>e</sup></b>
Overall	9 2.332 (18559)	169 2.345 (18708)	94.6 (89.6, 97.6)
<b>Age group (years)</b>			
16 to 17	0 0.003 (58)	1 0.003 (61)	100.0 (-3969.9, 100.0)
18 to 64	8 1.799 (14443)	149 1.811 (14566)	94.6 (89.1, 97.7)
65 to 74	1 0.424 (3239)	14 0.423 (3255)	92.9 (53.2, 99.8)
≥75	0 0.106 (805)	5 0.109 (812)	100.0 (-12.1, 100.0)
<b>At risk<sup>f</sup></b>			
Yes	4 1.083 (8584)	87 1.084 (8609)	95.4 (87.8, 98.8)
No	5 1.250 (9975)	82 1.261 (10099)	93.8 (85.0, 98.1)
<b>Age group (years) and at risk</b>			
16-64 and not at risk	5 1.012 (8172)	75 1.019 (8239)	93.3 (83.6, 97.9)
16-64 and at risk	3 0.790 (6329)	75 0.794 (6388)	96.0 (87.8, 99.2)
≥65 and not at risk	0 0.238 (1794)	7 0.241 (1849)	100.0 (29.5, 100.0)
≥65 and at risk	1 0.293 (2250)	12 0.290 (2218)	91.7 (44.2, 99.8)
<b>Obese<sup>g</sup></b>			
Yes	3 0.810 (6445)	68 0.832 (6582)	95.5 (86.2, 99.1)
No	6 1.522 (12108)	101 1.513 (12120)	94.1 (86.7, 97.9)
<b>Age group (years) and obese</b>			
16-64 and not obese	5 1.163 (9380)	89 1.162 (9422)	94.4 (86.4, 98.2)
16-64 and obese	3 0.637 (5116)	61 0.651 (5199)	95.0 (84.6, 99.0)
≥65 and not obese	1 0.358 (2715)	12 0.351 (2685)	91.8 (44.7, 99.8)
≥65 and obese	0 0.172 (1328)	7 0.180 (1382)	100.0 (27.4, 100.0)
<b>Sex</b>			
Female	5 1.149 (9102)	84 1.176 (9366)	93.9 (85.2, 98.1)
Male	4 1.183 (9457)	85 1.170 (9342)	95.3 (87.6, 98.8)
<b>Ethnicity</b>			
Hispanic or Latino	3 0.637 (5074)	55 0.638 (5090)	94.5 (83.2, 98.9)

<b>Efficacy Endpoint Subgroup</b>	<b>BNT162b2 N<sup>a</sup>=19965 Cases n<sup>1</sup><sup>b</sup> Surveillance Time<sup>c</sup> (n<sup>2</sup><sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=20172 Cases n<sup>1</sup><sup>b</sup> Surveillance Time<sup>c</sup> (n<sup>2</sup><sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)<sup>e</sup></b>
Not Hispanic or Latino	6 1.681 (13380)	114 1.693 (13509)	94.7 (88.1, 98.1)
<b>Race</b>			
American Indian or Alaska native	0 0.011 (104)	1 0.010 (104)	100.0 (-3511.0, 100.0)
Asian	1 0.095 (796)	4 0.097 (808)	74.4 (-158.7, 99.5)
Black or African American	0 0.187 (1758)	7 0.188 (1758)	100.0 (30.4, 100.0)
Native Hawaiian or other Pacific Islander	0 0.006 (50)	1 0.003 (29)	100.0 (-2112.1, 100.0)
White	7 1.975 (15294)	153 1.990 (15473)	95.4 (90.3, 98.2)
Multiracial	1 0.047 (467)	1 0.042 (424)	10.4 (-6934.9, 98.9)
Not reported	0 0.010 (90)	2 0.013 (112)	100.0 (-581.6, 100.0)
<b>Baseline SARS-CoV-2 Status</b>			
Positive <sup>h</sup>	1 0.056 (526)	1 0.060 (567)	-7.1 (-8309.9, 98.6)
Negative <sup>i</sup>	8 2.237 (17637)	164 2.242 (17720)	95.1 (90.1, 97.9)
Unknown	0 0.039 (396)	4 0.043 (421)	100.0 (-68.9, 100.0)

<sup>a</sup>. N = number of participants in the specified group.

<sup>b</sup>. n1 = Number of participants meeting the endpoint definition.

<sup>c</sup>. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

<sup>d</sup>. n2 = Number of participants at risk for the endpoint.

<sup>e</sup>. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

<sup>f</sup>. At risk is defined as having at least one of the Charlson comorbidity index (Appendix B, page 52) category or obesity (BMI ≥30 kg/m<sup>2</sup>).

<sup>g</sup>. Obese is defined as BMI ≥30 kg/m<sup>2</sup>.

<sup>h</sup>. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

<sup>i</sup>. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

The demographics of the participants with confirmed COVID-19 cases contributing to the primary efficacy analysis are displayed below in [Table 9](#).

**Table 9. Demographic Characteristics, Participants With Protocol Defined Case (Without Evidence of Infection Prior to 7 Days After Dose 2)**

<b>Characteristic</b>	<b>BNT162b2 (N<sup>a</sup>=8) N<sup>b</sup> (%)</b>	<b>Placebo (N<sup>a</sup>=162) N<sup>b</sup> (%)</b>	<b>Total (N<sup>a</sup>=170) N<sup>b</sup> (%)</b>
Sex: Female	5 (62.5)	81 (50.0)	86 (50.6)
Sex: Male	3 (37.5)	81 (50.0)	84 (49.4)
Age at Vaccination: Mean years (SD)	51.4 (12.47)	47.4 (15.21)	47.6 (15.09)
Age at Vaccination: Median (years)	51	48	48
Age at Vaccination: Min, max (years)	(30, 69)	(18, 79)	(18, 79)
Age Group: 16 to < 18 years	0	0	0
Age Group: 18 to < 65 years	7 (87.5)	143 (88.3)	150 (88.2)
Age Group: ≥ 65 to < 75 years	1 (12.5)	14 (8.6)	15 (8.8)
Age Group: ≥ 75 years	0	5 (3.1)	5 (2.9)
Race: American Indian or Alaska Native	0	1 (0.6)	1 (0.6)
Race: Asian	1 (12.5)	4 (2.5)	5 (2.9)
Race: Black or African American	0	7 (4.3)	7 (4.1)
Race: Native Hawaiian or Other Pacific Islander	0	1 (0.6)	1 (0.6)
Race: White	7 (87.5)	146 (90.1)	153 (90.0)
Race: Multiracial	0	1 (0.6)	1 (0.6)
Race: Not reported	0	2 (1.2)	2 (1.2)
Ethnicity: Hispanic or Latino	3 (37.5)	53 (32.7)	56 (32.9)
Ethnicity: Not Hispanic or Latino	5 (62.5)	109 (67.3)	114 (67.1)
Ethnicity: Not reported	0	0	0
Comorbidities <sup>c</sup> : Yes	4 (50.0)	86 (53.1)	90 (52.9)
Comorbidities: No	4 (50.0)	76 (46.9)	80 (47.1)
Comorbidity: Obesity	3 (37.5)	67 (41.4)	70 (41.2)

<sup>a</sup> N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.

<sup>b</sup> n = Number of participants with the specified characteristic.

<sup>c</sup> Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index (Appendix B, page 52) category or obesity only (BMI ≥30 kg/m<sup>2</sup>).

Only 3% of participants had evidence of prior infection at study enrollment, and additional analyses showed that very few COVID-19 cases occurred in these participants over the course of the entire study (9 in the placebo group and 10 in the BNT162b2 group, only 1 of which occurred 7 days or more after completion of the vaccination regimen – data not shown). The placebo group attack rate from enrollment to the November 14, 2020, data cut-off date was 1.3% both for participants without evidence of prior infection at enrollment (259 cases in 19,818 participants) and for participants with evidence of prior infection at enrollment (9 cases in 670 participants). While limited, these data do suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

Additional analyses of the first primary efficacy endpoint were conducted to evaluate the vaccine efficacy, by comorbidity status. VE point estimates were uniformly high across the comorbidities examined, though for some interpretation of the results is limited by small numbers of participants and/or cases.

**Table 10. Vaccine Efficacy: First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status, Among Participants Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy (7 Days) Population**

Efficacy Endpoint Subgroup	BNT162b2 (30 µg) N <sup>a</sup> =18198 Cases n <sup>1b</sup> Surveillance Time <sup>c</sup> (n <sup>2d</sup> )	Placebo N <sup>a</sup> =18325 Cases n <sup>1b</sup> Surveillance Time <sup>c</sup> (n <sup>2d</sup> )	Vaccine Efficacy % (95% CI <sup>e</sup> )
Overall	8 2.214 (17411)	162 2.222 (17511)	95.0 (90.0, 97.9)
Comorbidity			
No comorbidity	4 1.189 (9381)	76 1.197 (9482)	94.7 (85.9, 98.6)
Any comorbidity <sup>f</sup>	4 1.025 (8030)	86 1.025 (8029)	95.3 (87.7, 98.8)
Any malignancy	1 0.092 (704)	4 0.090 (681)	75.7 (-145.8, 99.5)
Cardiovascular	0 0.067 (534)	5 0.062 (492)	100.0 (-0.8, 100.0)
Chronic pulmonary disease	1 0.175 (1374)	14 0.171 (1358)	93.0 (54.1, 99.8)
Diabetes	1 0.176 (1372)	19 0.176 (1374)	94.7 (66.8, 99.9)
Obese (BMI≥30.0 kg/m <sup>2</sup> )	3 0.763 (6000)	67 0.782 (6103)	95.4 (86.0, 99.1)
Hypertension	2 0.567 (4413)	44 0.567 (4437)	95.4 (82.6, 99.5)
Diabetes (including gestational diabetes)	1 0.177 (1381)	20 0.178 (1384)	95.0 (68.7, 99.9)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

<sup>a</sup> N = number of participants in the specified group.

<sup>b</sup> n1 = Number of participants meeting the endpoint definition.

<sup>c</sup> Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

<sup>d</sup> n2 = Number of participants at risk for the endpoint.

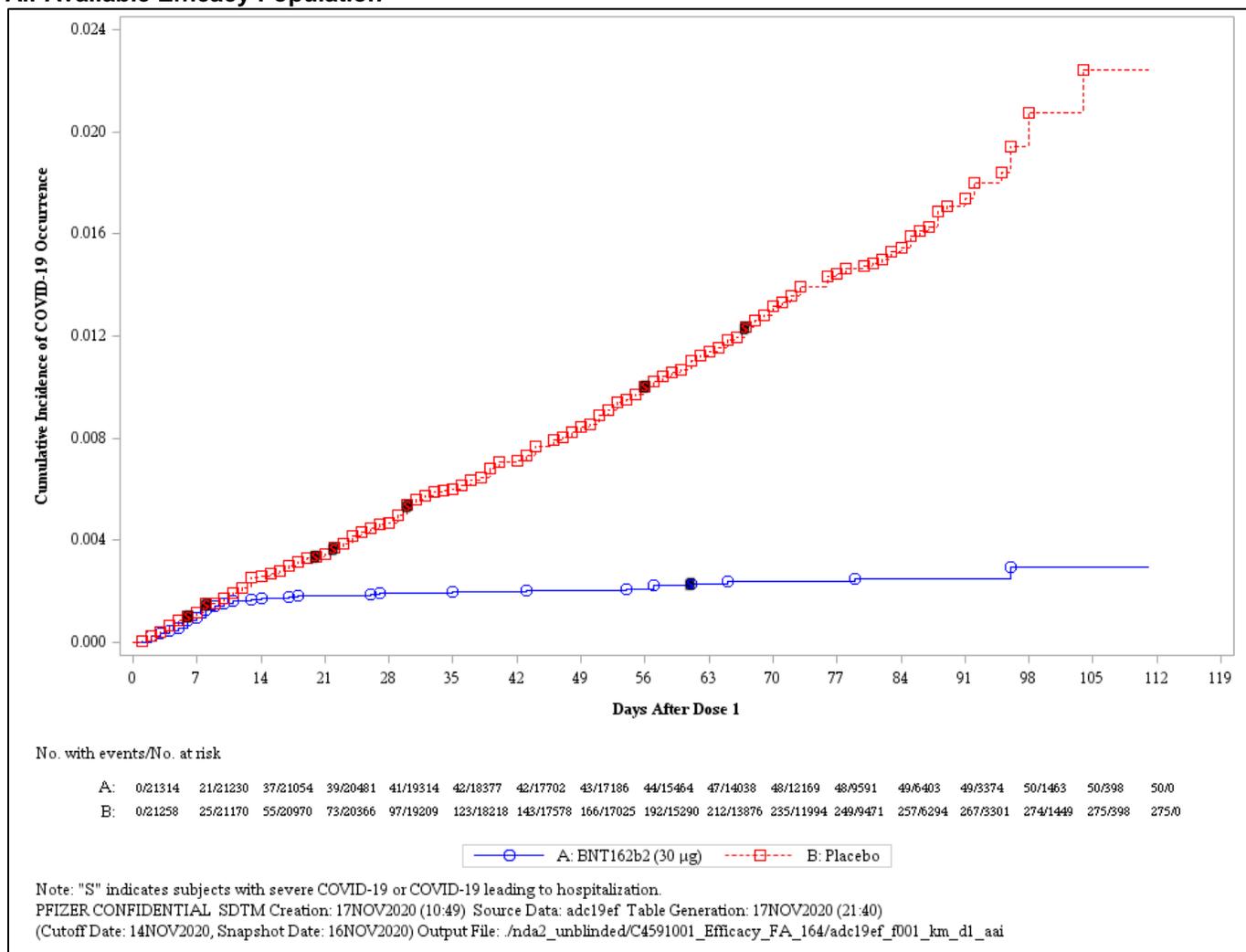
<sup>e</sup> Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

<sup>f</sup> Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least one of the Charlson comorbidity index (Appendix B, page 52) category or BMI ≥30 kg/m<sup>2</sup>.

## Cumulative Incidence Curves

Based on the cumulative incidence curve for the all-available efficacy population after Dose 1, (Figure 2), COVID-19 disease onset appears to occur similarly for both BNT162b2 and placebo groups until approximately 14 days after Dose 1, at which time point, the curves diverge, with more cases accumulating in the placebo group than in the BNT162b2 group, and there does not appear to be evidence of waning protection during the follow-up time of approximately 2 months following the second dose that is being evaluated at this point in time.

**Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Dose 1 All-Available Efficacy Population**



## Secondary Efficacy Analyses

The secondary efficacy endpoints evaluate the VE of BNT162b2 for the prevention of COVID-19 disease from 14 days after Dose 2 and based on the CDC’s definition of COVID-19 disease from 7 and 14 days after Dose 2. The case splits and VE for each of these secondary efficacy endpoints were each similar to the primary efficacy endpoints described above.

## Severe COVID-19 Cases

In the final analysis of the evaluable efficacy population (7 days), four participants had severe COVID-19 disease at least 7 days after Dose 2 (one subject who received BNT162b2 and three participants who received placebo). The vaccine recipient who had severe COVID-19 disease met the severe case definition because oxygen saturation at the COVID-19 illness visit was 93% on room air. The subject was not hospitalized, did not seek further medical care, and did not have risk factors for severe disease. The three placebo recipients who had severe COVID-19 disease met the severe case definition for the following reasons: one subject had an oxygen saturation of 92% on room air without other severe disease criteria, one subject was

hospitalized for noninvasive positive pressure ventilation with bilateral pneumonia, and one subject had an oxygen saturation of 92% and ICU admission for heart block. One of these placebo recipients with severe disease also had a body mass index > 30 kg/m<sup>2</sup> as a risk factor, while the other two participants did not have any risk factors for severe disease. The vaccine efficacy of this secondary efficacy endpoint is shown in [Table 11](#).

**Table 11. First Severe COVID-19 Occurrence from 7 Days after Dose 2 - Evaluable Efficacy Population**

<b>Secondary Efficacy Endpoint</b>	<b>BNT162b2 N<sup>a</sup>=18198 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=18325 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>	<b>Met Predefined Success Criterion*</b>
First severe COVID-19 occurrence from <u>7 days</u> after Dose 2 in participants <u>without</u> evidence of prior SARS-CoV-2 infection	1 2.215 (17411)	3 2.232 (17511)	66.4 (-124.8, 96.3) <sup>e</sup>	No

\*Success criterion: the posterior probability that true vaccine efficacy > 30% conditioning on the available data is >98.6% at the final analysis.

<sup>a</sup> N = number of participants in the specified group.

<sup>b</sup> n1 = Number of participants meeting the endpoint definition.

<sup>c</sup> Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 or 14 days after Dose 2 to the end of the surveillance period depending on specified endpoint.

<sup>d</sup> n2 = Number of participants at risk for the endpoint.

<sup>e</sup> Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.

<sup>f</sup> Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

In the all-available efficacy population, ten participants had severe COVID-19 disease after Dose 1 (one subject who received BNT162b2 and nine participants who received placebo). Five of the remaining six placebo recipients who had severe COVID-19 disease were hospitalized, two of whom were admitted to an intensive care unit. Five of these remaining six placebo recipients who had severe disease had at least one risk factor for severe disease. The total number of severe cases is small, which limits the overall conclusions that can be drawn; however, the case split does suggest protection from severe COVID-19 disease.

**Table 12. First Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population**

<b>Secondary Efficacy Endpoint</b>	<b>BNT162b2 N<sup>a</sup>=21669 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=21686 Cases n1<sup>b</sup> Surveillance Time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>
First severe case occurrence after Dose 1	1 4.021 (21314)	9 4.006 (21259)	88.9 (20.1, 99.7) <sup>f</sup>
After Dose 1 to before Dose 2	0	4	100.0 (-51.5, 100.0)
Dose 2 to 7 days after Dose 2	0	1	100.0 (-3800.0, 100.0)
≥7 Days after Dose 2	1	4	75.0 (-152.6, 99.5)

<sup>a</sup> N = number of participants in the specified group.

<sup>b</sup> n1 = Number of participants meeting the endpoint definition.

<sup>c</sup> Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 or 14 days after Dose 2 to the end of the surveillance period depending on specified endpoint.

<sup>d</sup> n2 = Number of participants at risk for the endpoint.

<sup>e</sup> Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.

<sup>f</sup> Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

## Additional Efficacy Analyses

Additional analyses of the first primary efficacy endpoint were conducted to evaluate the all-available efficacy population, for all participants regardless of evidence of prior infection through 7 days after Dose 2 (Table 13).

**Table 13. Primary Efficacy Endpoint –All-Available Efficacy Population**

Efficacy Endpoint	BNT162b2	Placebo	Vaccine Efficacy % (95% CI)
	N <sup>a</sup> =21669 Cases n <sup>1</sup> <sup>b</sup> Surveillance Time <sup>c</sup> (n <sup>2</sup> <sup>d</sup> )	N <sup>a</sup> =21686 Cases n <sup>1</sup> <sup>b</sup> Surveillance Time <sup>c</sup> (n <sup>2</sup> <sup>d</sup> )	
First COVID-19 occurrence after Dose 1 – Dose 1	50 4.015 (21314)	275 3.982 (21258)	82.0 (75.6, 86.9) <sup>f</sup>
After Dose 1 to before Dose 2	39	82	52.4 (29.5, 68.4)
Dose 2 to 7 days after Dose 2	2	21	90.5 (61, 98.9)
≥7 Days after Dose 2	9	172	94.8 (89.8, 97.6)

<sup>a</sup> N = number of participants in the specified group.

<sup>b</sup> n<sup>1</sup> = Number of participants meeting the endpoint definition.

<sup>c</sup> Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 or 14 days after Dose 2 to the end of the surveillance period depending on specified endpoint.

<sup>d</sup> n<sup>2</sup> = Number of participants at risk for the endpoint.

<sup>e</sup> Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.

<sup>f</sup> Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

VE in participants in the all-available efficacy population was similar to results in the evaluable efficacy population. The VE for the prevention of COVID-19 disease after Dose 1 is 82%, in the all-available efficacy population. Based on the number of cases accumulated after Dose 1 and before Dose 2, there does seem to be some protection against COVID-19 disease following one dose; however, these data do not provide information about longer term protection beyond 21 days after a single dose.

## Efficacy Summary

The data submitted in this EUA request were consistent with the recommendations set forth in the FDA Guidance on Emergency Use Authorization for Vaccines to Prevent COVID-19 and met the prespecified success criteria established in the protocol. In the planned interim and final analyses, vaccine efficacy after 7 days post Dose 2 was 95%, (95% CI 90.3; 97.6) in participants without prior evidence of SARS-CoV-2 infection and >94% in the group of participants with or without prior infection. Efficacy outcomes were consistently robust (≥93%) across demographic subgroups.

Efficacy against severe COVID-19 occurring after the first dose was 88.9% (95% CI 20.1, 99.7), with an estimated VE of 75.0% (95% CI -152.6, 99.5) (1 case in BNT162b2 group and 4 cases in placebo group) against severe COVID-19 occurring at least 7 days after Dose 2.

Among all participants (regardless of evidence of infection before or during the vaccination regimen), 50 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared with 275 cases in the placebo group, indicating an estimated VE of 82% (95% CI: 75.6%, 86.9%) against confirmed COVID-19 occurring after Dose 1, with VE of 52.4% (95% CI: 29.5%, 68.4%) between Dose 1 and Dose 2. The efficacy observed after Dose 1 and before Dose 2, from a post-hoc analysis, cannot support a conclusion on the efficacy of a single dose of the vaccine, because the time of observation is limited by the fact that most of the participants received a

second dose after three weeks. The trial did not have a single-dose arm to make an adequate comparison.

## 5.2.6. Safety

### Overview of Adverse Events

Table 14 below presents an overview of all adverse events in the phase 2/3 safety population. A higher proportion of vaccine recipients reported adverse events compared with placebo recipients, and this imbalance was driven by reactogenicity (solicited adverse events) reported in the 7 days following vaccination and unsolicited adverse events corresponding to reactogenicity symptoms among participants not in the reactogenicity subset (see presentation of unsolicited adverse events in a later section). Proportions of participants with serious adverse events, deaths, and withdrawals due to adverse events were balanced between treatment groups.

**Table 14. Study C4591001 Safety Overview- Ages 16 years and older**

<b>Participants Experiencing at Least One:</b>	<b>BNT162b2 n/N (%)</b>	<b>Placebo n/N (%)</b>
Immediate unsolicited AE Within 30 minutes after vaccination <sup>a</sup>		
Dose #1	78/18801 (0.4)	66/18785 (0.4)
Dose #2	52/18494 (0.3)	39/18470 (0.2)
Solicited injection site reaction within 7 days <sup>b</sup>		
Dose #1	3216/4093 (78.6)	525/4090 (12.8)
Dose #2	2748/3758 (73.1)	396/3749 (10.6)
Solicited systemic AE within 7 days <sup>b</sup>		
Dose #1	2421/4093 (59.1)	1922/4090 (47.0)
Dose #2	2627/3758 (69.9)	1267/3749 (33.8)
From Dose 1 through 1 month after Dose 2 <sup>a</sup>		
Unsolicited non-serious AE	5071/18801 (27.0)	2356/18785 (12.5)
SAE	103/18801 (0.5)	81/18785 (0.4)
From Dose 1 through cutoff date (safety population)		
SAE	124/18801 (0.7)	101/18785 (0.5)
From Dose 1 through cutoff date (all-enrolled) <sup>c</sup>		
Withdrawal due AEs	37/21621 (0.6)	30/21631 (0.5)
SAE	126/21621 (0.6)	111/21631 (0.5)
Deaths	2/21621 (0.0)	4/21631 (0.0)

Source: c4591001-safety-tables-ae3.pdf pages 216,446,459,463; c4591001-safety-tables-cos-reacto.pdf, pages 113-114.

n= number of participants with the specified reaction or AE.

<sup>a</sup> N: number of participants in the phase 2/3 safety population.

<sup>b</sup> N: number of participants in the reactogenicity subset of the phase 2/3 safety population.

<sup>c</sup> N: number of participants in the all-enrolled population.

Data analysis cutoff date: November 14, 2020.

### Solicited Local Reactions and Systemic Adverse Events

As of the cutoff date, solicited reactogenicity data in participants 16 and 17 years of age were not collected by e-diary and are not available. Symptoms consistent with solicited reactogenicity that were reported by these participants were collected and analyzed as unsolicited adverse events and are discussed with review of those data.

### Solicited Local Reactions

For each age group in the reactogenicity subset (younger: 18 to 55 years, older: >55 years) and overall (18 years and older), the median onset of local reactions in the vaccine group was 0 (day of vaccination) to 2 days after either dose and lasted a median duration between 1 and 2 days.

For both age groups, injection site pain was the most frequent solicited local adverse reaction. After dose 2, the younger age group reported any pain more frequently than the older age group (77.8% vs 66.1%) and pain characterized as moderate (27.1% vs. 18.0%); a similar pattern was observed after Dose 1. Injection site redness and swelling after each dose were generally similar for both age groups.

#### *Subgroup analyses by age*

**Table 15. Frequency of Solicited Local Reactions Within 7 Days After Each Vaccination, Reactogenicity Subset of the Phase 2/3 Safety Population\*, 18 to 55 Years of Age**

<b>Local Reaction</b>	<b>BNT162b2 Dose 1 N=2238 n (%)</b>	<b>Placebo Dose 1 N=2248 n (%)</b>	<b>BNT162b2 Dose 2 N=2045 n (%)</b>	<b>Placebo Dose 2 N=2053 n (%)</b>
<b>Pain<sup>a</sup></b>				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)
<b>Redness<sup>b</sup></b>				
Any	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
<b>Swelling<sup>b</sup></b>				
Any	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)

Source: adapted from EUA 27034, amendment 3, Table 17.

n = number of participants with the specified reaction.

N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

<sup>a</sup> Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity.

<sup>b</sup> Mild: 2.0 to ≤5.0 cm; moderate: 5.0 to ≤10.0 cm; severe: >10.0 cm.

\* Participants in the reactogenicity subset of the safety population ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

**Table 16. Frequency of Solicited Local Reactions Within 7 Days After Each Vaccination, Reactogenicity Subset of the Phase 2/3 Safety Population\*, >55 Years of Age and Older**

Local Reaction	BNT162b2	Placebo	BNT162b2	Placebo
	Dose 1	Dose 1	Dose 2	Dose 2
	N=1802	N=1792	N=1660	N=1646
	n (%)	n (%)	n (%)	n (%)
<b>Pain<sup>a</sup></b>				
Any	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)
<b>Redness<sup>b</sup></b>				
Any	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
<b>Swelling<sup>b</sup></b>				
Any	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)

Source: EUA 27036, amendment 3, Table 21.

n = number of participants with the specified reaction.

N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

<sup>a</sup> Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity.

<sup>b</sup> Mild: 2.0 to ≤5.0 cm; moderate: 5.0 to ≤10.0 cm; severe: >10.0 cm.

\* Participants in the reactogenicity subset of the safety population ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

### Solicited Systemic AEs

For each age group in the reactogenicity subset (younger: 18 to 55 years, older: >55 years) and overall (18 years and older), the median onset of systemic AEs in the vaccine group in general was 1 to 2 days after either dose and lasted a median duration of 1 day.

The frequency and severity of systemic AEs were higher in the younger than the older age groups. Within each age group, the frequency and severity of systemic AEs was higher after Dose 2 than Dose 1, except for vomiting and diarrhea, which was generally similar regardless of dose. For both age groups, fatigue, headache and new/worsened muscle pain were most common.

### *Subgroup analyses by age*

**Table 17. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Vaccination-Reactogenicity Subset of the Phase 2/3 Safety Population\*, 18 to 55 Years of Age**

Adverse Event	BNT162b2	Placebo	BNT162b2	Placebo
	Dose 1	Dose 1	Dose 2	Dose 2
	N=2238	N=2248	N=2045	N=2053
	n (%)	n (%)	n (%)	n (%)
<b>Fever</b>				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
>38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)

<b>Adverse Event</b>	<b>BNT162b2 Dose 1 N=2238 n (%)</b>	<b>Placebo Dose 1 N=2248 n (%)</b>	<b>BNT162b2 Dose 2 N=2045 n (%)</b>	<b>Placebo Dose 2 N=2053 n (%)</b>
<b>Fatigue<sup>a</sup></b>				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	46 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
<b>Headache<sup>a</sup></b>				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
<b>Chills<sup>a</sup></b>				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)
<b>Vomiting<sup>b</sup></b>				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
<b>Diarrhea<sup>c</sup></b>				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
<b>New or worsened muscle pain<sup>a</sup></b>				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
<b>New or worsened joint pain<sup>a</sup></b>				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
<b>Use of antipyretic or pain medication</b>	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Source: adapted from EUA 27036, amendment 3, Table 19.

n = number of participants with the specified reaction.

N = number of participants in the reactogenicity subset reporting at least 1 yes or no response for the specified reaction after the specified dose.

<sup>a</sup> Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity.

<sup>b</sup> Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration.

<sup>c</sup> Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours.

\* Participants in the reactogenicity subset of the safety population ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

**Table 18. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Vaccination-Reactogenicity Subset of the Phase 2/3 Safety Population\*, >55 Years of Age and Older**

<b>Adverse Event</b>	<b>BNT162b2 Dose 1 N=1802 n (%)</b>	<b>Placebo Dose 1 N=1792 n (%)</b>	<b>BNT162b2 Dose 2 N=1660 n (%)</b>	<b>Placebo Dose 2 N=1646 n (%)</b>
<b>Fever</b>				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
>38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Fatigue<sup>a</sup></b>				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)
<b>Headache<sup>a</sup></b>				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
<b>Chills<sup>a</sup></b>				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
<b>Vomiting<sup>b</sup></b>				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
<b>Diarrhea<sup>c</sup></b>				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
<b>New or worsened muscle pain<sup>a</sup></b>				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
<b>New or worsened joint pain<sup>a</sup></b>				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)

Adverse Event	BNT162b2	Placebo	BNT162b2	Placebo
	Dose 1	Dose 1	Dose 2	Dose 2
	N=1802	N=1792	N=1660	N=1646
	n (%)	n (%)	n (%)	n (%)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Source: EUA 27036, amendment 3, Table 23.

n = number of participants with the specified reaction.

N = number of participants in the reactogenicity subset reporting at least 1 yes or no response for the specified reaction after the specified dose.

<sup>a</sup> Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity.

<sup>b</sup> Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration.

<sup>c</sup> Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours.

\* Participants in the reactogenicity subset of the safety population  $\geq 16$  years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

### Unsolicited (non-serious) AEs

A higher frequency of unsolicited, non-serious adverse events was reported in the vaccine group compared to placebo group and was primarily attributed to local reactions and systemic adverse events in subjects not in the reactogenicity subset and are consistent with solicited reactions/events reported by reactogenicity subset participants during the first 7 days following vaccination. [Table 19](#) below presents unsolicited adverse events reported by at least 1% of participants in any treatment group for the phase 2/3 safety population.

Reports of lymphadenopathy were imbalanced with notably more cases in the vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Bell's palsy was reported by four vaccine participants and none in the placebo group. These cases occurred at 3, 9, 37, and 48 days after vaccination. One case (onset at 3 days postvaccination) was reported as resolved with sequelae within three days after onset, and the other three were reported as continuing or resolving as of the November 14, 2020 data cut-off with ongoing durations of 10, 15, and 21 days, respectively. The observed frequency of reported Bell's palsy in the vaccine group is consistent with the expected background rate in the general population, and there is no clear basis upon which to conclude a causal relationship at this time, but FDA will recommend surveillance for cases of Bell's palsy with deployment of the vaccine into larger populations. There were no other notable patterns or numerical imbalances between treatment groups for specific categories (system organ class or preferred term) of non-serious adverse events, including other neurologic, neuro-inflammatory, and thrombotic events, that would suggest a causal relationship to BNT162b2 vaccine.

**Table 19. Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants in any Treatment Group from Dose 1 to 1-month After Dose 2, Phase 2/3 Safety Population\*, 16 Years of Age and Older**

<b>System Organ Class Preferred Term</b>	<b>BNT162b2 N=18801 n (%)</b>	<b>Placebo N=18785 n (%)</b>	<b>Total N=37586 n (%)</b>
General disorders and administration site conditions	3521 (18.7)	737 (3.9)	4258 (11.3)
Injection site pain	2125 (11.3)	286 (1.5)	2411 (6.4)
Fatigue	1029 (5.5)	260 (1.4)	1289 (3.4)
Pyrexia	1146 (6.1)	61 (0.3)	1207 (3.2)
Chills	999 (5.3)	87 (0.5)	1086 (2.9)
Pain	455 (2.4)	36 (0.2)	491 (1.3)
Musculoskeletal and connective tissue disorders	1387 (7.4)	401 (2.1)	1788 (4.8)
Myalgia	909 (4.8)	126 (0.7)	1035 (2.8)
Arthralgia	212 (1.1)	82 (0.4)	294 (0.8)
Nervous system disorders	1158 (6.2)	460 (2.4)	1618 (4.3)
Headache	973 (5.2)	304 (1.6)	1277 (3.4)
Gastrointestinal disorders	565 (3.0)	368 (2.0)	933 (2.5)
Diarrhoea	194 (1.0)	149 (0.8)	343 (0.9)
Nausea	216 (1.1)	63 (0.3)	279 (0.7)

Source: FDA analysis.

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

%, n/N. n = number of participants reporting at least 1 occurrence of the specified event.

of any event. N = number of participants in the specified group. This value is the denominator for the percentage calculations.

\* Participants ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

### Subgroup analyses by age

16 and 17 years of age: the table below represents an FDA-generated summary of unsolicited AEs consistent with reactogenicity and AEs that occurred at ≥1% and higher in the BNT162b2 Vaccine Group, classified by MedDRA System Organ Class and Preferred Term.

**Table 20. Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants in any Treatment Group from Dose 1 to 1 Month After Dose 2, Phase 2/3 Safety Population\*, 16 and 17 Years of Age**

<b>System Organ Class Preferred Term</b>	<b>BNT162b2 N=53 n (%)</b>	<b>Placebo N=50 n (%)</b>	<b>Total N=103 n (%)</b>
General disorders and administration site conditions	7 (13.2)	3 (6.0)	10 (9.7)
Injection site pain	5 (9.4)	2 (4.0)	7 (6.8)
Pyrexia	5 (9.4)	0	5 (4.9)
Pain	2 (3.8)	0	2 (1.9)
Chills	1 (1.9)	0	1 (1.0)
Injury, poisoning and procedural complications	1 (1.9)	0	1 (1.0)
Concussion	1 (1.9)	0	1 (1.0)
Facial bones fracture	1 (1.9)	0	1 (1.0)
Road traffic accident	1 (1.9)	0	1 (1.0)
Investigations	1 (1.9)	0	1 (1.0)
Body temperature increased	1 (1.9)	0	1 (1.0)

Source: FDA analysis.

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

%, n/N. n = number of participants reporting at least 1 occurrence of the specified event.

of any event. N = number of participants in the specified group. This value is the denominator for the percentage calculations.

\* Participants ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

**Table 21. Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants in any Treatment Group from Dose 1 to 1 Month After Dose 2, Phase 2/3 Safety Population\*, 65 Years and Older**

<b>System Organ Class Preferred Term</b>	<b>BNT162b2 (N=4058) n (%)</b>	<b>Placebo (N=4043) n (%)</b>	<b>Total (N=8101) n (%)</b>
General disorders and administration site conditions	577 (14.2)	118 (2.9)	695 (8.6)
Injection site pain	361 (8.9)	39 (1.0)	400 (4.9)
Fatigue	175 (4.3)	44 (1.1)	219 (2.7)
Chills	143 (3.5)	19 (0.5)	162 (2.0)
Pyrexia	148 (3.6)	10 (0.2)	158 (2.0)
Pain	60 (1.5)	7 (0.2)	67 (0.8)
Musculoskeletal and connective tissue disorders	231 (5.7)	83 (2.1)	314 (3.9)
Myalgia	125 (3.1)	23 (0.6)	148 (1.8)
Arthralgia	42 (1.0)	21 (0.5)	63 (0.8)
Pain in extremity	33 (0.8)	10 (0.2)	43 (0.5)
Nervous system disorders	179 (4.4)	87 (2.2)	266 (3.3)
Headache	127 (3.1)	45 (1.1)	172 (2.1)
Gastrointestinal disorders	127 (3.1)	72 (1.8)	199 (2.5)
Diarrhea	49 (1.2)	26 (0.6)	75 (0.9)
Nausea	40 (1.0)	13 (0.3)	53 (0.7)

Source: FDA analysis.

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

%, n/N. n = number of participants reporting at least 1 occurrence of the specified event.

of any event. N = number of participants in the specified group. This value is the denominator for the percentage calculations.

\* Participants ≥16 years of age enrolled by October 9, 2020 and received at least 1 dose of vaccine or placebo.

Data analysis cutoff date: November 14, 2020.

FDA independently conducted standard MedDRA queries (SMQs) using FDA-developed software (MAED) to evaluate for constellations of unsolicited adverse event preferred terms that could represent various diseases and conditions, including but not limited to allergic, neurologic, inflammatory, and autoimmune conditions. The SMQs, conducted on the phase 2/3 all-enrolled safety population, revealed a slight numerical imbalance of adverse events potentially representing allergic reactions, with more participants reporting hypersensitivity-related adverse events in the vaccine group (137 [0.63%]) compared with the placebo group (111 [0.51%]). No imbalances between treatment groups were evident for any of the other SMQs evaluated.

#### Immediate AEs (phase 2/3 safety population)

The frequency of immediate AEs reported in the vaccine group was 0.4% after Dose 1 and <0.3% after Dose 2 and were mainly consistent with solicited reactogenicity events. In both study groups, the most frequently reported immediate AE was injection site pain (BNT162b2 vaccine 0.3%, placebo 0.2%).

#### Study Withdrawals due to an AE (all-enrolled population)

Of 43,448 enrolled participants, 37 (0.2%) vaccine recipients and 30 (0.1%) placebo recipients (0.1%), and no adolescents 16 to <18 years of age, withdrew from the study due to an AE. AEs in the SOC of General Disorders and Administration Site Conditions (7 vaccine, 3 placebo) was common, with injection site pain the most frequent (2 vaccine, 0 placebo).

## **Serious Adverse Events**

### Deaths

A total of six (2 vaccine, 4 placebo) of 43,448 enrolled participants (0.01%) died during the reporting period from April 29, 2020 (first participant, first visit) to November 14, 2020 (cutoff date). Both vaccine recipients were >55 years of age; one experienced a cardiac arrest 62 days after vaccination #2 and died 3 days later, and the other died from arteriosclerosis 3 days after vaccination #1. The placebo recipients died from myocardial infarction (n=1), hemorrhagic stroke (n=1) or unknown causes (n=2); three of the four deaths occurred in the older group (>55 years of age). All deaths represent events that occur in the general population of the age groups where they occurred, at a similar rate.

### Non-fatal SAEs

In the all-enrolled population of (total N=43,448), the proportions of participants who reported at least 1 SAE during the time period from Dose 1 to the data cutoff date (November 14, 2020) were 0.6% in the BNT162b2 vaccine group and 0.5% in the placebo group. The most common SAEs in the vaccine group which were numerically higher than in the placebo group were appendicitis (0.04%), acute myocardial infarction (0.02%), and cerebrovascular accident (0.02%), and in the placebo arm numerically higher than in the vaccine arm were pneumonia (0.03%), atrial fibrillation (0.02%), and syncope (0.02%). Occurrence of SAEs involving system organ classes and specific preferred terms were otherwise balanced between treatment groups, including no imbalance overall in cardiovascular serious adverse events.

Appendicitis was reported as a SAE for 12 participants, and numerically higher in the vaccine group: 8 vaccine participants ([appendicitis [n=7], appendicitis perforated [n=1]) and 4 placebo participants (appendicitis [n=2], appendicitis perforated [n=1], complicated appendicitis [n=1]). All of the vaccine participants (n=8) and 2 placebo participants were younger than 65 years of age. The cases were considered unrelated to vaccination by the study investigators and occurred no more frequently than expected in the given age groups. FDA agrees that there is no clear basis upon which to suspect that this imbalance represents a vaccine-related risk.

Three SAEs reported in the BNT162 group were considered by the investigator as related to vaccine or vaccine administration: shoulder injury, ventricular arrhythmia, and lymphadenopathy. The investigator and the sponsor thought that the shoulder injury was related to vaccine administration. Two SAEs in the BNT162b2 group and none in the placebo group were considered by the investigator, but not the Sponsor, as related to study vaccination: shoulder injury (n=1), ventricular arrhythmia in a participant with known cardiac conditions (n=1), and lymphadenopathy temporally following vaccination (n=1). In FDA's opinion following review of the adverse event narratives, two of these events were considered as possibly related to vaccine: shoulder injury possibly related to vaccine administration or to the vaccine itself, and lymphadenopathy involving the axilla contralateral to the vaccine injection site. For lymphadenopathy, the event was temporally associated and biologically plausible.

Among participants 16 to 17 years of age, there was 1 participant in the vaccine group who experienced an SAE of facial bones fracture, which was not considered related to study intervention by the investigator.

### Suspected COVID-19 Cases

As specified in the protocol, suspected cases of symptomatic COVID-19 that were not PCR-confirmed were not recorded as adverse events unless they met regulatory criteria for seriousness. Two serious cases of suspected but unconfirmed COVID-19 were reported, both in the vaccine group, and narratives were reviewed. In one case, a 36-year-old male with no medical comorbidities experienced fever, malaise, nausea, headache and myalgias beginning on the day of Dose 2 and was hospitalized 3 days later for further evaluation of apparent infiltrates on chest radiograph and treatment of dehydration. A nasopharyngeal PCR test for SARS-CoV-2 was negative on the day of admission, and a chest CT was reported as normal. The participant was discharged from the hospital 2 days after admission. With chest imaging findings that are difficult to reconcile, it is possible that this event represented reactogenicity following the second vaccination, a COVID-19 case with false negative test that occurred less than 7 days after completion of the vaccination series, or an unrelated infectious process. In the other case, a 66-year-old male with no medical comorbidities experienced fever, myalgias, and shortness of breath beginning 28 days post-Dose 2 and was hospitalized one day later with abnormal chest CT showing a small left-sided consolidation. He was discharged from the hospital 2 days later, and multiple nasopharyngeal PCR tests collected over a 10-day period beginning 2 days after symptom onset were negative. It is possible, though highly unlikely, that this event represents a COVID-19 case with multiple false negative tests that occurred more than 7 days after completion of the vaccination regimen, and more likely that it represents an unrelated infectious process.

Among 3410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1594 occurred in the vaccine group vs. 1816 in the placebo group. Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group. It is possible that the imbalance in suspected COVID-19 cases occurring in the 7 days postvaccination represents vaccine reactogenicity with symptoms that overlap with those of COVID-19. Overall though, these data do not raise a concern that protocol-specified reporting of suspected, but unconfirmed COVID-19 cases could have masked clinically significant adverse events that would not have otherwise been detected.

### Subgroup Analyses

There were no specific safety concerns identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection, and occurrence of solicited, unsolicited, and serious adverse events in these subgroups were generally consistent with the overall study population.

### **Pregnancies**

Female study participants of childbearing potential were screened for pregnancy prior to each vaccination, with a positive test resulting in exclusion or discontinuation from study vaccination. The study is collecting outcomes for all reported pregnancies that occur after vaccination, or before vaccination and not detected by pre-vaccination screening tests. Twenty-three pregnancies were reported through the data cut-off date of November 14, 2020 (12 vaccine, 11 placebo). Study vaccination occurred prior to the last menstrual period (LMP) in 5 participants (4 vaccine, 2 placebo), within 30 days after LMP in 8 participants (4 vaccine, 6 placebo), >30 days after LMP in 1 participant (0 vaccine, 2 placebo), and date of LMP not known in 5 participants (4 vaccine, 1 placebo). Unsolicited AEs related to pregnancy include spontaneous abortion and retained products of conception, both in the placebo group. Pregnancy outcomes are otherwise

unknown at this time.

### **Clinical Laboratory Evaluations**

Clinical laboratory tests (hematology, chemistries) were assessed in study BNT162-01 and C4591001 phase 1. The only common laboratory abnormality reported throughout the studies was transient decreases in lymphocytes 1-3 days after Dose 1, which increased in frequency with increasing dose, were mostly Grade 1-2, generally normalized at the next laboratory assessment 6-8 days after Dose 1 and did not occur after Dose 2. Among C4591001 phase 1 participants who received the 30 µg dose of BNT162b2, transient decreases in lymphocytes post-Dose 1 occurred in 5 of 12 participants 18-55 years of age and in 4 of 12 participants 65-85 years of age. These transient hematological changes were not associated with clinical symptoms.

### **Safety Summary**

The information provided by the Sponsor was adequate for review and to make conclusions about the safety of BNT162b2 in the context of the proposed indication and population for intended use under EUA. The number of participants in the phase 2/3 safety population (N=37586; 18801 vaccine, 18785 placebo) meets the expectations in FDA's Guidance on Development and Licensure of Vaccines to Prevent COVID-19 for efficacy, and the median duration of at least 2 months follow-up after completion of the 2-dose primary vaccination series meets the agency's expectations in FDA's Guidance on its Emergency Use Authorization for Vaccines to Prevent COVID-19. The all-enrolled population contained more participants >16 years of age, regardless of duration of follow-up (43448; 21720 vaccine, 21728 placebo). The demographic and baseline characteristics of the all-enrolled population and the safety population were similar. Although the overall median duration of follow-up in the all-enrolled population was less than 2 months, because the protocol was amended to include subpopulations such as individuals with HIV and adolescents, the data from both populations altogether provide a comprehensive summary of safety.

Local site reactions and systemic solicited events after vaccination were frequent and mostly mild to moderate. The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%); severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after Dose 2 than after Dose 1, and were generally less frequent in adults ≥55 years of age (≤2.8%) as compared to younger participants (≤4.6%). Among adverse events of special interest, which could be possibly related to vaccine, lymphadenopathy was reported in 64 participants (0.3%): 54 (0.5%) in the younger (16 to 55 years) age group; 10 (0.1%) in the older (>55 years) age group; and 6 in the placebo group. The average duration of these events was approximately 10 days, with 11 events ongoing at the time of the data cutoff. Bell's palsy was reported by four vaccine participants. From Dose 1 through 1 month after Dose 2, there were three reports of Bell's palsy in the vaccine group and none in the placebo group. This observed frequency of reported Bell's palsy is consistent with the expected background rate in the general population. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to BNT162b2 vaccine.

A total of six deaths occurred in the reporting period (2 deaths in the vaccine group, 4 in placebo). In the vaccine group, one participant with baseline obesity and pre-existing atherosclerosis died 3 days after Dose 1, and the other participant experienced cardiac arrest

60 days after Dose 2 and died 3 days later. Of the four deaths in the placebo arm, the cause was unknown for two of them, and the other two participants died from hemorrhagic stroke (n=1) and myocardial infarction (n=1), respectively; three deaths occurred in the older group (>55 years of age). All deaths represent events that occur in the general population of the age groups where they occurred, at a similar rate.

The frequency of non-fatal serious adverse events was low (<0.5%), without meaningful imbalances between study arms. The most common SAEs in the vaccine arm which were numerically higher than in the placebo arm were appendicitis (0.04%), acute myocardial infarction (0.02%), and cerebrovascular accident (0.02%), and in the placebo arm numerically higher than in the vaccine arm were pneumonia (0.03%), atrial fibrillation (0.02%), atrial fibrillation (0.02%) and syncope (0.02%). Appendicitis was the most common SAE in the vaccine arm. There were 12 participants with SAEs of appendicitis; 8 in the BNT162b2 group. Of the 8 total appendicitis cases in the BNT162b2 group, 6 occurred in the younger (16 to 55 years) age group and 2 occurred in the older (>55 years) age group (one of the cases in the older age group was perforated). One of the 6 participants with appendicitis in the younger age group also had a peritoneal abscess. Cases of appendicitis in the vaccine group were not more frequent than expected in the general population.

## **6. Sponsor's Plans for Continuing Blinded, Placebo-Controlled Follow-Up**

The Sponsor plans to offer vaccination to participants  $\geq 16$  years of age who originally received placebo and who become eligible for receipt of BNT162b2 according to local or national recommendations. The Sponsor proposes that these participants will be unblinded upon request and will have the opportunity to receive BNT162b2 as part of the study. The Sponsor also proposes that all placebo recipients  $\geq 16$  years of age will be offered BNT162b2 after completing 6 months of follow-up after Dose 2, if they did not request and receive vaccine previously. The participants will provide consent to receive vaccination and to continue follow-up. For these participants, the Sponsor plans a total follow up period of 18 months, with one visit 1-month postvaccination and subsequent phone contacts at 1, 6, and 18 months postvaccination. Safety and efficacy monitoring during this period will include collection of AEs, SAEs, and screening and diagnosing COVID-19 cases.

## **7. Pharmacovigilance Activities**

Pfizer submitted a Pharmacovigilance Plan (PVP) to monitor safety concerns that could be associated with Pfizer-BioNTech COVID-19 Vaccine. The Sponsor identified vaccine-associated enhanced disease including vaccine-associated enhanced respiratory disease as an important potential risk. Use in pregnancy and lactation and vaccine effectiveness are areas the Sponsor identified as missing information. In addition to the safety concerns specified by the Sponsor, FDA requested that the Sponsor update their PVP to include missing information in pediatric participants less than 16 years of age.

The Sponsor will conduct both passive and active surveillance activities for continued vaccine safety monitoring. Passive surveillance activities will include submitting spontaneous reports of the following events to the Vaccine Adverse Event Reporting System (VAERS) within 15 days:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

The Sponsor will also conduct periodic aggregate review of safety data and submit periodic safety reports at monthly intervals. Each periodic safety report is required to contain descriptive information which includes:

- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest
- Newly identified safety concerns in the interval
- Actions taken since the last report because of adverse experiences (e.g., changes made to Vaccination Provider fact sheets, changes made to studies or studies initiated)

Sponsor studies will include completion of long-term follow-up from ongoing clinical trials as well as the following three planned active surveillance studies. Of note, the Sponsor will submit plans for a clinical study to assess safety and immunogenicity in pregnant women and has proposed active surveillance studies designed to monitor vaccination during pregnancy within populations expected to receive the vaccine under EUA.

- Study Protocol Number C4591008. The Sponsor proposes to survey 20,000 U.S. health care workers enrolled in the COVID-19 HERO registry as well as health care workers in certain participating health care facilities about adverse events of special interest, and other clinically significant events of interest after vaccination with the Pfizer-BioNTech COVID-19 Vaccine. Incidence rates of these events in this cohort will be compared to expected rates. The respondents would receive follow-up surveys for a 30-month period.
- Study Protocol Number C4591011. This study is an active safety surveillance evaluation conducted within the Department of Defense Health System Databases using data derived from electronic health records and medical service claims among covered U.S. military and their families. Rates of safety events of interest in vaccinated participants will be compared to unvaccinated comparators. The study will be conducted for 30 months.
- Study Protocol Number C4591012. This study is an active surveillance study for adverse events of special interest and other clinically significant events associated with the Pfizer-BioNTech COVID-19 Vaccine using the Veteran's Health Administration electronic medical record database. Vaccinated participants will be compared to unvaccinated participants or to recipients of seasonal influenza vaccine. The study will be conducted for 30 months.

Currently, the primary objective of all three proposed studies above is descriptive, and the list of adverse events in the studies has not been finalized. FDA will provide feedback on these studies after further review.

### **Reporting to VAERS and Pfizer, Inc.**

Providers administering the Pfizer-BioNTech COVID-19 Vaccine must report to VAERS (as required by the National Childhood Vaccine Injury Act) and to Pfizer the following information associated with the vaccine of which they become aware:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

## **Additional VAERS Reporting**

An additional source of VAERS reports will be through a program administered by the CDC known as v-safe. V-safe is a new smartphone-based opt-in program that uses text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. The system also will provide telephone follow-up to anyone who reports medically significant (important) adverse events. Responses indicating missed work, inability to do normal daily activities, or that the recipient received care from a doctor or other healthcare professional will trigger the VAERS Call Center to reach out to the participant and collect information for a VAERS report, if appropriate.

## **8. Benefit/Risk Assessment in the Context of Proposed Indication and Use Under EUA**

### **8.1. Known Benefits**

The known benefits among recipients of the proposed vaccine relative to placebo are:

- Reduction in the risk of confirmed COVID-19 occurring at least 7 days after Dose 2
- Reduction in the risk of confirmed COVID-19 after Dose 1 and before Dose 2
- Reduction in the risk of confirmed severe COVID-19 any time after Dose 1

The protocol-specified 2-dose vaccination regimen was highly effective in preventing PCR-confirmed COVID-19 occurring at least 7 days after completion of the vaccination regimen. Additional primary efficacy analyses in the all-available efficacy population, including participants who had protocol violations, showed consistency with outcomes in the primary analysis population. Efficacy findings were also consistent across various subgroups, including racial and ethnic minorities, participants aged 65 years and older, and those with one or more of the following conditions: obesity, diabetes, hypertension, and chronic cardiopulmonary diseases. While limited, available data suggest that individuals with previous SARS-CoV-2 infection can be at risk of COVID-19 (i.e., re-infection) and may benefit from vaccination.

Among participants with no evidence of COVID-19 prior to vaccination, the vaccine was effective in reducing the risk of COVID-19 and severe COVID-19 after Dose 1. Fewer severe cases were also observed in the vaccine recipients relative to recipients of placebo during the follow up period after Dose 1. The findings post Dose 1, from a post-hoc analysis, cannot be the basis to assess the potential efficacy of the vaccine when administered as a single dose because the period of observation is limited by the fact that most participants received a second dose three weeks after the first one.

### **8.2. Unknown Benefits/Data Gaps**

#### **Duration of protection**

As the interim and final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months.

#### **Effectiveness in certain populations at high-risk of severe COVID-19**

Although the proportion of participants at high risk of severe COVID-19 is adequate for the overall evaluation of safety in the available follow-up period, the subset of certain groups such as immunocompromised individuals (e.g., those with HIV/AIDS) is too small to evaluate efficacy outcomes.

### **Effectiveness in individuals previously infected with SARS-CoV-2**

The primary endpoint was evaluated in individuals without prior evidence of COVID-19 disease, and very few cases of confirmed COVID-19 occurred among participants with evidence of infection prior to vaccination (although more cases occurred in the placebo group compared with the vaccine group). Therefore, available data are insufficient to make conclusions about benefit in individuals with prior SARS-CoV-2 infection. However, available data, while limited, do suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

### **Effectiveness in pediatric populations**

The representation of pediatric participants in the study population is too limited to adequately evaluate efficacy in pediatric age groups younger than 16 years. No efficacy data are available from participants ages 15 years and younger. Although adolescents 16 to 17 years of age were included in the overall efficacy analysis, only one confirmed COVID-19 case was reported in this age group. However, it is biologically reasonable to extrapolate that effectiveness in ages 16 to 17 years would be similar to effectiveness in younger adults. Efficacy surveillance continued beyond November 14, 2020, and the Sponsor has represented that additional data will be provided in a BLA.

### **Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections**

The study enrollment and follow-up occurred during the period of July 27 to November 14, 2020, in various geographical locations. The evolution of the pandemic characteristics, such as increased attack rates, increased exposure of subpopulations, as well as potential changes in the virus infectivity, antigenically significant mutations to the S protein, and/or the effect of co-infections may potentially limit the generalizability of the efficacy conclusions over time. Continued evaluation of vaccine effectiveness following issuance of an EUA and/or licensure will be critical to address these uncertainties.

### **Vaccine effectiveness against asymptomatic infection**

Data are limited to assess the effect of the vaccine against asymptomatic infection as measured by detection of the virus and/or detection of antibodies against non-vaccine antigens that would indicate infection rather than an immune response induced by the vaccine. Additional evaluations will be needed to assess the effect of the vaccine in preventing asymptomatic infection, including data from clinical trials and from the vaccine's use post-authorization.

### **Vaccine effectiveness against long-term effects of COVID-19 disease**

COVID-19 disease may have long-term effects on certain organs, and at present it is not possible to assess whether the vaccine will have an impact on specific long-term sequelae of COVID-19 disease in individuals who are infected despite vaccination. Demonstrated high efficacy against symptomatic COVID-19 should translate to overall prevention of COVID-19-related sequelae in vaccinated populations, though it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections and may be associated with sequelae that are either late-onset or undetected at the time of infection (e.g., myocarditis). Additional evaluations will be needed to assess the effect of the vaccine in preventing long-term effects of COVID-19, including data from clinical trials and from the vaccine's use post-authorization.

### **Vaccine effectiveness against mortality**

A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality. However, non-COVID vaccines (e.g., influenza) that are efficacious against disease have also been shown to prevent disease-associated death.<sup>11-14</sup> Benefits in preventing death should be evaluated in large observational studies following authorization.

### **Vaccine effectiveness against transmission of SARS-CoV-2**

Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination. Demonstrated high efficacy against symptomatic COVID-19 may translate to overall prevention of transmission in populations with high enough vaccine uptake, though it is possible that if efficacy against asymptomatic infection were lower than efficacy against symptomatic infection, asymptomatic cases in combination with reduced mask-wearing and social distancing could result in significant continued transmission. Additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection.

### **8.3. Known Risks**

The vaccine has been shown to elicit increased local and systemic adverse reactions as compared to those in the placebo arm, usually lasting a few days. The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%). Adverse reactions characterized as reactogenicity were generally mild to moderate. The number of subjects reporting hypersensitivity-related adverse events was numerically higher in the vaccine group compared with the placebo group (137 [0.63%] vs. 111 [0.51%]). Severe adverse reactions occurred in 0.0-4.6% of participants, were more frequent after Dose 2 than after Dose 1 and were generally less frequent in older adults (>55 years of age) ( $\leq 2.8\%$ ) as compared to younger participants ( $\leq 4.6\%$ ). Among reported unsolicited adverse events, lymphadenopathy occurred much more frequently in the vaccine group than the placebo group and is plausibly related to vaccination.

Serious adverse events, while uncommon (<1.0%), represented medical events that occur in the general population at similar frequency as observed in the study. Three SAEs in the BNT162b2 group were considered related by the investigator, but not the Sponsor, as related to study vaccination: shoulder injury (n=1), ventricular arrhythmia in a participant with known cardiac conditions (n=1), and lymphadenopathy temporally related following vaccination (n=1). We considered two of the events as possibly related to vaccine: the shoulder injury possibly due to vaccine administration or the vaccine itself and lymphadenopathy. Lymphadenopathy was temporally associated and biologically plausible.

No specific safety concerns were identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection. Although participants 16 to 17 years of age were enrolled in the phase 3 trial, safety data for this age group is limited. However, available data are consistent with the safety profile in the adult population, and it is biologically reasonable to extrapolate the greater safety experience in adults, in particular younger adults, to the oldest pediatric age group of 16 to 17 years.

## 8.4. Unknown Risks/Data Gaps

### Safety in certain subpopulations

There are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as children less than 16 years of age, pregnant and lactating individuals, and immunocompromised individuals.

### Adverse reactions that are very uncommon or that require longer follow-up to be detected

Following authorization of the vaccine, use in large numbers of individuals may reveal additional, potentially less frequent and/or more serious adverse events not detected in the trial safety population of nearly 44,000 participants over the period of follow up at this time. Active and passive safety surveillance will continue during the post authorization period to detect new safety signals.

A numerically greater number of appendicitis cases occurred in the vaccine group but occurred no more frequently than expected in the given age groups and do not raise a clear concern at this time for a causal relationship to study vaccination. Although the safety database revealed an imbalance of cases of Bell's palsy (4 in the vaccine group and none in the placebo group), causal relationship is less certain because the number of cases was small and not more frequent than expected in the general population. Further signal detection efforts for these adverse events will be informative with more widespread use of the vaccine.

### Vaccine-enhanced disease

Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and/or licensure.

## 9. References

1. Zhu N, Zhang D, Wang W, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. *The New England journal of medicine*. 2020;382(8):727-733.
2. Coronaviridae Study Group of the International Committee on Taxonomy of V. The species Severe acute respiratory syndrome-related coronavirus: classifying 2019-nCoV and naming it SARS-CoV-2.
3. Lu R, Zhao X, Li J, et al. Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. *Lancet (London, England)*. 2020;395(10224):565-574.
4. Hoffmann M, Kleine-Weber H, Schroeder S, et al. SARS-CoV-2 Cell Entry Depends on ACE2 and TMPRSS2 and Is Blocked by a Clinically Proven Protease Inhibitor. *Cell*. 2020;181(2):271-280.e278.
5. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb–3 and 360bbb-3b. (2011).
6. FDA. Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19. June 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>.

7. National Vaccine Injury Compensation Program. Vaccine Injury Table, Revised and Effective March 21, 2017. <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf>.
8. International Coalition of Medicines Regulatory Authorities. Statement on continuation of vaccine trials. <http://www.icmra.info/drupal/en/covid-19/statement-on-continuation-of-vaccine-trials>. 2020.
9. Krause PR, Fleming TR, Longini IM, et al. Placebo-Controlled Trials of Covid-19 Vaccines - Why We Still Need Them. *The New England journal of medicine*. 2020.
10. Wendler D, Ochoa J, Millum J, Grady C, Taylor HA. COVID-19 vaccine trial ethics once we have efficacious vaccines. *Science*. 2020:eabf5084.
11. Roush SW, Murphy TV, Vaccine-Preventable Disease Table Working Group, the. Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States. *JAMA*. 2007;298(18):2155-2163.
12. Verhees RAF, Dondorp W, Thijs C, Dinant GJ, Knottnerus JA. Influenza vaccination in the elderly: Is a trial on mortality ethically acceptable? *Vaccine*. 2018;36(21):2991-2997.
13. Flannery B, Reynolds SB, Blanton L, et al. Influenza Vaccine Effectiveness Against Pediatric Deaths: 2010–2014. 2017;139(5):e20164244.
14. Rolfes MA, Flannery B, Chung JR, et al. Effects of Influenza Vaccination in the United States During the 2017-2018 Influenza Season. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. 2019;69(11):1845-1853.

## 10. Appendix A. Study BNT162-01

### Design

Study BNT162-01 is an ongoing, first-in-human, phase 1 dose-level finding study conducted in Germany to evaluate the safety and immunogenicity of several different candidate vaccines, including BNT162b2. Twelve adults 18 to 55 years of age received 30µg BNT162b2.

Secondary and exploratory objectives were specified to describe the immune response, measured by functional antibody titer, antibody binding assay, and cell-mediated immune responses (cytokines associated with Th1 and Th2 responses to assess for the induction of a balanced versus Th1 or Th2 dominant immune response) at baseline and various time points after vaccination, specifically 7 days post Dose 2. Adverse event monitoring was the same as in study C4591001.

### Results

No SAEs were reported in the BNT162-01 safety database included in the EUA submission, and the safety profile for BNT162b2 in this study was similar to that in the much larger study, C4591001.

Evaluable ELISPOT data were available from 39 participants across dose levels of BNT162b2 (data cutoff date was 17 September 2020). Evaluable intracellular cytokine staining and FACS data were available from 36 participants across dose levels of BNT162b2 (cutoff date was 04 September 2020). Data for serology results for serum neutralizing titers were available for 45 participants across dose levels of BNT162b2 (data cutoff date was 18 September 2020). Most participants who received both doses of BNT162b2 had evidence of SARS-CoV-2 S protein-specific CD4+ (39/39, 100%) and CD8+ (35/39, 89.7%) T cell responses. These T cell responses were directed against different parts of the antigen, including epitopes in the RBD, indicating the induction of multi-epitope responses by BNT162b2. Functionality and polarization of S-specific BNT162b2-induced SARS-CoV-2 T cells were assessed by intracellular accumulation of cytokines IFN $\gamma$ , IL-2, and IL-4 measured after stimulation with overlapping peptide pools representing the full-length sequence of the whole SARS-CoV-2 S protein. For benchmarking, PBMC fractions from 15 convalescent patients with virologically confirmed COVID-19 were used. The Th1 polarization of the T helper response was characterized by the IFN $\gamma$  and IL-2 production, and only minor IL-4, production upon antigen-specific (SARS-CoV-2 S protein peptide pools) re-stimulation. The SARS-CoV-2 neutralizing geometric mean titer (GMTs) increased over baseline after Dose 1, with a boost effect after Dose 2 that was most pronounced at the 30 µg dose level.

Thus, the immunogenicity results from Study BNT162-01 showed evidence of antibody-mediated SARS-CoV-2 neutralization and a Th1 polarization in the cell-mediated cellular immune responses in healthy adults 18 to 55 years of age, which supports the final dose selection and prospect of benefit for the enrollment of larger numbers of participants in Study C4591001.

## **11. Appendix B. Charlson Comorbidity Index**

This index is based on a list of 19 conditions identified from diagnoses in hospital and physician data. Each condition is assigned a weight from 1 to 6. The index score is the sum of the weights for all identified conditions (Charlson et al., 1987). An index score of 0 indicates no comorbid conditions, while higher scores indicate a greater level of comorbidity.

Charlson Index Diagnoses: Cancer, Chronic Pulmonary Disease, Diabetes without Complications, Congestive Heart Failure, Cerebrovascular Disease, Dementia, Renal Disease, Peripheral Vascular Disease, Myocardial Infarction, Diabetes with Complications, Paraplegia and Hemiplegia, Connective Tissue Disease-Rheumatic Disease, Peptic Ulcer Disease, Mild Liver Disease, Metastatic Carcinoma, Moderate or Severe Liver Disease, HIV/AIDS.

Reference: Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987; 40(5):373–383. [PubMed: 3558716]

**12. Appendix C. Guidance for Industry: Emergency Use Authorization for Vaccines to Prevent COVID-19**

[Emergency Use Authorization for Vaccines to Prevent COVID-19](#)

January 19, 2021

Representative Karen M. Rohr,  
Chair, Human Services Committee  
North Dakota Legislative Assembly  
600 East Boulevard  
Bismarck, ND 58505

Senator Judy Lee  
Vice Chair, Human Services Committee  
North Dakota Legislative Assembly  
600 East Boulevard  
Bismarck, ND 58505

Dear Chair Rohr, Vice Chair Lee, and Members of the Human Services Committee,

I am writing in support of bills HB 1306, HB 1307, and HB 1320. I have a BSN in nursing and a graduate doctoral degree in Chiropractic. I've worked in health RESTORATION for over of 12 years. I've worked in ICU work as an RN before continuing my Doctoral education. Because we take a different view of the human body (one that looks at triggers of dysfunction and why the body breaks down, as opposed to the end point-disease) I see protection from being injured is paramount in protecting people who choose to be responsible for their own health.

There are questions that need to be asked when considering coercion of health care choices.

"Are my health choices private? Will I eventually need to divulge what I eat, my exercise/fitness routine, Lab findings, Sexual orientation, and history? Will my health care choices determine my ability to access my bank accounts, To get on an airplane, or To fill gas?"

"Do vaccines do what you are taught to believe they do?"

"Who should make your health care decisions- you or your government?"

"If there are admitted, inherent dangers to a health care decision, should you be coerced into that health care decision?"

"What about people with known side effects to inoculation? Will they be treated as second rate citizens?"

For the record, I would like to enter in some important information, as coercion of health care choices is a very slippery slope. A year ago I was laughed at for saying we will be given vaccination ID's and will need to prove status for travel. Today, it has become a reality.

1. Vaccines are classified as biologics. This means that they are NOT subject to true placebo controlled studies. Rarely, if ever, are they studied against a true placebo. Almost every study uses other vaccines (example: the astrazeneca covid-19 study used the meningitis vaccine) <sup>1</sup> and/or the equally as risky ingredients (adjuvants like alumimum or mercury) in vaccines as a

“control” which allows them to hide expected adverse reactions with other reactions in the placebo group. Adjuvants have the capability of producing neuroinflammation which can lead to damage to the central and peripheral Nerve System.<sup>2</sup> Encephalopathy is a form of neuroinflammation. Encephalopathy can lead to autism and other neurologic and immune related disorders.

2. Vaccine injuries are severely underreported. Less than 1% of adverse events are ever reported. This has been researched and can be validated:<sup>3</sup>

“Adverse events from drugs and vaccines are common but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). **Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of “problem” drugs and vaccines that endanger public health.** New surveillance methods for drug and vaccine adverse effects are needed. **Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting:** reporting is not part of clinicians’ usual workflow, takes time, and is duplicative.”<sup>3</sup>

This brings out the inconvenient truth that adverse events are 100 times more common than the mainstream media and medical doctors would like to admit.

I have personal experience with this, and a good example is the HPV inoculation. However as listed above, is prevalent in many more. Public marketing campaigns downplay risks and overestimate efficacy. They ignore the actual data (or lack thereof) to unduly influence the public. They will tell you that injuries are estimated to be “one in a million”. However, since moving back to North Dakota 10 years ago, I have taken care of THREE teenagers in the Burleigh/Morton area alone whose severe symptomatology (diagnosed as POTS disease) began within 7 days of their HPV inoculation. Based on basic math and how many teenaged people there are in the Bismarck-Mandan area alone, along with how many I see, these numbers are massively higher than publicized. Then put into the equation that I came across these people randomly, for other reasons like sports injuries. This means the I am likely to have seen an extremely small minority of these people effected. So you have to ask, how does this happen? When questioned, the parents and patients had no idea to even ponder a link or to share with their doctor. Furthermore, not a single medical doctor had questioned them about inoculation history prior to onset of their problems. It was not until I asked the question about inoculation history that the family began to put the pieces together, and when they then inquired to their medical doctor, there was no testing or validation, nor was it reported to VAERS (the Vaccine Adverse Event Reporting System), a government entity responsible for diverting tax dollars to pay out damages caused by vaccines.

3. Drug companies are all exempt from paying out damages for vaccine damage, even though many of the biggest vaccine production companies are convicted felons for fraud and marketing—Pfizer,<sup>4</sup> Johnson & Johnson,<sup>5</sup> Astrazeneca,<sup>6,7</sup> and Merck all have some of the largest fines ever given out in court due to fraud, false marketing, kickbacks and bribery, false claims act related, and drug or medical equipment safety violation. (but hey, they “Pledged” transparency

in their studies, so we can trust them, right?)<sup>8</sup> Many, including Pfizer, Glaxo, and Sanofi are convicted felons. They have no impetus to improve vaccine safety or improve studies. Therefore, those who question safety have valid concerns.

4. Vaccines do not create health. Until recently, the US government has not bothered to study vaccinated and non-vaccinated populations. However, recently, Dr. Paul Thomas published research in his own practice in regards chronic disease prevalence in children fully vaccinated, partially vaccinated, and nonvaccinated. Because of the published findings, politically he is facing a “witchhunt” and is being targeted by the powers that be (note who is the largest lobbying company in the world—the pharmaceutical industry). Nonvaccinated children had significantly less chronic disease than the other two groups.<sup>9</sup> If vaccines create health, then why is the vaccinated group much sicker than the nonvaccinated group?
5. My health care choices are MY health care choices. To even INQUIRE about inoculations is an intrusion of my HIPAA privacy laws. Furthermore, where does the intrusion stop? Once the vaccine tracking digitalized system comes out, will it lead to medical martial law?
6. We also know that the covid injection has caused a large number of anaphylactic reactions. We have ZERO long term safety data, regardless of what self-appointed experts’ postulate. Without vigorous, accurate tracking (which, as referenced above, has never happened) how can this even be performed? The “placebo groups” (again, many are not even a real placebo) are being given the Covid vaccine themselves. I have anaphylactic food allergies (16 of 38 foods tested via IgE blood response testing). Many people have food allergies that they are unaware of. I CANNOT take the chance of injecting myself with these dangerous chemicals. People are dying from this intervention. Whether the mainstream media, social media sites, and the medical profession and want to censor it or not, it is happening. It saddens me that we even have to have a bill protecting my RIGHT to health and health choices, and to weight my OWN risks and benefits of a procedure.
7. To coerce someone into a forced medical procedure, based on false premises is not only wrong, but it can also be considered fraudulent. First, we must delineate the difference between SARS covid-2 and “Covid-19”. SARS covid-2 is the infection. Covid-19 are the symptoms of infection (like influenza vs “the flu”). The marketing of “90%-95% efficacy has NOTHING to do with ability to infect/transmit SARS-CoV-2. It refers to decreasing symptoms in a small subset of individuals. **It is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product or service can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence**, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made.

Definitions Per the CDC: Immunity: Protection from an infectious disease. If you are immune to a disease, **you can be exposed to it without becoming infected**.

Vaccine: A product that stimulates a person’s immune system to produce immunity to a specific disease, **protecting the person from that disease**. Vaccines are usually

administered through needle injections but can also be administered by mouth or sprayed into the nose.

This is taken directly from the Pfizer phased 3 study:

### **8.2. Unknown Benefits/Data Gaps**

#### **Duration of protection**

As the interim and final analyses have a limited length of follow-up, it is not possible to assess sustained efficacy over a period longer than 2 months.

#### **Effectiveness in certain populations at high-risk of severe COVID-19**

Although the proportion of participants at high risk of severe COVID-19 is adequate for the overall evaluation of safety in the available follow-up period, the subset of certain groups such as immunocompromised individuals (e.g., those with HIV/AIDS) is too small to evaluate efficacy outcomes.

#### **Effectiveness in individuals previously infected with SARS-CoV-2**

The primary endpoint was evaluated in individuals without prior evidence of COVID-19 disease, and very few cases of confirmed COVID-19 occurred among participants with evidence of infection prior to vaccination (although more cases occurred in the placebo group compared with the vaccine group). Therefore, available data are insufficient to make conclusions about benefit in individuals with prior SARS-CoV-2 infection. However, available data, while limited, do suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

### **Vaccine effectiveness against asymptomatic infection**

Data are limited to assess the effect of the vaccine against asymptomatic infection as measured by detection of the virus and/or detection of antibodies against non-vaccine antigens that would indicate infection rather than an immune response induced by the vaccine. Additional evaluations will be needed to assess the effect of the vaccine in preventing asymptomatic infection, including data from clinical trials and from the vaccine's use post-authorization.

### **Vaccine effectiveness against long-term effects of COVID-19 disease**

COVID-19 disease may have long-term effects on certain organs, and at present it is not possible to assess whether the vaccine will have an impact on specific long-term sequelae of COVID-19 disease in individuals who are infected despite vaccination. Demonstrated high efficacy against symptomatic COVID-19 should translate to overall prevention of COVID-19-related sequelae in vaccinated populations, though it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections and may be associated with sequelae that are either late-onset or undetected at the time of infection (e.g., myocarditis). Additional evaluations will be needed to assess the effect of the vaccine in preventing long-term effects of COVID-19, including data from clinical trials and from the vaccine's use post-authorization.

### **Vaccine effectiveness against mortality**

A larger number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against mortality. However, non-COVID vaccines (e.g., influenza) that are efficacious against disease have also been shown to prevent disease-associated death.<sup>11-14</sup> Benefits in preventing death should be evaluated in large observational studies following authorization.

### **Vaccine effectiveness against transmission of SARS-CoV-2**

Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination. Demonstrated high efficacy against symptomatic COVID-19 may translate to overall prevention of transmission in populations with high enough vaccine uptake, though it is possible that if efficacy against asymptomatic infection were lower than efficacy against symptomatic infection, asymptomatic cases in combination with reduced mask-wearing and social distancing could result in significant continued transmission. Additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection.

8. Where there is clear risk, there needs to be freedom of choice. Coercion by public pressure is unethical. And we know that there will be pressure through lobbyists to coerce businesses and other entities to enforce these expectations just like they have the masking and shutdown practices.

Finally, I would like to bring up a glaring problem in society today, particularly with these HEALTH and LIFE MANDATES/COERCIONS. If this is truly about health, why is it that it always comes to drugs/injections? What about building and supporting a strong, robust, balanced immune response? What about addressing the triggers that lead to a damaged, incompetent immune response?

**The cold hard fact is that there are ALWAYS going to be new viruses. Are we now setting precedence that every new virus needs an inoculation? In less than a year we are being told that there are additional strains of Coronavirus and more inoculations being developed. Guess what, they are not going anywhere. Will they just tell us we need to stay inside forever and keep giving more and more injections? The solution is not in more drugs. The solution lies in restoring normal immune function and addressing the reasons why people's immune response fails them. This is one thing that Sars Covid-2 has brought to light. 94% of people have comorbidities, the largest number being obesity and type 2 diabetes, which most have similar underlying mechanisms. Are we going to start mandating certain waist sizes as well? I have a novel idea. How about we admit that the United States is one of the most chronically ill countries and the the prescription drug culture we live in is not working. If you are truly healthy, your body handles these dis-eases as it should. Why should I as someone who studies these things daily need to follow the same path as the rest of the country, who is CLEARLY on the wrong path. If you want me to be responsible for other people's health, then let me mandate what foods people eat, how much exercise people get, what testing they do, what nutrients they consume... I hope that sounds preposterous, because this is what it sounds like to me.**

Food and lifestyle factors play a MAJOR role in whether someone gets sick or stays well. IT is crucial for a balance, normal t-cell response and overall health. Why has this been all-but ignored and ridiculed for the last 10 years, especially the last 10 months. We have the burleigh-morton task force ridiculing the courageous people that have brought this up and taken a stand. Medical doctors threatening me for telling people that they need to be responsible for their own health. I've been saying that for 12 years. Covid didn't change that. It has always been a problem but now we are seeing the downstream effects and we either need to change course or sleep in the bed we make. I don't have to be part of the sick care cycle. And I should have the freedom to opt out for whatever means I feel necessary.

Thank you for your time. I would be happy to answer any of your questions.

Dr. Steve Nagel, DC

180 Health Solutions

1. <https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222h1r.html>
2. <https://www.hilarispublisher.com/open-access/vaccines-and-neuroinflammation.pdf>
3. <https://digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system>
4. <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history>
5. <https://www.usatoday.com/story/money/2019/10/09/johnson-johnson-8-billion-over-risperdal-gynecomastia-case/3916878002/>
6. <https://www.justice.gov/opa/pr/pharmaceutical-giant-astrazeneca-pay-520-million-label-drug-marketing>
7. <https://www.nytimes.com/2003/06/21/business/astrazeneca-pleads-guilty-in-cancer-medicine-scheme.html>
8. <https://violationtracker.goodjobsfirst.org/prog.php?parent=glaxosmithkline>
9. <https://www.mdpi.com/1660-4601/17/22/8674/htm>



Article

# Relative Incidence of Office Visits and Cumulative Rates of Billed Diagnoses Along the Axis of Vaccination

James Lyons-Weiler <sup>1,\*</sup>  and Paul Thomas <sup>2</sup><sup>1</sup> The Institute for Pure and Applied Knowledge, Pittsburgh, PA 15101, USA<sup>2</sup> Integrative Pediatrics, Portland, OR 97225, USA; paulthomasmd@drpaul.md

\* Correspondence: jim@ipaknowledge.org

Received: 23 October 2020; Accepted: 18 November 2020; Published: 22 November 2020



**Abstract:** We performed a retrospective analysis spanning ten years of pediatric practice focused on patients with variable vaccination born into a practice, presenting a unique opportunity to study the effects of variable vaccination on outcomes. The average total incidence of billed office visits per outcome related to the outcomes were compared across groups (Relative Incidence of Office Visit (RIOV)). RIOV is shown to be more powerful than odds ratio of diagnoses. Full cohort, cumulative incidence analyses, matched for days of care, and matched for family history analyses were conducted across quantiles of vaccine uptake. Increased office visits related to many diagnoses were robust to days-of-care-matched analyses, family history, gender block, age block, and false discovery risk. Many outcomes had high RIOV odds ratios after matching for days-of-care (e.g., anemia (6.334), asthma (3.496), allergic rhinitis (6.479), and sinusitis (3.529), all significant under the Z-test). Developmental disorders were determined to be difficult to study due to extremely low prevalence in the practice, potentially attributable to high rates of vaccine cessation upon adverse events and family history of autoimmunity. Remarkably, zero of the 561 unvaccinated patients in the study had attention deficit hyperactivity disorder (ADHD) compared to 0.063% of the (partially and fully) vaccinated. The implications of these results for the net public health effects of whole-population vaccination and with respect for informed consent on human health are compelling. Our results give agency to calls for research conducted by individuals who are independent of any funding sources related to the vaccine industry. While the low rates of developmental disorders prevented sufficiently powered hypothesis testing, it is notable that the overall rate of autism spectrum disorder (0.84%) in the cohort is half that of the US national rate (1.69%). The practice-wide rate of ADHD was roughly half of the national rate. The data indicate that unvaccinated children in the practice are not unhealthier than the vaccinated and indeed the overall results may indicate that the unvaccinated pediatric patients in this practice are healthier overall than the vaccinated.

**Keywords:** pediatrics; vaccines; adverse events; relative incidence of office visit

## 1. Introduction

Vaccines are widely regarded as safe and effective within the medical community and are an integral part of the current American medical system. While the benefits of vaccination have been estimated in numerous studies, negative and nonspecific impact of vaccines on human health have not been well studied. Most recently, it has been determined [1,2] that variation exists in individual responses to vaccines, that differences exist in the safety profile of live and inactivated vaccines, and that simultaneous administration of live and inactivated vaccines may be associated with poor outcomes. Studies have not been published that report on the total outcomes from vaccinations, or the increase or decrease in total infections in vaccinated individuals.

Pre-licensure clinical trials for vaccines cannot detect long-term outcomes since safety review periods following administration are typically 42 days or less [3]. Long-term vaccine safety science relies on post-market surveillance studies using databases such as the US Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC's) Vaccine Adverse Events Reporting System (VAERS) and the Vaccine Safety Datalink. VAERS [4] is a passive reporting system in which, according to Ross 2011 [5], "fewer than 1% of vaccine adverse events are reported." The Vaccine Safety Datalink (VSD) can, in principle, according to the Institute of Medicine (IOM, 2013) [6], be used to compare outcomes of vaccines and unvaccinated children. Based on the IOM's recommendation, in 2016, the CDC published a white paper (CDC, 2016 [7]; Glanz et al., 2016 [8]) on studying the safety of their recommended pediatric vaccine schedule. Unfortunately, to date, no studies have been published comparing a diversity of outcomes of vaccinated and unvaccinated children using the VSD.

There are serious limitations inherent to long-term vaccine safety studies as currently implemented. Post-licensure studies on vaccine safety typically employ an " $N$  vs.  $N + 1$ " design of analysis, meaning they compare fully vaccinated children with fully vaccinated children missing only one vaccine. Despite reports of increases in vaccine cessation, virtually none of the post licensure-vaccine safety studies have included comparisons to groups completely unexposed to vaccines.

A few independent (non-CDC) studies do exist that have compared outcomes between vaccinated and unvaccinated children. A small survey study of 415 families with homeschooled children by Mawson et al., 2017 [9] that compared vaccinated with completely unvaccinated children reported increased risk of many diagnoses among the vaccinated children including (condition, fold-increase): allergic rhinitis (30.1), learning disabilities (5.2), attention deficit hyperactivity disorder (ADHD) (4.2), autism (4.2), neurodevelopmental disorders (3.7), eczema (2.9), and chronic illness (2.4). The increased risk of neurodevelopmental disorders appeared to be higher in cases of preterm births. A study from Germany (Schmitz et al., 2011) [10] reported no increases in adverse outcomes other than atopy.

A limitation of both of these studies is that they relied on parental surveys, and both had a small unexposed group. A further limitation in the German study [10] is that they also defined a child as unexposed to vaccines even if they received vaccination for varicella, rotavirus, pneumococcal, meningococcal, influenza, and/or others; the study, therefore, is not "vaccinated vs. unvaccinated". Studies of Diphtheria, Pertussis, and Tetanus (DTP) vaccine that had an unexposed group found an increased risk of mortality (Mogensen et al., 2017) [11] and asthma (McDonald et al., 2008) [12] in the vaccine exposed group. Gallagher and Goodman, 2008 [13] reported increased ASD in a hepatitis B vaccine-exposed group. Studies funded by the pharmaceutical industry or conducted by the CDC typically tend to find no harm associated with vaccination, while studies conducted without pharmaceutical industry funding have often found harm.

Hooker and Miller 2020 [14] recently found an increase in odds ratio (OR) in developmental delay (OR 2.18), asthma (OR 4.49), and ear infection (OR 2.13) in vaccinated children compared to unvaccinated children in a study using data from three practices. In the current study, we assess the total outcomes of patients ranging in age from 2 months to 10.4 years of all children in a pediatric practice that have not been vaccinated compared to those who have been variably vaccinated based on medical records using a novel measure, the Relative Incidence of Office Visit (RIOV), and compare results from that measure to results obtained using odds ratios of incidence of diagnoses.

## 2. Materials and Methods

### 2.1. Data Source and Provenance

A detailed proposal for a retrospective study was submitted to an Institutional Review Board (IRB), and was approved (Pro00031853 letter dated 7 May 2019). The data source for this study was all billing and medical records of Integrative Pediatrics, a private pediatric practice located in Portland, Oregon. Data collected from True North Data (Mill Creek, WA, USA) were de-identified by trained and honest brokers with the Institute for Pure and Applied Knowledge (IPAK) affiliation

who were certified to de-identify patient data as required under the Health Insurance Portability and Accountability Act (HIPAA), thus ensuring that the data analysts never saw identified data. Outcomes were represented by International Classification of Diseases (ICD) codes (See Supplementary Materials Table S1). Coded data were matched back to the identified medical and billing record to provide a data parity check by our honest brokers team.

## 2.2. Inclusion/Exclusion Criteria

All patients that were born into the practice between 1 June 2008 and 27 January 2019, with a first visit before 60 days of life and a last visit after 60 days. All inclusion/exclusion criteria applied are outlined in Figure 1.

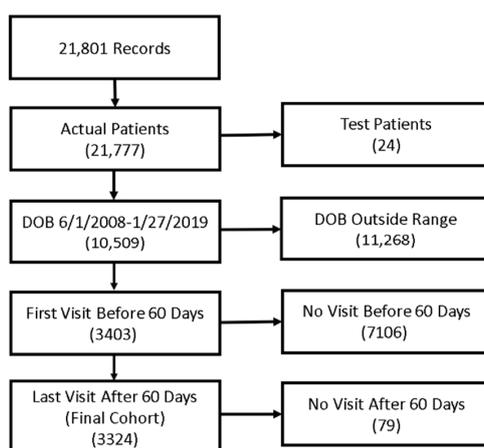


Figure 1. Inclusion criteria diagram.

## 2.3. Study Population

The inclusion/exclusion criteria lead to 3324 patients, of which 2763 were variably vaccinated, having received 1 to 40 vaccines (Figure 1).

## 2.4. Demographics

The study population had similar proportions of males and females (Table 1). Nearly all patients had been breastfed in both the vaccinated (96.6%) and the unvaccinated (98%) conditions. Among the vaccinated, 25.16% had a family history of autoimmunity, whereas among the unvaccinated, 31% had the same characteristic. Functionally, this also likely reflects the net effects of decisions between the patient/doctor dyad in determining risk of long-term poor outcomes sometimes associated with vaccination.

Table 1. Demographic variables in the analyzed data set.

Category	Unvaccinated (N = 561)	Vaccinated (N = 2763)	$\chi^2$	<i>p</i>
Male (N,%)	279 (49.7%)	1432 (51.8%)	0.819	0.365
Female (N,%)	282 (50.3%)	1331 (48.2%)		
Breastfed (N,%)	550 (98%)	2670 (96.6%)	3.037	0.081
			<b>T-test</b>	
FHA (any)	174 (31%)	695 (25.16%)	28.239	<0.00001
Mean DOC	741	1525	17.69	<0.00001
DOC matched	741	741 (N = 561)	0	1.0
Mean BW (kg) unmatched	3.3	3.28	0.509	0.305

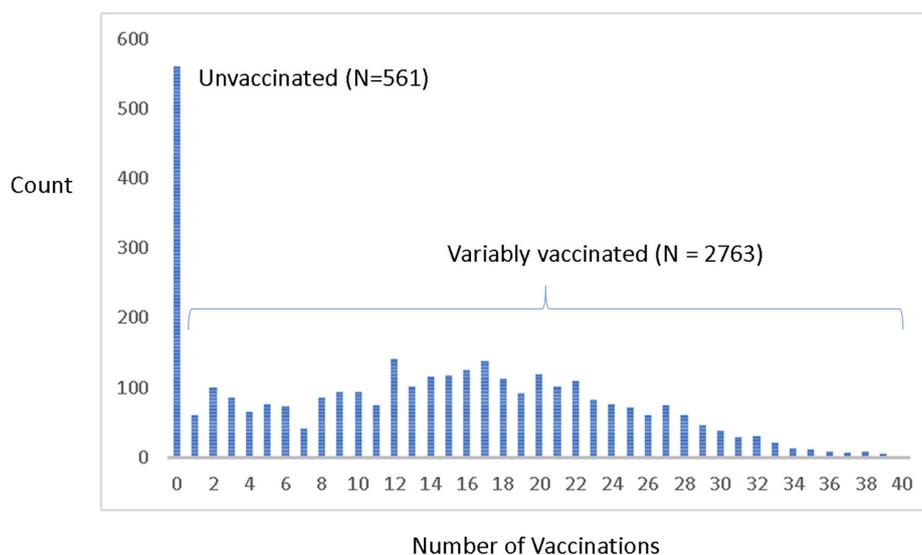
DOC = "Days of Care" = (day of age at last record – day of age at first record); FHA = family history of autoimmunity (at least one condition); Mean BW = average body weight (day 1). The "T-test" is in bold in the table because it is a column subheader.

## 2.5. Variation in Vaccination

The study population has a great diversity in vaccination uptake (Figure 2), reflecting the combined outcome of the patient/physician dyad considering vaccine risk information leading to informed consent on the part of the patients in the practice.

Given the potential of a cohort effect leading to time-based trends in vaccination and to protect against health-care seeking behavior, we calculated for each patient the number of days of care (DOC) as the number of days between the last and first office visits. Importantly, DOC is the range from first to last recorded visits for each patient and is not expected to be influenced overall by healthcare seeking behavior. Among the vaccinated, the mean DOC was 1525 days; among the unvaccinated, the mean DOC was 741 days. This reflects age of patient, not healthcare seeking behavior (prior to matching, unvaccinated: min age, 2 months, mean age 2 years 1 month, and max age 10 years 1 month; vaccinated: min age 2 months, mean age 4 years 3 months, and max age 10 years 6 months; after DOC matching, average age in the vaccinated was also 2 years 1 month). The difference in DOC between the vaccinated and unvaccinated groups was highly significant prior to DOC matching (Student's  $t$ ,  $p < 0.0001$ ). The patient populations did not differ in mean predicted birthweight (unvaccinated 3.3 kg; vaccinated 3.28 kg,  $p = 0.61$  (Student's  $t$ )).

From this analysis, only DOC could be a potential confounding variable, potentially collinear with patient age, given full consideration by a matched analysis (see below).



**Figure 2.** Distribution of vaccination across the patient cohort.

## 2.6. Analysis 1. Relative Incidence of Average Billed Visitation Rates in Percentile Vaccinating vs. Unvaccinated (Aka “Whole Cohort” Analysis: Unblocked and Unmatched)

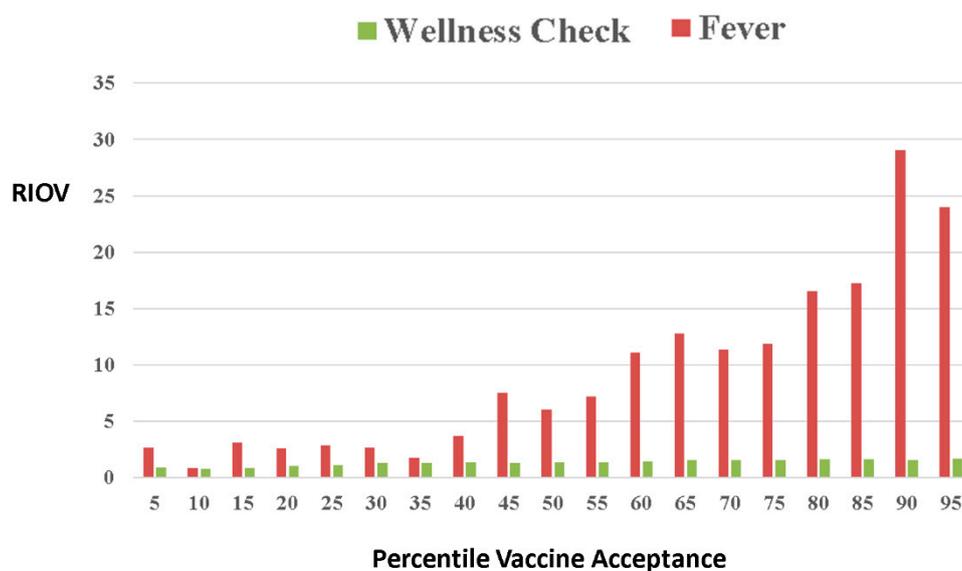
### 2.6.1. Relative Incidence of Office Visit (RIOV)

Typical retrospective analyses of association of outcomes and vaccine exposure rely on the incidence of conditions, which is the percentage of a group with a particular diagnosis of interest. This is the equivalent of “at least one billed office visit”, which is a specific form of “at least  $n$  office visits” related to a diagnosis. Use of incidence-only is therefore an arbitrary decision on data representation. We generalized the approach by considering the incidence of office visits over each patients’ record related to a diagnosis. First, patients were ranked by the number of vaccines accepted. For controls, the average incidence of billed visitations per conditions was calculated within percentiles ranging from the 5th (least vaccinated) to the 90th percentile of vaccination acceptance (Figure 3). For the study outcomes, data were represented as quartiles.

Average incidence of office visit ratio (RIOV) plots for the vaccinated ( $OV_V$ ) and unvaccinated ( $OV_{UV}$ ) groups were used to provide assurance of the robustness of the results in the study design and design of analysis. In some cases, the percentile groups in the non-vaccinating end of the immunization axis had zero patients; in those cases, the value of the least vaccinating percentile was used as the denominator for the relative incidence to avoid division by zero. In contrast therefore to “most vaccinated” (“MV”) to “unvaccinated” (“UV”), such analyses were therefore “most vaccinated” vs. “least vaccinated” (“LV”) patients. This modification had to be applied to the billed diagnoses of “developmental speech delay” and “pain”. The  $y$ -axis in the graphical representation of the data in the percentile analysis is the average incidence of related visitations per condition at a given percentile of vaccination/the average incidence of the related visitations per condition in the unvaccinated ( $OV_V/OV_{UV}$ ). Incidence ratios were calculated as a ratio of average incidence per patient in each percentile compared to the un- or least-vaccinated group (the latter to avoid division by zero, e.g., ADHD); they are equivalent to an expression of relative risk of diagnosis for each study outcome.

### 2.6.2. Natural Positive and Negative “Controls”

It is well known that “fever” is a side effect of vaccination. In this analysis, we therefore used incidence of “fever” as positive controls on trends in the data. Similarly, “Well Child” visits can be considered a type of negative control given that they were regularly scheduled events and that they set a comparator value of RIOV for other outcomes (Figure 3).



**Figure 3.** Relative Incidence of Office Visit (RIOV) percentile vaccinated vs. unvaccinated design of analysis: power decreases from left to right; thus, a stable trend (increase or decrease) becomes noteworthy. The data shown are for the Relative Incidence of Office Visits (RIOVs) to average incidence ratio of billed office visits related to fever in the vaccinated compared to the unvaccinated ( $OV_V/OV_{UV}$ ) conditions and for “Well Child” visit on the right. For all the clinical conditions studied, RIOV reflects the total number of billed office visits per condition per group, reflecting the total disease burden on the group and the population that it represents.

### 2.7. Analysis 2. Odds Ratio Analysis of Incidence of Diagnoses

For comparison to the RIOV method, the same data were also analyzed using a classical odds ratio of incidence of diagnoses using the rates of diagnosis of each condition in the vaccinated and unvaccinated groups using 95% confidence interval testing. Odds ratios per each  $i$ th diagnosis were calculated as the standard ratio of the rate of exposure in those with the diagnosis ( $p_{1,i}$ ) to the rate of exposure in those without diagnosis ( $p_{2,i}$ ), i.e.,

$$OR_i = \frac{p_{1,i}/(1-p_{1,i})}{p_{2,i}/(1-p_{2,i})} \quad (1)$$

Relative risk ratios for each of the  $i$ th conditions with  $n_{1i}$  vaccinated in  $D_1$  diagnosed and  $n_{2i}$  vaccinated among  $D_2$  without diagnosis was calculated as

$$RR_i = \frac{n_{1,i}/(D_{1,i})}{n_{2,i}/(D_{2,i})} \quad (2)$$

Z-tests of proportion were conducted to provide  $p$ -values. Effect size was estimated with absolute risk difference (ARD), calculated as (vaccinated diagnosis rate – unvaccinated diagnosis rate).

### 2.8. Analysis 3. Days-of-Care (DOC)-Matched Vaccinated vs. Unvaccinated RIOV Analysis

Because this is an observational retrospective study, a potential limitation of the time-agnostic analysis is that more recent and younger patients' parents in the practice have opted to vaccinate less frequently and, being younger, have fewer office visits. Thus, fewer diagnoses may be expected to be related to lower exposures due to the combined effects of age (less time) and vaccine choice behaviors. Given this shift occurring in vaccination choices over time, it is possible that a false signal may be embedded due to temporal population-wide shifts due to unmeasured factors, such as cultural shifts in attitudes toward vaccination unrelated to personal outcomes or specific risk. Therefore, an additional analysis was conducted to assess the signal in Days-of-Care (DOC)-matched groups. For each unvaccinated patient, a patient with identical or closest DOC values was selected (without bias) from among the more numerous vaccinated patients. RIOV analysis was conducted on the resulting two groups.

### 2.9. Analysis 4. DOC-Matched OR on Incidence of Diagnoses. Vaccinated vs. Unvaccinated

As a comparison to analysis 3, odds ratios of incidence using diagnoses were calculated on the same data resulting from the matching of patients for DOC.

### 2.10. Analysis 5. Cumulative Office Visit Risk (COV Relative Risk)

To provide another view on the data considering the dimension of time, we calculated for all vaccinated patients and separately for the unvaccinated the number of diagnoses of all of the conditions studied at each day of life considering the vaccinated patients born into the practice ( $N = 2763$ ) compared to the unvaccinated patients ( $N = 561$ ). We also then calculated the cumulative office visits per each day of life. It is important to note that, in these analyses, a patient can have office visits related to the same diagnosis multiple times. These two representations of the data provide a clear graphical representation of the comparison of the vaccinated and unvaccinated and seem to also provide some insight into the typical timing of onset of a study outcome. Cumulative incidence of risk of office visit (RIOV) would be the cumulative numbers divided by the number of patients per group and would thus also reflect age-specific cumulative probabilities (risk of diagnosis-related office visit). Due to the imbalance in study design, the COV curve for the unvaccinated are expressed as the adjusted number

of office visits expected if the study had been balanced with equal numbers to make the two curves directly comparable in scale when expressed as numbers of office visits (multiplier factor 4.9).

#### 2.11. Analysis 6. Family History Blocked RIOV Analysis

Data on family history of autoimmune disorders or autism were used to block patients into those who had a family history on record (FH+) and those who did not (FH-; blocked design). Average RIOV ratios were calculated to determine whether increased vaccination was associated with increased relative incidence of office visitations in both clinical groups (similar to analysis 1), given family history (FH+ and FH-). The results are not otherwise matched or blocked.

#### 2.12. Analysis 7. RIOV vs. OR Incidence of Diagnoses Power Simulation Comparison

A comparison of the power of the test statistics RIOV and OR on incidence is provided to demonstrate the relative power of RIOV to detect differences and associations compared to odds ratio of diagnoses. Poisson variables drawn from distinct theoretical populations were analyzed using both RIOV (full values of  $x_i$ ) and OR on incidence ( $x_i > 0$ ). For the simulation, 1000 measurement sets  $X = \{x_1, x_2, x_3 \dots x_n\}$  drawn from a Poisson distribution of 400,000 random values were used to simulate two groups (each of size  $N = 400$ ) for each Poisson  $\lambda$  value ranging from 1 to 1.1 (step 0.01). The null data ( $\lambda = 1$ ) were used to represent the unvaccinated with no effect.

We simulated an increased effect of vaccines on office visits by increasing  $\lambda$  from 1.01 to 1.1 (step 0.01), with 400,000 values at each level of  $\lambda$ . Increased levels of  $\lambda$  represent increased numbers of office visits due to negative effects of vaccines. The data were analyzed using OR of incidence counting each individual value of  $x_i > 0$  as a positive diagnosis and again using RIOV, leaving the generated values of  $x_i$  in both simulated groups intact.

#### 2.13. Analysis 8. Gender Blocks

We blocked the cohort data into gender blocks (males and females). RIOV analysis was conducted on the vaccinated vs. unvaccinated in both gender blocks.

#### 2.14. Analysis 9. Age (Youngest Third and Oldest Third) Blocks

One of the honest brokers ranked the patients by date of birth and sent a set of age-ranked identifiers to the analyst (J.L.-W.). The data were blocked into the youngest 1/3 and the oldest 1/3. RIOV analysis was conducted on the vaccinated vs. unvaccinated in both age blocks.

#### 2.15. Analysis 10

We compiled and presented the number of diagnoses for infections targeted by vaccines (considering the CDC pediatric schedule) in the vaccinated and unvaccinated groups in the full cohort. We evaluated each vaccine targeted infection individually and analyzed the association between vaccination status and overall occurrence of vaccine-targeted infections using vaccine-targeted diagnoses. We studied the incidence of vaccine-targeted diagnoses in the vaccinated and unvaccinated groups using the  $\chi^2$  test.

### 3. Results

The overall full-cohort RIOV analysis of the vaccinated ( $N = 2763$ ) vs. unvaccinated ( $N = 561$ ) groups are presented in Table 2. There were no cases of ADHD in the unvaccinated group.

**Table 2.** RIOV and test of proportions of office visits per condition for the fully vaccinated (N1 = 2763) vs. (never) unvaccinated (N2 = 561) groups comparison: these results are not adjusted for days of care. CI = confidence interval.

Condition	Vaxxed	Unvaxxed	RIOV	95% CI	Z	p
Fever	759	17	9.065	8.801	12.476	<0.0001
“Well Child” Visits	32,826	4987	1.336	1.149	6.540	<0.0001
Ear Pain	269	16	3.414	3.232	5.310	<0.0001
Otitis media	3105	216	2.919	2.518	23.441	<0.0001
Conjunctivitis	1018	87	2.376	1.935	9.783	<0.0001
Eye Disorders (Other)	277	31	1.814	1.586	3.350	0.0008
Asthma	336	13	5.248	5.065	6.693	<0.0001
Allergic Rhinitis	405	12	6.853	6.662	8.158	<0.0001
Sinusitis	107	5	4.345	4.240	3.566	0.00036
Breathing Issues	621	44	2.866	2.561	7.898	<0.0001
Anemia	979	36	5.522	5.181	13.603	<0.0001
Eczema	512	23	4.520	4.281	8.479	<0.0001
Urticaria	174	17	2.078	1.908	3.027	0.00244
Dermatitis	742	105	1.435	0.992	4.034	<0.0001
Behavioral Issues	343	17	4.097	3.900	6.087	<0.0001
Gastroenteritis	688	30	4.656	4.374	6.543	<0.0001
Weight/Eating Disorders	1115	90	2.515	2.056	10.264	<0.0001
Seizure	43	8	1.091	0.985	0.229	0.8181

RIOVs were calculated using the number of patients as the sample size in each group (Vaxxed and Unvaxxed) with the exception of well-child visits and otitis media visits, both of which were greater in number than the number of patients.

### 3.1. Analysis 1 Results, Unmatched and Unblocked

RIOV analysis views across deciles provide a graphical view on the trends in the data (e.g., Figure 3). Recalling that the data are represented as the average incidence of billed office visits for patients in each percentile of the vaccine acceptance/unvaccinated groups, the statistic is the incidence of office visits in each percentile relative to the non-vaccinating portion of the population, but it is not relative risk of diagnosis. Results for outcomes were presented by study outcome cluster in quartiles for clarity.

Examination of the unmatched, unblocked results shows widespread increased RIOV among outcomes with all but seizures, and the developmental delay outcomes were significant. Those results are consistent with low power due to low overall incidence in the cohort. These results are not adjusted for days of care.

**R1.1. Group A: Autoimmune Respiratory Illnesses.** Large increases in office visits were found among the vaccinated group in this group of respiratory illnesses. Our quartile representation shows consistent increases in the incidence of office visits for allergy, allergic rhinitis, asthma, sinusitis, and breathing issues with increased vaccine acceptance compared to the unvaccinated group (Figure 4A). In the most vaccinated quartile compared to unvaccinated comparison, the relative risks (and lower CI) of office visits related to these conditions were estimated for asthma (16.01), allergic rhinitis (20.64), sinusitis (11.32), and breathing issues (6.52); all were highly significant in univariate analysis ( $p < 0.0001$ ).

**R1.2. Group B: Attention Deficit/Hyperactive Disorder and Behavioral Issues.** Because there were no cases of ADHD in the unvaccinated group, the quartile analysis uses a comparison to the least vaccinated decile to avoid division by zero. Large increases were found in office visits among the vaccinated compared to the unvaccinated groups in outcomes in this group as well. The quartile representation shows large increases in ADHD and moderately large increases in behavioral issues (Figure 4B). Both of these conditions had highly significant relative incidences of office visit (ADHD, RIOV = 53.74; behavioral issues, 10.28) ( $p < 0.00001$ ).

**R1.3 Group C: Ear Pain, Otitis media, and Eye Disorders.** Issues with the ear showed a range of increases with vaccine acceptance over the quartiles; in the last quartile, the differences were all

significant (ear pain (RIOV = 10.37), otitis media (RIOV = 7.03), and eye disorders (5.53) (Figure 4C) ( $p < 0.00001$ ).

R1.4. Group D: Autoimmune Conditions of the Skin and Blood. Skin reactions commonly observed and sometimes attributed to vaccination showed consistent, moderate increases in RIOV in the last quartile of eczema (2.315), urticaria (4.81), and dermatitis (2.72) (Figure 4D);  $p < 0.0001$ .

R1.5. Group E: Gastroenteritis, Weight/Eating Disorders, and Seizure. The RIOV of both gastroenteritis and weight/disorders increased over the quartiles with increased vaccine uptake, as did seizure (Figure 4E).

R1.6. Group F: speech, language, social, and learning delays showed variable but nonsignificant response over the axis of vaccination. Autism was only significant at the third quartile (Figure 4F).

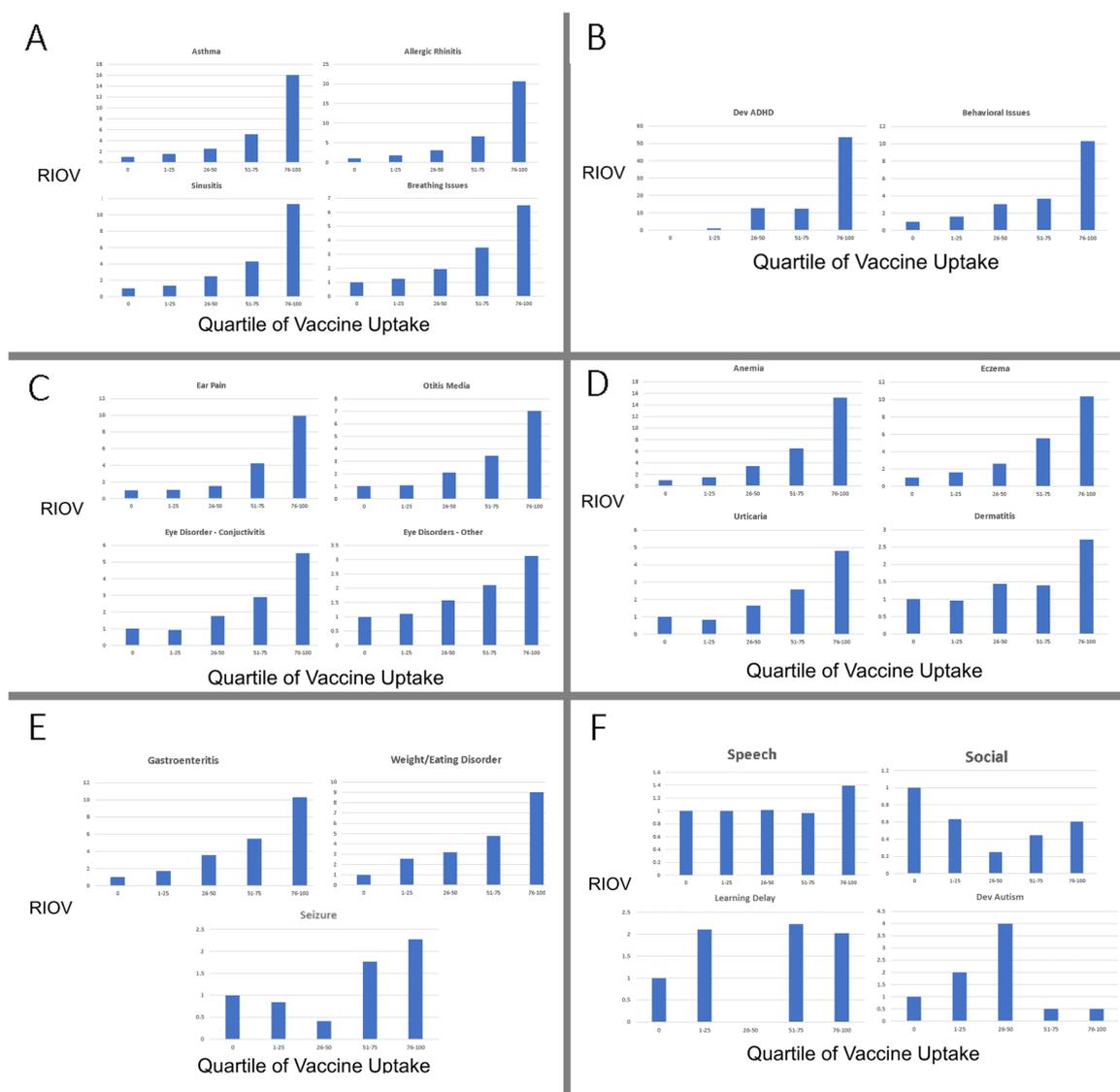
Sensitivity analysis for multiple hypothesis testing in the full cohort data did not change the outcome of analyses for most comparisons. Specifically, an increase of the critical value of Z on the test of proportions from 9.98 to 18 resulted in no loss of significance except for seizure; when increased to 19, dermatitis and behavioral issues lost significance.

Associations were found comparing the most vaccinated quartile for most of the outcomes (Table 3) with the exception of developmental delays and autism spectrum disorders (Figure 4). Following the same analysis protocol for all other conditions, the rate of autism was found to be higher at the third quartile of vaccine uptake compared to unvaccinated (Figure 4F). This is expected given that families with children with autism may be inclined to opt out of the vaccination program, potentially reflecting a signal of informed choice by families excluding them from the higher vaccinated quartile.

**Table 3.** RIOV analysis of outcomes of the vaccinated vs. unvaccinated groups, matched for Days of Care (DOC) matched comparison (N1 = 561 and N2 = 561).

Condition	Vaxxed	Unvaxxed	RIOV	Test of Proportions		
				95% CI	Z	P(Z)
Fever	78	17	4.596	4.412	6.547	<0.00001
“Well Child” Visit	5204	4989	1.045	1.041	2.156	0.0307
Ear Pain	18	16	1.127	1.022	0.354	0.726
Otitis media	355	216	1.646	1.001	8.312	<0.00001
Conjunctivitis	113	87	1.301	1.023	2.042	0.04136
Eye Disorders—Other	38	31	1.228	1.076	0.877	0.3788
Asthma	20	13	1.541	1.437	1.317	0.186
Allergic Rhinitis	21	12	1.753	1.649	1.600	0.1096
Sinusitis	6	5	1.202	1.143	0.306	0.756
Breathing Issues	75	44	1.708	1.502	3.015	0.00252
Anemia	130	36	3.618	3.361	7.912	<0.00001
Eczema	64	23	2.788	2.613	4.581	<0.00001
Urticaria	14	17	0.825	0.925	−0.541	0.5892
Dermatitis	86	105	0.821	1.090	−1.459	0.1443
Behavioral Issues	54	17	3.182	3.026	4.452	<0.00001
Gastroenteritis	89	30	2.972	2.763	5.728	<0.00001
Weight/Eating Disorders	147	92	1.601	1.288	4.023	<0.00001
Seizure	10	8	0.798	0.067	0.874	0.6312
Respiratory Infection	703	382	2.682	1.134	51.85	<0.00001

The calculation of Z for “Well Child” visits compared the proportion of number of office visits per group to the total number of days of care (length of time in practice; per group: vaccinated = 416,101, unvaccinated 416,056) in this DOC-matched analysis.



**Figure 4.** RIOV axis of vaccination percentile vaccine uptake analysis: incidence of study outcome-related office visits relative to that found in the 2763 variably vaccinated compared to the 561 unvaccinated groups for each percentile of vaccine uptake on the *x*-axis. (A) Autoimmune respiratory illnesses; (B) attention deficit/hyperactive disorder and behavioral issues; (C) ear pain, otitis media, and eye disorders; (D) autoimmune conditions of the skin and blood; (E) gastroenteritis, weight/eating disorders, and seizure; and (F) development delays in speech, learning, and social interactions and autism spectrum disorder.

### 3.2. Analysis 2 Results. Odds Ratio on Incidence of Diagnoses

When the data are represented as the number of patients in each group who had at least one record of an office visit related to a given condition, the signals remain (Table 4). Incidence of diagnoses of each condition was compared between the 561 unvaccinated and the 2763 vaccinated individuals. This result is similar overall to the RIOV analysis; we present the odds ratio, relative risk, lower than 95% of each, along with the absolute risk difference (vaccinated – unvaccinated) in Table 4. Among all of the outcomes, allergic rhinitis and anemia had the highest OR; anemia, weight/eating disorders, and respiratory infection showed the highest absolute risk difference (ARD; all increased in the vaccinated).

**Table 4.** Incidence of diagnoses of conditions in the vaccinated vs. unvaccinated groups in the population under study.

Outcome	OR	RR	Relevant 95% CI	ARD *	Significant
Fever	9.57	8.08	5.35/7.45	0.15	+/+
Ear Pain	4.11	3.87	2.22/3.40	0.06	+/+
Otitis media	3.11	2.2	2.49/2.11	0.12	+/+
Otitis externa	3.832	3.756	1.395/3.000	0.02	+/+
Conjunctivitis	2.67	2.21	2.04/2.08	0.15	+/+
Eye Disorders (Other)	1.9	1.82	1.24/1.61	0.04	+/+
Ear Disorders	2.359	2.32	1.08/1.86	0.02	+/+
Asthma	3.496	3.361	1.77/2.87	0.04	+/+
Allergic Rhinitis	6.479	5.595	3.31/5.31	0.08	+/+
Sinusitis	3.529	3.451	1.42/2.79	0.02	+/+
Breathing Issues	2.46	2.238	1.74/2.04	0.08	+/+
Anemia	6.334	4.482	4.68/4.6	0.21	+/+
Eczema	4.763	4.301	2.86/3.89	0.09	+/+
Urticaria	2.258	2.183	1.29/1.87	0.03	+/+
Dermatitis	1.591	1.482	1.22/1.37	0.06	+/+
Behavioral Issues	3.13	1.8	1.80/2.60	0.05	+/+
Gastroenteritis	4.479	3.587	2.98/3.56	0.13	+/+
Weight/Eating Disorders	3.146	2.489	2.41/2.35	0.183	+/+
Allergy—Food	2.24	2.23	0.52/1.47	0.004	-/+
Pain	2.569	2.236	1.759/2.147	0.0754	+/+
Respiratory Infection	1.716	1.365	1.351/1.255	0.131	+/+

\* ARD = absolute risk difference, calculated as (vaccinated diagnosis rate – unvaccinated diagnosis rate). Odds ratios and relative risk ratios were calculated as described in the Methods section (Equations (1) and (2), respectively). The +, – symbols represent the significance of the OR and RR statistics for each condition for the relevant (upper or lower) 95% CI.

### 3.3. Analysis 3 Results. Days of Care (DOC) Matched Vaccinated vs. Unvaccinated RIOV Analysis

Due to the likelihood of confounding on DOC, DOC-matched results inform on the robustness of associations. DOC matching also led to matching by age; the average rank of age in both the vaccinated and unvaccinated groups was nearly identical (Student's  $t$ ,  $p = 0.919$ ). Average age at last office visit was also not significantly different (Student's  $t$ ,  $p = 0.95$ ). The average age of first office visit differed only by 2 days (6 days vs. 8 days, Student's  $t$ ,  $p < 0.001$ ).

### 3.4. Analysis 4 Results. DOC-Matched Incidence

In the analysis of days-of-care-matched data represented as incidence, many of the conditions for which associations were found in the RIOV analysis were found to be undetectable by OR and Relative Risk analysis (Table 5). This included ear pain, eye disorders, ear disorders, asthma, allergic rhinitis, sinusitis, and urticaria (Table 5). Otitis externa, anemia, and respiratory virus infection had the highest absolute risk differences.

While RIOV is reduced in the DOC-matched analysis, the significance of an increased proportion of cases in the vaccinated individuals compared to unvaccinated individuals remains for most outcomes. Risk of seizure was significant for confidence interval testing in this matched analysis but not for Z-test ( $p = 0.6321$ ). Some comparisons had too few counts in the DOC-matched analysis to be reliable (e.g., food allergy had 1 case in the vaccinated group and 2 in the unvaccinated group).

**Table 5.** Analysis 4: DOC-matched incidence analysis.

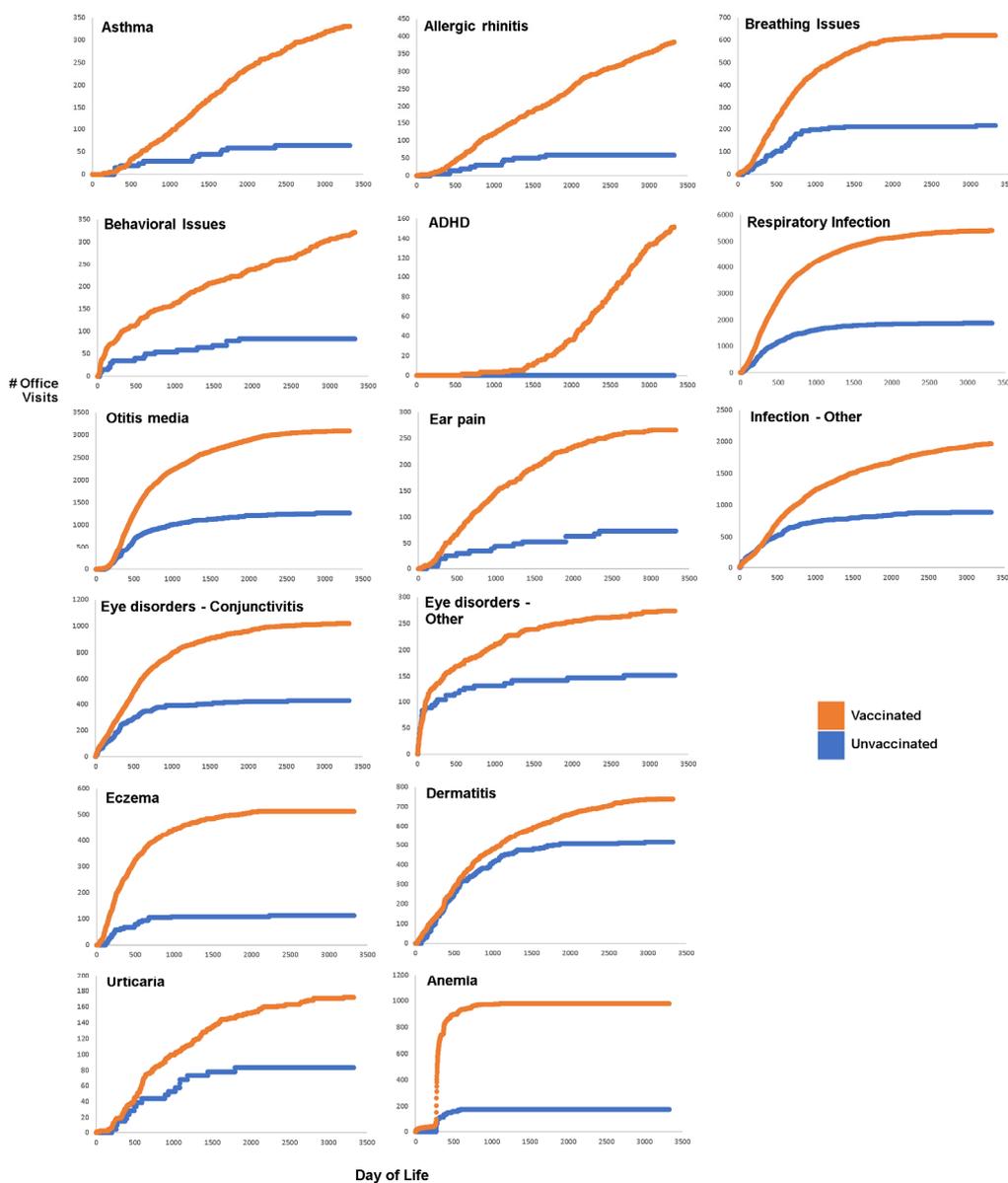
Outcome	OR	RR	95% CI	ARD	Significance
Fever	3.88	3.66	2.02/2.75	0.057	+,+
Ear Pain	1.559	1.57	0.723/0.966	0.01	-, -
Otitis media	1.551	1.4	1.17/1.22	0.078	+,+
Otitis externa	2.01	1.996	0.602	1	+,+
Conjunctivitis	1.323	1.273	0.942/1.05	0.033	-,+
Eye Disorders—Other	1.25	1.24	0.729/0.879	0.011	-, -
Ear Disorders	1.29	1.28	0.476/0.671	0.003	-, -
Asthma	1.224	1.22	0.503/0.679	0.003	-, -
Allergic Rhinitis	1.452	1.44	0.615/0.842	0.007	-, -
Sinusitis	1.2	1.2	0.364/0.540	0.008	-, -
Breathing Issues	1.614	1.549	1.504/1.217	0.037	+,+
Anemia	3.216	2.865	2.098/2.368	0.103	+,+
Eczema	2.822	2.682	1.57/2.01	0.047	+,+
Urticaria	1	1	0.471/0.595	0	-, -
Dermatitis	0.884	0.898	1.27/1.13	-0.012	+,+
Behavioral Issues	2.13	2.067	1.11/1.45	0.0266	+,+
Gastroenteritis	2.785	2.572	1.74/2.054	0.073	+,+
Weight/Eating Disorders	1.915	1.721	1.386/1.47	0.089	+,+
Allergy—Food	0.498	0.499	5.51/3.53	-0.001	-, -
Seizure	1.756	1.746	0.511/0.836	0.0053	-, -
Infection—Respiratory	1.716	1.365	1.351/1.255	0.131	+,+
Pain	1.274	1.255	0.783/0.927	0.014	-, -

The symbols “+, -” denote the significance of the relevant (upper or lower) 95% CI analysis for OR and RR.

### 3.5. Analysis 5 Results. Cumulative Office Visits

The visual impact of the cumulative office visit plots is striking; more so than other plots, the time element (day of life) provides an index by which to compare the accumulation of human pain and suffering from potential vaccine side effects (Figure 5). These results are worth studying closely and noticing the variation among the cumulative office visits per condition and the stark differences between the rates of billed office visits in the most and unvaccinated patients born into the practice.

False discovery sensitivity analysis performed by increasing of the critical of value of  $Z$  (test of proportions) from 9.98 to 18 caused a loss of significance for ear and eye conditions only. All other conditions were robustly significant to  $Z_{crit} < 19.2$  (behavioral issues). The remainder of the conditions retained significance well beyond  $Z_{crit} = 24$ .



**Figure 5.** Analysis 5. Cumulative office visits in the vaccinated (orange) vs. unvaccinated (blue) patients born into the practice: the clarity of the age-specific differences in the health fates of individuals who are vaccinated (2763) compared to the 561 unvaccinated in patients born into the practice over ten years is most strikingly clear in this comparison of the cumulative numbers of diagnoses in the two patient groups. The number of office visits for the unvaccinated is adjusted by a sample size multiplier factor (4.9) to the expected value as if the number of unvaccinated in the study was the same as the number of vaccinated.

### 3.6. Analysis 6 Results. Family History-Blocked RIOV Analysis

The relative incidence of visitation per condition for patients with family history of autoimmune conditions and those patients with no record of family history of autoimmune conditions indicate variation among conditions in the likelihood of family history playing a role, either biologically or by influencing patient choice, in the association of vaccine uptake and outcome (Table 6). Within the pattern (Score FH+ >> Score FH-), family history of autoimmunity itself is consistent with a biological risk factor of the outcome. This was the pattern for fever, sinusitis, and potentially anemia. Within the pattern (Score FH+ << Score FH-), this is consistent with the signal of vaccine choice, implying that further vaccine uptake may have increased the risk of the condition in the unvaccinated. This was

the case in otitis externa, asthma, allergic rhinitis, and dermatitis. In this analysis: FH + N1 = 175 vaccinated, N2 = 88 unvaccinated; FH−, N1 = 385 vaccinated, and N2 = 186 unvaccinated.

**Table 6.** RIOV score blocked by family history and implication for co-factor status.

Condition	FH+	FH−	Pattern *	Consistent w/Risk Cofactor? **
Fever	21.826	3.818	+,+	yes
“Well Child” Visit	2.690	1.009	+,-	yes
Ear Pain	10.500	13.427	+,+	no
Otitis externa	0.988	9.242	-,+	yes
Otitis media	30.500	21.715	+,+	maybe
Conjunctivitis	19.266	13.443	+,+	maybe
Other Eye Disorder	2.343	3.902	+,+	maybe
Asthma	8.143	19.030	+,+	yes
Allergic Rhinitis	18.382	54.339	+,+	yes
Sinusitis	27.316	8.282	+,+	yes
Breathing Issues	9.524	10.188	+,+	no
Anemia	29.302	20.027	+,+	maybe
Eczema	17.292	13.718	+,+	maybe
Urticaria	4.135	4.404	+,+	no
Dermatitis	1.470	4.922	-,+	yes
Sezure	0.989	0.634	-,-	no
Respiratory Infection	4.556	5.396	+,+	no

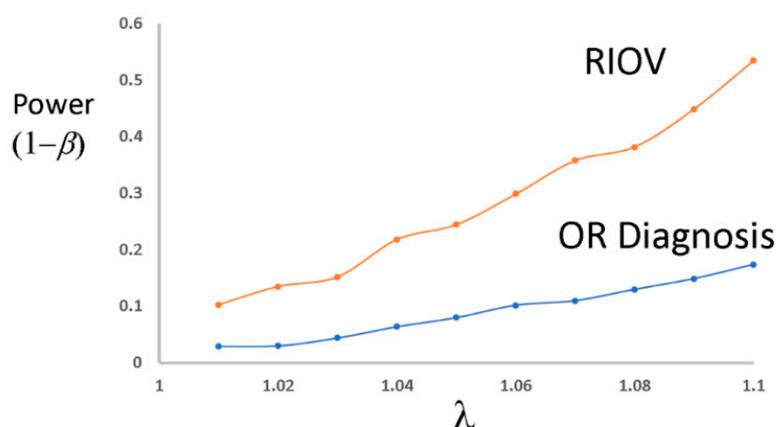
\* +,+ CI testing significant in both comparisons, +,- significant under FH+ block but not FH- block, etc. \*\* Yes = FH is a likely co-risk factor for outcome. Numerators (N1 and N2) for both groups were adjusted in fever and “Well Child” visits by a factor of 20; Otitis externa, anemia, and Otitis externa (factor of 2) and Otitis media (factor of 3). This does not change the RIOV score but allows the Z-test score to be estimated.

### 3.7. Analysis 7 Results. Power Simulation

The resulting 1000 comparison sets at each value of  $\lambda$  (N1 = 400  $\lambda$  = 1.0 vs. N2 = 400  $\lambda$  = 1.x for each  $\{x = 0.01, 0.02, 0.03 \dots 0.50\}$ ) were analyzed twice, first as an odds ratio of “diagnosis” (“0” = no diagnosis vs. “>0” = diagnoses). The second analysis conducted was a ratio of relative incidence of office visits, with each groups’ sum of values within each comparison group representing the total number of office visits being compared.

The simulations were not intended to precisely model the data from the current study; instead, it is intended to demonstrate the principle that the loss of information caused by using the incidence of health condition rather than the more sensitive measure of the number of office visits results in a loss of power to detect adverse events.

Over the range studied, the average increase in power achieved from the analysis using RIOV compared to the odds ratio of diagnoses was doubled over that of odds ratio on incidence of diagnoses (133%) (Figure 6). RIOV was more powerful compared to OR on rates of diagnosis over the simulated range. Our results demonstrate that drug and vaccine safety studies should employ RIOV rather than OR on rates of diagnosis of health conditions that might be attributable to the treatment, therapy, or vaccine.



**Figure 6.** Simulated demonstration of increased power of RIOV (number of office visits) relative to the power of odds ratio of incidence of diagnoses (at least one office visit).

### 3.8. Analysis 8. Gender Blocks

In the gender block analysis, the following conditions were significant in both the male and female RIOV comparisons: fever, “Well Child” visits, ear pain, otitis media, conjunctivitis, eye disorders (other), asthma, sinusitis, breathing issues, anemia, eczema, behavioral, gastroenteritis, and weight/eating disorder. The developmental delays were largely underpowered for robust analysis due to low overall rates in the practice, but two conditions were significantly lower in the vaccinated females (autism) and males (social development). These results, provided as a table with RIOV values and exact  $p$ -values of  $Z$  in Supplementary Materials Table S2, were not DOC- or age-matched.

### 3.9. Analysis 9 Age Blocks: Oldest Third and Young Third Blocked Analysis

The following conditions were significantly increased ( $p < 0.05$ ) in the vaccinated group in both age blocks: fever, otitis media, conjunctivitis, sinusitis, breathing issues, anemia, gastroenteritis, and weight/eating disorder. The following conditions were significantly increased in the vaccinated group in the younger (more recent) age block only: asthma and allergic rhinitis. The following conditions were significantly increased in the older age block only: “Well Child” visit and eczema. None of the developmental delay categories were significantly increased in either the older or younger age blocks, likely due to low power. Social delay was significantly increased in the unvaccinated older age block. Two health outcomes, pain and respiratory infection, were increased in the unvaccinated group under the older block but were not significantly different in the younger block. These results, requested by a peer reviewer, demonstrate robustness of many associations to blocking by age and by gender and are provided as tables in Supplementary Materials Table S3 (including RIOV values and exact  $p$ -values of  $Z$ ).

### 3.10. Analysis 10 Results—Vaccine-Targeted Diagnoses

There was a total of 41 vaccine-targeted diagnoses in patients born into the practice, mostly (by far) in varicella (29) and less so in pertussis (10). Overall, the groups show differences in vaccine-targeted diagnoses (Table 7;  $\chi^2 = 0.292$ ,  $p = 0.588$ ). The rates of any diagnosis were vaccinated, 7/2647 (0.00264) and unvaccinated, 34/561 (0.0499). The odds ratio of having a diagnosis of any vaccine-targeted infection ( $D_{xV}/D_{xUV}$ ) was 0.054 (0.114),  $Z$ -score, 7.155,  $p < 0.0001$ . Relative risk of any vaccine-targeted diagnosis was 0.053 (0.119),  $Z = 7.117$ ,  $p < 0.0001$ , number needed to treat (NNT) = 21.15 (17.72 to 26.225 (benefit)).

**Table 7.** Incidence of vaccine-targeted diagnoses in the study cohort.

Vaccine Targeted Diagnosis	Vaccinated	Unvaccinated	Deaths
Diphtheria	0	0	0
Hepatitis A	0	0	0
Hepatitis B	0	0	0
HiB *	0	0	0
Measles	0	0	0
Meningococcus	0	0	0
Mumps	0	0	0
Pertussis	1	9	0
Pneumococcal	0	0	0
Rotavirus	0	2	0
Rubella	0	0	0
Tetanus	0	0	0
Varicella	6	23	0
Total **	7	34	0

\* Haemophilus influenzae type B; \*\* Overall for all  $\chi^2 = 99.51$ .  $p < 0.00001$ .

The overall probability (risk) of a vaccine-targeted diagnosis in the unvaccinated, however, was only 0.0123, among 13 conditions. It is important to note that zero deaths have been attributed to any vaccine-targeted diagnosis in this practice over the study period.

#### 4. Discussion

The analysis of total outcomes related to vaccine and drug exposures is rarely conducted. It is made complex due to factors such as changes in trends in vaccine or drug acceptance, and the very signal sought—indication of adverse events from vaccines—can be changed by decisions made to avoid vaccine injury by those at risk. We have shown that the outcome of observational studies is sensitive to the choice of test of association and have presented a test (RIOV) more powerful than odds ratios on incidence (Figure 6).

Matching on DOC provides protection against healthcare-seeking behavior because each patient in the vaccinated group is matched to a person in the unvaccinated group with nearly identical length of records in the practice. This also led to matching on age, adding protection against incidental temporal confounds in changes over time in vaccination trends or schedules: both the vaccinated and unvaccinated matched samples are representative of the entire age range of the study cohort. Most of the differences in ratios persist comparing the full cohort analysis when the data were matched for DOC (Analysis 2; Table 3). All RIOV were  $>1$ , indicating increased risk of office visit for a specific outcome, except seizure, urticaria, and dermatitis. The change in direction of seizure likely points to “cessation of vaccination signal” following initial events. The difference between the vaccinated and unvaccinated groups was no longer significant for dermatitis following matching for DOC.

The variation in vaccination was the outcome of the final decisions on the part of the patients after consulting with their physicians in the practice. This adherence to the tenets of informed consent, as required by federal regulations for both medical practice and for post-market surveillance studies, is also a key element built into “The Vaccine Friendly Plan” (VFP), developed in a manner to space aluminum-containing vaccines out and to avoid aluminum-containing vaccines (ACVs) whenever a non-ACV is available. The net effects of these changes on aluminum accumulation in children is described in [15]. Children on the CDC schedule would have on average received more vaccines in total; considering the most vaccinated of the VFP compared to the CDC schedule reveals that CDC-scheduled children receive 14 more vaccines by age 2 compared to those most vaccinated on the VFP; by age 5 years, children receive 4 more vaccines (CDC 6, VFP 2), and by ten years, children receive six more vaccines under the CDC schedule compared to the VFP (CDC + 8, VFP, +2). This represents a

total of 24 additional vaccines those on the CDC schedule would have received in 2019 compared to the most vaccinated individuals in this retrospective study. Children on the CDC schedule also would have received more instances of more than one ACV per visit and a larger number of ACVs.

We have found higher rates of office visits and diagnoses of common chronic ailments in the most vaccinated children in the practice compared to children who are completely unvaccinated. The data clearly show different odds of developing many of these adverse health conditions. We have demonstrated in many ways that most of the statistical associations found tend to be robust to age in cohort (days of care), vaccination range, and family history. The first of these is the contrast in the increase in fever cf. “Well Child” visit (Figure 3). The second is robustness of the results to adjustment to days of care provided and of course robustness to the age-matched design as well.

Vaccination appears to have had the largest impact on anemia and respiratory virus infection on the number of office visits in the vaccinated compared to the unvaccinated groups. Due to a small number of cases and corresponding low power, neurodevelopmental conditions and seizures are not well studied using the data available. Autism, at a study-wide rate of 8 per 1000, is far lower than the national rate (18.5–21 per 1000). Speech, learning, and social delays were found to have different full-cohort practice-wide incidences of 0.023, 0.003, and 0.009, respectively. Future studies with less restrictive inclusion criteria that also avoid temporal confounding by matched DOC may help us better characterize these populations in the practice.

Our family history of autoimmune conditions analysis points to numerous conditions likely carrying a genetic risk of vaccine-related adverse health effects. This, however, is only one study from data from a single practice, so any absence of a pattern consistent with a genetic risk of adverse health effects should not be taken as evidence of absence of a role of genetic risk. Larger studies able to estimate the interaction term between family history and vaccine exposure should be undertaken.

Previous studies such as the Mawson study (2017) [9] reported high odds ratios for allergic rhinitis (30.1), learning disabilities (5.2), ADHD (4.2), autism (4.2), neurodevelopmental disorders (3.7), eczema (2.9), and chronic illness (2.4) but were limited because they were based on survey data. While not necessarily fatal to a study, the highly charged nature of the vaccine risk research brings a special concern over survey respondents who might, for the sake of advocacy, seek or unintentionally emphasize their unvaccinated child’s lack of diagnoses or amplify their vaccinated child’s larger number of diagnoses. Recall bias is a potential factor in this setting, and therefore, our results go a long way to validate those on the Mawson (2017) [9] study. The age range in that study was also restricted to 6- to 12-year-olds, precluding the comparison of the cumulative rates from day 1 of life. Survey studies in the future should obtain HIPAA permissions to access at least a portion of patients’ medical records to at least estimate the accuracy of responses compared to medical records from a sample. Despite limitations of survey studies, our results validate many of these results.

Numerous studies conducted in the past have found an association of vaccination with adverse health effects. Numerous studies reporting an association of individual vaccines with adverse study outcomes are too numerous to cite here; many more such studies are reviewed online [16]. For example, a prior study reported a vaccination association with asthma and allergy (e.g., Hurwitz and Morgenstern, 2000) [17].

Concerned over healthy user bias (HUB), i.e., healthier individuals accepting more vaccines leading to differences in study outcome are alleviated in this practice, the physicians and patients overtly came to a joint decision on whether to vaccinate on a patient-by-patient and vaccine-by-vaccine basis. As originally described, if “healthy user bias” was the explanation problem, we would see more illness in the unvaccinated; we found the opposite. We do see the potential signal of informed avoidance of vaccine injury with informed consent and without coercion potentially weakening associations of vaccine injury. This type of effect has historically been interpreted as a form of healthy user bias, but it can be equally interpreted as the signal of avoidance of vaccine injury due to informed consent. Our design of analysis allows the detection of some potential instances (e.g., autism, in which

some individuals at risk of adverse outcome who otherwise would have been in quartiles 3 and 4 stopped vaccinating).

Glanz et al., 2003 [18] found that parents who tended to not accept all vaccines or who delayed vaccines were 2 times more likely to report that they began thinking about vaccines before their child was born and were also 8 times more likely to report that they constantly reevaluate their vaccine decisions than parents who accepted all vaccines. Notably, the signal of change in vaccination behavior following adverse events via informed consent would appear to be detectable as a reduction in the overall incidence of adverse outcomes in the unvaccinated group and fewer office visits related to those outcomes. This opposing trend is the opposite of the expectation that physicians may be more likely to admit the unvaccinated for health issues than the vaccinated (described by [18]). Lifestyle differences between the vaccinated and unvaccinated groups in this practice cannot explain the large difference in outcomes, and if they do, then it would be objective to conclude that everyone should adopt the lifestyle followed by the unvaccinated if they want healthier children. That lifestyle choice includes, for many families, avoiding some or all vaccines, and thus, the lifestyle choice concern is inextricably linked to vaccine exposure.

Because we are considering the potential effects of cumulative vaccination, the potential problem of reverse temporal association with appropriately juxtaposed association is undefined in our study. The RIOV design of analysis makes the reverse temporal association irrelevant, as in the vaccinating population, the cumulative number of vaccinations over the course of a decade is the independent variable. For reverse temporal association concern to manifest, all or most of the diagnoses would have had to occur prior to the first vaccine, which is extremely unlikely (and are not at all what our data show). Our accumulation diagrams make clear the general tendencies toward requiring medical attention for outcomes in vaccinated vs. unvaccinated segments of the patient population in a distinctly age-specific manner. We have focused on the cumulative effects of vaccines on overall health and therefore, this concern cannot logically apply to the study as it is designed.

#### *4.1. Caveat on Applicability of Results (Generalizability)*

Data from this single and unique practice provides a unique opportunity to examine variation in outcomes associated with variation in vaccination. A number of unique factors may limit the generalizability of these findings to other practices, including the fact that patients in the practice appear to be, on average, becoming healthier over time with less chronic illness and seem to have lower frequencies of certain health issues compared to national trends. Under the Vaccine Friendly Plan, parental choice leads to cessation of vaccination more frequently if certain health indications present following vaccination, leading, by observation, to a reduction in identifiable adverse health conditions. Therefore, our results may or may not generalize to other practices but could be expected to apply to practices that adopt the Vaccine Friendly Plan over the next ten years. Our results are likely conservative compared to practices that do not screen actively for patients who might experience further health complications due to vaccines. We conducted our analyses and present our results and interpretation with these caveats in mind.

We have been keenly aware of the brewing political controversies around vaccination studies, including the public's increased awareness of the dearth of long-term randomized prospective clinical studies that use inert placebos such as saline. Many studies have failed to detect the association of vaccines with adverse outcomes; however, they have mostly used correlative retrospective studies focused on odds ratios of mere incidence and have largely been agnostic to intrinsic methodological power. A white paper for conducting retrospective studies on vaccines [6,7] suggests adjusting/correcting for variables that correlate with vaccination status and/or outcomes. This is an incorrect and risky strategy; in a situation with highly collinear independent variables, adjusting for co-risk factors can remove variation in the model important to finding accurate interpretive context of the main variable of interest and prevents the development of risk models to avoid adverse vaccine outcomes. The CDC's white paper has fostered the widespread practice of selecting a subset of available

variables as confounders for adjusted analyses when the functional relationships among collinear variables are not well established, a feat that Vansteelandt et al., 2010 [19] consider “impossible”. The protocol introduces serious risks of model misspecification due to adjusting for variables that correlate with outcomes and overadjustment of highly and sometimes multicollinear variables without formal model selection protocols and should be discontinued.

The use of objective criteria for model selection is rare, and the common practice of arbitrary selection of potential confounders could conflate signals when study outcome measures or measurements collinear with study outcome measures are treated as confounders. This increases the risk of overadjustment bias (See Schisterman et al., 2009 [20]). Not all potential confounders are in fact confounders; they may in fact represent a co-risk factor that could be used to predict risk of adverse events. “Adjusting” for risk factors of vaccine adverse events would undo signals expected to be functionally related to risk of vaccine toxicity; these include birthweight, gestational age, mother’s income, and mother’s age, all variables that are likely multicollinear and may well be important functional indicators of specific risk to vaccine adverse events. Repeated rounds of analysis of the same data set following observation of results to achieve a desired result (toward or away from statistical significance) without showing all the stages of analysis is now understood to increase the likelihood of bias and can be seen as “*p*-hacking” (George et al., 2016) [21] or “results-peeking”. Such activities undertaken to achieve a desired result and failure to bring forward the full set of alternative or interim results should be discouraged by scientific journals publishing any type of observational research studies on any subdiscipline of research.

We recommend stratification and blocking with RIOV, which makes explicit the robustness of the association in different subpopulations. It also makes transparent the effect of subgroup sample size on power. Underpowered designs and methods should not yield presented hypothesis testing results (negative or positive) as definitive as they can have misleading and potentially disastrous effects on public health policies.

Given the massive abundance of electronic medical record data, the dearth of independent studies such as ours on vaccine safety is conspicuous. The value of any vaccination program must be seen as a product of the total net health effects of the individual vaccines in the program, and negative findings should provide an agency for a shift in their use, respect for patient choice, and regulation of their excipients and vaccine formulation.

It is little appreciated that the results of observational studies—including retrospective vaccine safety studies—can depend to a large degree on the statistical method(s) selected and the variables used to “adjust for” variation as found in an observational data set. We have introduced a new measure—RIOV—as a more powerful alternative to the commonly used odds ratios of incidence of diagnosis. We have shown OR on incidence of diagnosis to be, via our simulations (Analysis 7), a less powerful test than RIOV. OR on incidence is in fact a de facto lossy transform (binarization of a continuous variable office visits) of RIOV. Office visits carry more information than diagnoses; specifically, measures based on the number of office visits will carry information on severity in addition to the number of yes/no ever-diagnoses. Our days-of-care-matched incidence (diagnosis only) analysis appears to be the least powerful analysis when odds ratio using incidence is considered; reduced power of OR on incidence relative to RIOV analysis may explain the failure of many prior studies to detect an association between exposure to vaccines and adverse health effects. The realization that studies of the relative occurrence of office visits is a more powerful measure than incidence of diagnoses means that future vaccine studies can be made more capable of detecting real associations of adverse outcomes associated with vaccination.

Many families across the United States who are not vaccinating or who have stopped vaccinating their child or children or who choose to partially vaccinate often choose to opt out as a direct result of adverse health observations following vaccination, including health conditions that to date have not been attributed to vaccination based on epidemiological studies. Parents are almost universally told by their child’s health care provider that the health issue was not due to the vaccine, in spite of growing

evidence in the scientific literature that supports both plausible mechanisms of action for chronic illnesses including epidemiological associations. It is now apparent that the commonly reported lack of association of adverse events may be due to the use of a test statistic with low intrinsic power and due to problems including model misspecification and overadjustment bias and that further research is needed to update guidelines and recommendations via additional studies.

We attribute the relative dearth of epidemiological findings similar to ours to a number of factors, including the use of incidence of diagnoses, which is clearly likely to be (on first principles) a less sensitive measure of differences in vaccine-induced disease burden. Importantly, RIOV is a readily accessible measure that likely has a higher power to detect associations than ratios of incidence or odds ratio. The underreporting of adverse events to VAERS is also a factor precluding the detection of adverse events that can be attributed to vaccines. According to the US CDC (CDC, 2020) [22] and the US Department of Health and Human Services (HHS) [23], healthcare providers should report to VAERS (a) any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations and (b) an adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine. Also, the CDC reports that healthcare providers are strongly encouraged to report to VAERS (a) any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event and (b) vaccine administration errors. Finally, the CDC reports that vaccine manufacturers are required to report to VAERS all adverse events that come to their attention; they are also required to pass on such reports to the Food and Drug Administration.

Regardless of such recommended reporting, the inquiry by Harvard Pilgrim (Ross et al., 2011) [5] on underreporting found that vaccine adverse events are underreported to VAERS by a factor of 100. If doctors are not reporting events because they believe they are not attributable to vaccines and VAERS is the primary resource by which new adverse events are detected, heretofore, undetected adverse events are not discovered. Families experiencing vaccine-induced chronic illnesses not yet recognized by science as adverse outcomes to vaccination are going to object strenuously to mandatory vaccination policies, and science will lag behind the public awareness of vaccine-induced human pain and suffering. This lag is currently undermining trust in public health vaccine policies, government regulating and licensing agencies, vaccine makers, and proponents of vaccination—including most of mainstream media in the US—who insist all vaccines are universally “safe and effective.”

This study, and others, indicates that the correct path forward should include the enforceable requirement of all physicians to report all adverse health events recorded in medical records over an extended period to capture those adverse events that are latent, whether they are already recognized by the HHS or not, so as to empower users of the VAERS system to be better able to detect adverse outcomes associated with vaccination. Mandatory adoption of an ESP-VAERS-like adverse event detection system embedded in electronic medical record systems in practices and clinics would be beneficial toward a full understanding of vaccine-related morbidity and mortality in our populations and could lead to a significant increase in overall health. This study also provides information on diagnosed infections targeted by pediatric vaccines.

#### 4.2. Strengths and Limitations

Factors such as sample size limitations, likely due to changes in vaccine acceptance following initial adverse events, limit our ability to robustly test hypotheses of association for some outcomes, especially in neurodevelopmental disorders and vaccination and seizures. If a link does exist, the absence of clear associations is likely due the small number of patients in the practice with neurodevelopmental disorders and seizures, which, ironically, may be due in part to the respect for patient preference, leading to informed choices by families at potential risk.

A related potential limitation includes that, because the data used were from billed diagnoses (in the case of outcomes) or billed vaccination, there may be some occurrences that were missed if insurance did not cover those events for a given patient (e.g., ASD diagnosed via a family

counselor/psychologist/psychiatrist). Similarly, diagnoses of developmental delay outside of the office may have not made it into the medical record for some patients. However, given that part of our data representation of such diagnoses was a per-patient count of reports of such diagnoses, the effects of these possible sampling limitations is likely mostly restricted to neurodevelopmental delays, and such an effect is more likely in outcomes related to data for a limited number of diagnoses than on vaccination data.

A criticism of association studies that detect negative health effects of vaccines is that some unknown, unmeasured confounder, or set of confounders might offer an alternative explanation. An example is the concern that our results may be explicable by other, unmeasured, healthier lifestyle choices made by families who also do not vaccinate. This seems highly unlikely given the relationships between increased adverse outcomes and vaccine acceptance, and lifestyle choices do not seem to be plausible explanations for many of the outcomes we have measured, although exposures to environmental substances such as cigarette smoke and acetaminophen (paracetamol), and malnutrition, which are known to impact negatively the immune system and development, cannot be ruled out as additive or multiplicative risk factors to vaccine adverse reactions and to the examined outcomes. The positive control outcome “fever” (Figure 3) points to a pattern expected following vaccination with no known or suspected relationship to lifestyle choices. However, if it were so, it would appear that our collective priority as a medical community should not be the pursuit of complete vaccination across the population but instead studies on what those other lifestyle choices might include and massive recommendations toward improving the lifestyle choices across the population.

Our study also has numerous strengths: the sample is fully representative of the practice population, and our design protocol had robust data provenance (parity checking) and rigorous data analysis. We avoided overadjustment bias and used a more powerful test to detect adverse events, demonstrated the robustness of the results to analysis assumptions, and have been careful to avoid overdrawn conclusions.

## 5. Conclusions

We could detect no widespread negative health effects in the unvaccinated other than the rare but significant vaccine-targeted diagnosis. We can conclude that the unvaccinated children in this practice are not, overall, less healthy than the vaccinated and that indeed the vaccinated children appear to be significantly less healthy than the unvaccinated.

We concur with Mawson et al., 2017 [9], who reported: “Further research involving larger, independent samples is needed to verify and understand these unexpected findings in order to optimize the impact of vaccines on children’s health.”

We also concur with Hooker and Miller 2020 [14], who wrote: “Further study is necessary to understand the full spectrum of health effects associated with childhood vaccination”.

Other pediatric practices with variably vaccinating populations should be studied using a methodology similar to ours to attempt to refute or validate our findings and those of Mawson et al., 2017 [9], Hooker and Miller 2020 [14], and the numerous studies that have reported adverse health following vaccination. We are particularly interested in further study of the relationship between specific vaccines and combination of vaccines on specific outcomes as well as the relationship between the uptake of specific types of vaccines—inactivated, live virus, and aluminum-adjuvanted—with specific outcomes. Larger studies using electronic medical records from major medical institutions should be undertaken by research teams with no financial interest in the outcome of the studies (e.g., revenue from vaccination and from treatment of vaccine-related adverse outcomes).

Unintended and nonspecific consequences of vaccination, such as increased risk of chronic health conditions from vaccine exposures, must also be examined to determine if for any vaccine-targeted infection alternative methods of infection-avoidance or effective treatments that reduce disease sequela are available and preferable to vaccination in various circumstances, as has been reported by Cowling

et al., 2012 [24] and by Wolff (Wolff, 2020) [25]. Our findings are consistent with the concern that vaccination may increase respiratory virus infection risk, clearly a grave concern in the age of COVID-19.

Our finding of a robust signal of anemia deserves follow up: aluminum is known to bind to transferrin [26] and, in so doing, may interfere with the proper deposition of iron in the bones of children. Iron deficiency can also contribute to febrile seizures, a known side effect of some vaccines. Our society should work to identify safer vaccine schedules and safer adjuvants [27–35] and to reduce autoimmunity risk by removing unsafe epitopes—peptide sequences from pathogens or human cell line remnants in vaccines that match human proteins in sequence or structure from any tissue [36]—would seem expeditious, kind, and wise.

Future studies should now focus on the relative incidence of billed office visits, now that it has been shown to be a more sensitive and powerful measure of outcomes with a larger dynamic range than binary yes/no incidence of diagnoses.

**Supplementary Materials:** The following are available online at <http://www.mdpi.com/1660-4601/17/22/8674/s1>: 'Table S1: ICD code mapping'; Table S2: 'LW and Thomas Supplemental S2 Gender Block Results 2.8.xlsx'; Table S3: 'LW and Thomas Supplemental S3 Age Blocks R2.9.xlsx'.

**Author Contributions:** P.T. directed the care of the patients in the study; P.T. conceived of the study concept; both J.L.-W. and P.T. designed the study; J.L.-W. designed the analysis strategy, and J.L.-W. conceived of and executed the data analysis including the power simulations and drafted the first manuscript; two anonymous honest brokers de-identified the data and provided a data parity check; all technical errors in the execution of analysis, if any, are the sole responsibility of J.L.-W. All authors have read and agreed to the published version of the manuscript.

**Funding:** This research was funded by donations from the public to The Institute for Pure and Applied Knowledge (IPAK; <http://ipaknowledge.org>). None of the donors had any input into the scope or design of the study or the decision to publish. IPAK is a not-for-profit research organization.

**Acknowledgments:** We are indebted to the public for funding this study via donations to the Institute for Pure and Applied Knowledge. None of the donors had any influence on the scope or direction of the study. We are also deeply indebted to two anonymous honest brokers whose expertise in handling the deidentification and data parity checking made this study possible. Given negative social pressures and direct threats of undue consequences on individuals who participate in studies that cast any negative light on vaccines or the practice of vaccination, we respect their anonymity. We are also indebted to a spreadsheet checker for his time double- and cross-checking our many data analysis spreadsheets for errors or inconsistencies. All errors in the design or execution of analysis are the responsibility of J.L.W. We are especially grateful to three anonymous reviewers for their time and expertise and especially to reviewer #1 for providing in-depth critical and useful review of this study.

**Conflicts of Interest:** J.L.W. has, in the past, been but is no longer a compensated expert witness in cases in the US National Vaccine Injury Compensation Program. P.T. receives income in the form of royalties from the sale of his book, and he receives income from the sale and administration of vaccines in his practice. P.T. is the owner of Integrative Pediatrics, the population for this study, and is the author of the book "The Vaccine-Friendly Plan: Dr. Paul's Safe and Effective Approach to Immunity and Health—from Pregnancy Through Your Child's Teen Years" by Balantine Books 2016.

## References

1. Benn, C.S.; Fisker, A.B.; Rieckmann, A.; Sørup, S.; Aaby, P. Vaccinology: Time to change the paradigm? *Lancet Infect Dis.* **2020**, *20*, e274–e283. [[CrossRef](#)]
2. Aaby, P.; Jensen, H.; Samb, B.; Cisse, B.; Sodemann, M.; Jakobsen, M.; Poulsen, A.; Rodrigues, A.; Lisse, I.M.; Simondon, F.; et al. Differences in female-male mortality after high-titre measles vaccine and association with subsequent vaccination with diphtheria-tetanus-pertussis and inactivated poliovirus: Reanalysis of West African studies. *Lancet* **2003**, *361*, 2183–2188. [[CrossRef](#)]
3. CDC. Report an Adverse Event to VAERS. 2020. Available online: <https://vaers.hhs.gov/reportevent.html> (accessed on 15 August 2020).
4. Tan, T.Q.; Gerbie, M.V.; Flaherty, J.P. *The Vaccine Handbook*. Oxford University Press: New York, NY, USA, 2017.
5. Lazarus, R.; Klompas, M. Electronic Support for Public Health—Vaccine Adverse Event Reporting System (ESP:VAERS). Grant. Final Report, Grant ID: R18 HS 017045. 2010. Available online: <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf> (accessed on 16 August 2020).

6. Institutes of Medicine (National Academy of Sciences) Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule; Board on Population Health and Public Health Practice; Institute of Medicine. *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*. National Academies Press (US): Washington, DC, USA, 27 March 2013.
7. CDC. White Paper on Studying the Safety of the Immunity Schedule: For the Vaccine Safety Datalink 2018. Available online: [https://www.cdc.gov/vaccinesafety/pdf/whitepapersafety\\_web.pdf](https://www.cdc.gov/vaccinesafety/pdf/whitepapersafety_web.pdf) (accessed on 14 August 2020).
8. Glanz, J.M.; Newcomer, S.R.; Jackson, M.L.; Omer, S.B.; Bednarczyk, R.A.; Shoup, J.A.; DeStefano, F.; Daley, M.F. White Paper on studying the safety of the childhood immunization schedule in the Vaccine Safety Datalink. *Vaccine* **2016**, *34*, A1–A29. [[CrossRef](#)]
9. Mawson, A.R.; Ray, B.D.; Bhuiyan, A.R.; Jacob, B. Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12- year old U.S. children. *J. Transl. Sci.* **2017**, *3*, 1–12. [[CrossRef](#)]
10. Schmitz, R.; Poethko-Müller, C.; Reiter, S.; Schlaud, M. Vaccination status and health in children and adolescents: Findings of the German Health Interview and Examination Survey for Children and Adolescents (KiGGS). *Dtsch. Arztebl. Int.* **2011**, *108*, 99–104. [[CrossRef](#)]
11. Mogensen, S.W.; Andersen, A.; Rodrigues, A.; Benn, C.S.; Aaby, P. The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment. *EBioMedicine* **2017**, *17*, 192–198. [[CrossRef](#)] [[PubMed](#)]
12. McDonald, K.L.; Huq, S.I.; Lix, L.M.; Becker, A.B.; Kozyrskyj, A.L. Delay in diphtheria, pertussis, tetanus vaccination is associated with a reduced risk of childhood asthma. *J. Allergy Clin. Immunol.* **2008**, *121*, 626–631. [[CrossRef](#)] [[PubMed](#)]
13. Gallagher, C.; Goodman, M. Hepatitis B triple series vaccine and developmental disability in US children aged 1–9 years. *Tox. Environ. Chem.* **2008**, *5*, 997–1008. [[CrossRef](#)]
14. Hooker, B.S.; Miller, N.Z. Analysis of health outcomes in vaccinated and unvaccinated children: Developmental delays, asthma, ear infections and gastrointestinal disorders. *SAGE Open Med.* **2020**, *8*, 1–11. [[CrossRef](#)] [[PubMed](#)]
15. McFarland, G.; LaJoie, E.; Lyons-Weiler, J. Acute exposure and chronic retention of aluminum in three vaccine schedules and effects of genetic and environmental variation. *J. Trace. Elem. Med. Biol.* **2020**, *58*, 126444. [[CrossRef](#)]
16. Vaccine Safety Commission. 2020. Available online: <https://vaccinesafetycommission.org> (accessed on 24 August 2020).
17. Hurwitz, E.L.; Morgenstern, H. Effects of diphtheria-tetanus-pertussis or tetanus vaccine on allergies and allergy-related respiratory symptoms among children and adolescents in the United States. *J. Manip. Physiol. Therap.* **2000**, *23*, 81–90. [[CrossRef](#)]
18. Glanz, J.M.; Wagner, N.M.; Narwaney, K.J.; Shoup, J.A.; McClure, D.L.; McCormick, E.V.; Daley, M.F. A mixed methods study of parental vaccine decision making and parent-provider trust. *Acad. Pediatr.* **2013**, *13*, 481–488. [[CrossRef](#)] [[PubMed](#)]
19. Vansteelandt, S.; Bekaert, M.; Claeskens, G. On Model Selection and Model Misspecification in Causal Inference. *SSRN Electron. J.* **2010**, *21*, 7–30. [[CrossRef](#)]
20. Schisterman, E.F.; Cole, S.R.; Platt, R.W. Overadjustment Bias and Unnecessary Adjustment in Epidemiologic Studies. *Epidemiology* **2009**, *20*, 488–495. [[CrossRef](#)]
21. George, B.J.; Beasley, T.M.; Brown, A.W.; Dawson, J.; Dimova, R.; Divers, J.; Goldsby, T.U.; Heo, M.; Kaiser, K.A.; Keith, S.W.; et al. Common scientific and statistical errors in obesity research. *Obesity* **2016**, *24*, 781–790. [[CrossRef](#)]
22. CDC. Reporting Adverse Events. Available online: <https://www.cdc.gov/vaccinesafety/hcproviders/reportingadverseevents.html> (accessed on 24 August 2020).
23. US Department of Health and Human Services. Vaccine Adverse Event Reporting System: Report an Adverse Event to VAERS. 2020. Available online: <https://vaers.hhs.gov/reportevent.html> (accessed on 1 March 2020).
24. Cowling, B.J.; Fang, V.J.; Nishiura, H.; Chan, K.-H.; Ng, S.; Ip, D.K.M.; Chiu, S.S.; Leung, G.M.; Peiris, J.S.M. Increased risk of noninfluenza respiratory virus infections associated with receipt of inactivated influenza vaccine. *Clin. Infect. Dis.* **2012**, *54*, 1778–1783. [[CrossRef](#)]

25. Wolff, G.G. Influenza vaccination and respiratory virus interference among Department of Defense personnel during the 2017–2018 influenza season. *Vaccine* **2020**, *38*, 350–354. [[CrossRef](#)]
26. Papageorgiou, V.; Vargiami, E.; Kontopoulos, E.; Kardaras, P.; Economou, M.; Athanassiou-Mataxa, M.; Kirkham, F.J.; Zafeiriou, D.I. Association between iron deficiency and febrile seizures. *Eur. J. Paediatr. Neurol.* **2015**, *19*, 591–596. [[CrossRef](#)]
27. Crépeaux, G.; Gherardi, R.K.; Authier, F.-J. ASIA, chronic fatigue syndrome, and selective low dose neurotoxicity of aluminum adjuvants. *J. Allergy Clin. Immunol. Pract.* **2018**, *6*, 707. [[CrossRef](#)]
28. Exley, C. An aluminium adjuvant in a vaccine is an acute exposure to aluminium. *J. Trace Elements Med. Biol.* **2020**, *57*, 57–59. [[CrossRef](#)]
29. Crépeaux, G.; Eidi, H.; David, M.-O.; Baba-Amer, Y.; Tzavara, E.; Giros, B.; Authier, F.-J.; Exley, C.; Shaw, C.A.; Cadusseau, J.; et al. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective low dose neurotoxicity. *Toxicology* **2017**, *375*, 48–57. [[CrossRef](#)] [[PubMed](#)]
30. Gherardi, R.K.; Crépeaux, G.; Authier, F.-J. Myalgia and chronic fatigue syndrome following immunization: Macrophagic myofasciitis and animal studies support linkage to aluminum adjuvant persistency and diffusion in the immune system. *Autoimmun. Rev.* **2019**, *18*, 691–705. [[CrossRef](#)] [[PubMed](#)]
31. Masson, J.-D.; Crépeaux, G.; Authier, F.-J.; Exley, C.; Gherardi, R.K. Critical analysis of reference studies on the toxicokinetics of aluminum-based adjuvants. *J. Inorg. Biochem.* **2018**, *181*, 87–95. [[CrossRef](#)] [[PubMed](#)]
32. Mold, M.; Umar, D.; King, A.; Exley, C. Aluminium in brain tissue in autism. *J. Trace Elem. Med. Biol.* **2018**, *46*, 76–82. [[CrossRef](#)] [[PubMed](#)]
33. Morris, G.; Puri, B.K.; Frye, R.E. The putative role of environmental aluminium in the development of chronic neuropathology in adults and children. How strong is the evidence and what could be the mechanisms involved? *Metab. Brain Dis.* **2017**, *32*, 1335–1355. [[CrossRef](#)] [[PubMed](#)]
34. Petrik, M.S.; Wong, M.C.; Tabata, R.C.; Garry, R.F.; Shaw, C.A. Aluminum Adjuvant Linked to Gulf War Illness Induces Motor Neuron Death in Mice. *NeuroMolecular Med.* **2007**, *9*, 83–100. [[CrossRef](#)]
35. Erigolet, M.; Eaouizerate, J.; Ecouette, M.; Ragunathan-Thangarajah, N.; Eaoun-Sebaiti, M.; Gherardi, R.K.; Ecadusseau, J.; Authier, F.-J. Clinical Features in Patients with Long-Lasting Macrophagic Myofasciitis. *Front. Neurol.* **2014**, *5*, 230. [[CrossRef](#)]
36. Lyons-Weiler, J. Pathogenic priming likely contributes to serious and critical illness and mortality in COVID-19 via autoimmunity. *J. Transl. Autoimmun.* **2020**, *3*, 1–5. [[CrossRef](#)]

**Publisher’s Note:** MDPI stays neutral with regard to jurisdictional claims in published maps and institutional affiliations.



© 2020 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (<http://creativecommons.org/licenses/by/4.0/>).

Written Testimony of Edward F. Fogarty, MD in regards to HB1307, HB1320 and HB1306 prepared for the North Dakota House Human Services Committee 01/19/2021.

Dear HHS Committee Members,

I am strongly in favor of the passage of HB1307, HB1320 and HB1306. These three bills revolve around the matters of protection of our citizens from participation in fraudulent medical and healthcare marketplaces in my opinion as a physician.

My experience as a North Dakota physician who has been a leading researcher in hyperbaric medicine and recovery of various forms of acute and chronic brain injury also informs my opinion on the importance of these bills whose passage would serve as a firewall to greater potential harms of our citizenry from product liabilities of vaccines of any sort.

Our federal government in 1986 gave immunity to all vaccine manufacturers for liability of any sort relating to their products. This has led to an entire industry running amok on matters of safety. In 2020, with our nation in a declared state of war on SARS-CoV2, I believe we have all seen how powerful the medical/pharmaceutical lobby really is and its impact on our public health department in ND as well as the very governance of our state through the executive branch.

These three bills will provide some "relief" for the encroachment of the amalgams of government/public health and global pharmaceutical companies into our most sacred decision making over our own health and immune system modifications as well as those of our children's health, well being and development.

HB1307 provisions prohibiting public facilities to demand proof of vaccination is critically important to prevent the further encroachment for what many see as a medical tyranny fed by the current pandemic. Proof of IMMUNITY rather than proof of compliance in a corrupt marketplace is the more medically sound course for any of these considerations. The marketplace of healthcare does not want to lose the opportunity to "over-vaccinate" American populations who may already be immune to diseases such as COVID19 through prior infection or vaccination. Sadly many of my own colleagues in medicine fail to understand that diagnostic laboratory studies can show that a particular vaccine is not only unnecessary but a fraudulent waste of health care resources. I addressed some of these concerns in a Bismarck Tribune Opinion piece on 03/23/2008:

[https://bismarcktribune.com/news/opinion/mailbag/a-proposal-on-vaccinations/article\\_e41b2f91-d75f-511d-92d7-eeef199e8f91.html](https://bismarcktribune.com/news/opinion/mailbag/a-proposal-on-vaccinations/article_e41b2f91-d75f-511d-92d7-eeef199e8f91.html)

HB320 is extremely important for North Dakota's citizens as state and local government mandates on vaccination might technically be unconstitutional under the laws of North Dakota itself in regards to the employment doctrine set forth in our constitution. The ND Constitution under Article VIII, section 1 indicates that all public schools are open to all children of the state. Our citizens who see the corruptions of medicine, government and law at the federal level in these matters, should be afforded the sanctuary of refusal of vaccination under prior ND laws giving philosophical, medical and religious exemptions in this arena. Behavioral economics issues have begun to show our nation and our state that we have significant percentage of people questioning the safety and need for some of these medical products that have no liability for causing harm. I believe we need this law in ADDITION to the free will provisions of exemptions, this law will send a message to government bodies who would rather their needs whether honest or fraudulent be met before the people of North Dakota's rights are protected.

I have seen MANY coercive manipulations of my fellow North Dakotans in these matters of vaccine mandates. There is a nurse in Jamestown who has loss of consciousness with every vaccination for influenza, ostensibly this person is going through this safety racket to keep her job?

I fear that many of you on this committee may have family members or yourself as well placed under duress for standing up for your right to medical decision making over vaccines and in the future, now that we have a class of vaccines that is manipulating genomics at the ribosomal level, when will the state/medical/industrial complex start mandating even greater modifications of our very being in service to the “greater good” or indirectly the billionaire cronies of elected officials? On February 20, 2019, I published this Open Letter to the State of Washington which also reiterates that state officials ought to be careful regarding their own needs to protect their own health freedoms in this realm.

<https://informedchoicewa.org/education/an-open-letter-from-edward-f-fogarty-md/>

It should be noted that I also called into question the use of ND taxpayer dollars for the “aid package through ND Public Health” in the containment of the 2019 Washington measles outbreak. Why did our state tax dollars go to another state’s response to a measly generally non-fatal disease of childhood that engendered infection “parties” in the 1960s which some of you no doubt are old enough to have participated in for contracting mother natures version of an important immunological conditioning agent. Mayo Clinic is working on research to use measles infections therapeutically against untreatable cancers. Merck, which makes MMR under FDA licensure in America has been in a decade long battle for maintaining this licensure as the live attenuated corporate viruses here are not provoking a strong enough response anymore to maintain the licensure under scientific titer checking protocols that many US physicians are now using in their clinical practices. Yes, many of my Integrative Medicine colleagues around the country are doing titer checks on the MMR series and finding that the mumps component is not provoking a safe level of antibodies after 2 doses. This is the crux of a Federal False Claims Act lawsuit in Eastern Pennsylvania filed by whistleblower scientists and several physicians against Merck.

<https://www.courthousenews.com/class-says-merck-lied-about-mumps-vaccine/>

The news piece above is from June of 2012. As some of you who may have read many of my emails to you and the Governor in the last 3 months may know, I am a proponent of education of many issues in the interface of law, medicine and government. One of the more important SCOTUS decisions in this nation’s history is that of Throckmorton (1878) wherein the doctrine of “fraud vitiates all” was introduced. Please stand strong for yourselves, your families and your fellow North Dakotans and pass all three of these bills. HB1306 is needed for your grandchildren and great grandchildren to develop under a more natural milieu. As the leading state expert who is a physician/scientist that has reversed cognitive declines in a few of our state’s elders via a gentle detoxification process of mild hyperbaric air and oxygen therapies, I can show you dozens of scientific studies that show infant mammals have an exquisitely sensitive respiratory drive center that lies in close proximity to the bloodstream for carbon dioxide sampling. When CO2 levels increase in the bloodstream, babies especially have a fine tuned response to increasing the respiratory rate so that CO2 (a metabolic toxin) is off-gassed to the atmosphere quickly through the lungs. As the sampling of science below shows, mammalian infants can have other toxins, including aluminum and mercury from vaccines interfere with the development of the tiny cluster of important neurons developing in these respiratory center drives.

But if you cannot understand the science below (see appendix), that is okay as we have a grand opportunity from the 2020 pandemic experiences to see how many SIDS deaths did not occur in 2020 during the pandemic as 0-12 month old American children were, on the whole basically in a delayed CDC vaccination schedule. This experiment by the hand of God and mother nature has already happened and we should now commit some limited funds to a simple epidemiology study (IN THE RIGHT HANDS) that can show the decline of SIDS rates in our children corresponding to the delay of vaccinations in our family's children. A paired relative risk could be obtained temporally by looking at the 2017, 2018, and 2019 birth cohorts on a month by month basis. The null hypothesis would be that the ND Babies born in April of the 3 years prior had the same risk of SIDS as though born in April 2020, and the other major months of access restrictions to medical facilities in 2020 for moms and their newborns would likely disprove the "null" hypothesis.

In summary, as many of you surely may have guessed from my communications with you over the last 3 months, I believe as a physician who's understanding of economic wellness that carries into my practice of medical education, communication and real world procedural and diagnostic medicine - we would be remiss as a political body to fail our grandchildren by failing to pass all three of these bills. Thank you for your time and attention.

Respectfully submitted,

Edward "Ted" Fogarty, MD  
800 MUNICH DR  
BISMARCK, ND  
01/19/2021  
1245 PM



APPENDIX:

[https://ecf.cofc.uscourts.gov/cgi-bin/show\\_public\\_doc?2013vv0611-73-0](https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2013vv0611-73-0)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3170075/>

<https://pubmed.ncbi.nlm.nih.gov/28918379/>

[https://bismarcktribune.com/news/opinion/mailbag/a-proposal-on-vaccinations/article\\_e41b2f91-d75f-511d-92d7-eeef199e8f91.html](https://bismarcktribune.com/news/opinion/mailbag/a-proposal-on-vaccinations/article_e41b2f91-d75f-511d-92d7-eeef199e8f91.html)

Now that the courts have recognized a link between vaccinations and autism, we need to revisit public policy. Individual vaccines can't get much safer, but vaccine protocols can. The 2008 Centers for Disease Control protocol for pediatric vaccines is not the safest way to accomplish the goal of immunity to multiple infectious diseases in an individual.

A vast majority of children will not be affected by the administration of vaccinations. But if epidemiological purposes can be met with a more directed approach, there is no reason to endanger a genetically vulnerable child with unneeded boosters. Titer checking protocols are inherently safer for individuals, especially in the at-risk families for autism.

A simple lab test to check titers can tell you whether an additional "booster" is needed. The vast majority of kids, 95 percent, are immune for life to measles-mumps and rubella after one dose. Multi-shot vaccine protocols are a boon to vaccine companies, not North Dakota families. Pediatricians using titer checks would shift resources from multinational vaccine corporations to North Dakota hospitals via laboratory services utilization.

The argument against this approach has always been, "It's too troublesome," and "What if we lose the patient to follow-up?" These are legitimate concerns, but is it fair to make the social assumptions that no one in this state sees their pediatrician after the first few months of a baby's life?

As the art moves forward in vaccinomics, the future will show how easily we can do this better. We now have simple finger-stick titer checking technology for HIV antibodies. This could be ported into titer checking systems for vaccine efficacy, and the University of North Dakota School of

Medicine could be the institution that leads the charge on this innovative research. It will take some time to calibrate such systems, but we can do it here better than anywhere because of our high compliance with vaccination in this state and our close-knit medical and governmental communities. Even current policy needs some modification in light of the growing public concerns in vaccine safety due to the Hanna Poling case. She is the child of parents who hold M.D., Ph.D., R.N. and J.D. degrees. They would probably advocate as I, after their experience, that parents need to be made aware of better ways to vaccinate. The first modification of law and policy that should occur is a disclosure on consent forms for vaccine boosters. A child may already be immune for life in certain series after one dose of vaccine (live virus vaccines have incredible long-lived titers and high first response rates). A titer check can obviate the need for an unneeded booster; shouldn't the public be made aware of this? This is particularly important in families with high rates of autoimmune disease.

In my own experience, I lost my vaccine records, and in order to get into medical school, I had a whole series titer (antibody) check to prove that I was immune to the diseases we all need protection from in this incredibly helpful arm of medicine.

To ensure that this is done appropriately for your child is to be a loving parent, and to push your colleagues in medicine and government is to be a certain kind of patriot. To fail to educate parents on this option is engendering the socialistic mentality of a cradle-to-grave caretaker federalist system. Governments and school districts would be better served to require titer levels, not written records of vaccine shots. Titer levels are scientific evidence of immunity. A vaccine record actually isn't, as it can be forged.

All U.S. physicians and state legislators should thoroughly read the Simpsonwood Transcripts ([www.nationalautismassociation.org/library.php](http://www.nationalautismassociation.org/library.php)). This is the most honest assessment of the relationship of vaccines to autism and shows a clear signal of "uncertain" strength.

The CDC conveniently "forgets" to publish the transcript as part of the timeline of understanding the relationship of vaccines to autism. This is clearly a lack of transparency at the federal level of health policy, a timely discussion in light of John Irby's front-page piece in the March 16 Tribune. Federal mandates turn a blind eye to the at-risk child harmed by vaccines. We are abusing the molecular machinery of some of our more fragile children to protect vaccine companies, it's a deal with the devil that all of us in medicine hate having to make; I make it every day as a member of the medical specialty, radiology, that deals the most heavy metals and known teratogens to U.S. citizens.

The integrity and smarts of our state level public health officers is getting usurped by the federal government whose agencies are drunk on the influence of multinational corporations, especially in medicine and pharmaceuticals. As a father of an autistic child, I will fight the federal government's continuing to abuse certain vulnerable children in this nation's war against disease. We don't send everyone to the front line of other wars, why aren't we more discriminating in this one?

North Dakota physicians know how to better vaccinate the children of this state than the CDC. We all need to get behind the pediatrics and public health community of North Dakota to improve this art in scientific ways. It may be a decade before that happens, but we can do it.

*(Dr. Edward "Ted" Fogarty is a Bismarck radiologist. - Editor)*

**<https://informedchoicewa.org/education/an-open-letter-from-edward-f-fogarty-md/>**

Excerpts below:

“This is not only a costly loss of worker productivity, influenza vaccines are a yearly unethical experiment because of the lack of any safety studies on these medical products. Influenza vaccines are distributed within weeks of their development and have repeatedly been found contaminated after market release in the last 20 years. Our national healthcare security through the workforce of physicians, nurses, laboratory and radiology technologists is placed at risk for political espionage even as more vaccines are manufactured in jurisdictions that could use these products as Trojan horses for slow viruses or prions. Epidemiologically, my colleagues in public health, Neurology or Infectious Disease will need years and many exposures to identify a signal if such covert biological warfare is occurring even now.”

“We do not have the ability to easily understand who is at risk of vaccine injury in children, especially our newborns, we pour billions into individualized care of the legislative-age crowd on pharmacogenomic safety studies so that products like Vioxx do not destroy lives of our learned elders. As we have never done anything of the sort in public health and policy for our most developmentally and eugenically vulnerable wildcards of mixed genes in American families, we practice tacit genetic discrimination in the access to public education. Our school budgets are skyrocketing on the increasing numbers of special needs children.

“If removing philosophical exemptions to participation in fraudulent unregulated markets are what your collective actions bring to bear in your state, you may find liabilities that you did not anticipate. I can say this without reservation, the most pervasive molecular crime against humanity in the last 20 years has been the use of aluminum injections on day one of life which have no medical indication. Diagnostic medicine has long ago marked the crime of medical assault on American babies whose mothers' obstetric laboratory panels have shown millions of times over that they are delivering antibodies against the Hep B vaccine itself to their fetuses. There is no medical indication for a vaccine on day one of life outside of active infection of the mother. The rest of my colleagues in medicine would be sued or lose their license for serial billing of the state or insurance companies on completely worthless un-indicated interventions like Hep B on day one, or for that matter, at 2 months of life.

“With growing whistleblower cases coming out of the woodwork in scientific fraud are you really ready to cast this lot towards your constituents’ children and families. The U.S. Department of Justice has a case against Merck in Pennsylvania for the scandalous corporate racketeering of scientists that were told to spike the data for mumps to pass the bar of 95% efficacy, ostensibly so that Merck would not lose the monopoly on MMR in this country. I believe you can all see now that the only check and balance in the system against fraud in vaccine science is a public consumer (parents) becoming aware within our nation discourse regarding these issues. Please hold the line on the philosophical exceptions for the greater good of Washington’s political well-being. Forcing your youngest citizens to participate in a fraud and racketeering scheme is a violation of basic human rights. We first need ethical corporate leadership in the vaccine industry before we can trust our genetically-disabled to the gross negligence of entire generations of humans being treated like cattle. Thank you for your time and attention, may the wisdom of the great decision makers of history help you discern the best for your state regarding philosophical exemptions.”

2/20/2019

EFF3MD

HOUSE HUMAN SERVICES  
ROBIN WEISZ, CHAIRMAN JANUARY 19, 2021

TESTIMONY BY  
ALEXIS WANGLER  
RE: HOUSE BILL NO. 1307

Mr. Chairman and members of the House Human Services, my name is Alexis Wangler. I am the Co-Founder and President of the 501(c)(3) nonprofit Health Freedom North Dakota. This is my written testimony in regard to House Bill No. 1307.

I am strongly in favor of this bill. Individuals have the right to goods, services, and access to facilities regardless of many factors including immunization status. Immunization status is one part of our medical records. No one, without our permission, has the right to access our medical records. It would be a HIPAA violation to require someone to give his or her immunization status in order to have access to goods, services, and facilities.

Like all medicine, immunizations are not one size fits all. There are definitely risks associated with immunizations including death. To deny someone access to goods, services, and facilities based on immunization status is downright discrimination. Discrimination is discrimination and it is wrong.

Because a person or business would be discriminating against an individual based on vaccination status, I agree that there should be a civil penalty to those who violate this bill. If there is no penalty, what will stop the discrimination from taking place? Nothing will.

Thank you for your time and consideration.

The right to choose whether or not to take a vaccine is a basic human right

An unvaccinated person is NOT a filthy vector of disease guilty of spreading diseases they do not have, just because a pharmaceutical company says so. Likewise, it is not a crime to be exposed to the environment, to acquire infections, and gain lifelong immunity to a long list of pathogens.

By pushing for mandatory Covid -19 Vaccination, or imposing social restrictions on those who refuse, the COVID-19 vaccine is paving the way for nonconsensual medical experimentation on the general public.

Since the beginning of the pandemic, world leaders have warned that social distancing, mask wearing, travel restrictions and other measures will become part of our new normal. Be that as it may, the refrain we keep hearing from the likes of Bill Gates, Dr. Anthony Fauci and a long list of other world leaders is that any sense of normalcy will remain elusive until or unless the entire global population gets vaccinated against COVID -19. It cannot, since it has only been evaluated for its ability to lessen COVID-19 symptoms, not reduce the risk of infection, hospitalization or death.

While some COVID-19 vaccines have been granted emergency use authorization, they still haven't even completed Stage 3 clinical trials. Data for some end points won't even be collected until 24 months after injection. As such, they are still entirely experimental.

COVID-19 vaccines adverse side effects are still relatively unknown due to the fanatical warp speed at which they were developed. It's also unknown whether they might affect fertility. A real concern is the vaccine could trigger a response rendering a woman infertile.

Pfizers mRNA vaccine contains polyethylene glycol that may trigger fatal allergic reactions in many who receive the vaccine.

This all according to an article researched and written by Dr. Joseph Mercola

Big Pharma holds no liability for injury or death. –

These are experimental vaccines and therefore must fall under the umbrella of human rights violations if it is forced upon people.

It also violate the Nuremburg Code of informed consent.

One unvaccinated person affects those around them. Many people are unable to get vaccines, because of medical issues. Allowing healthy people to opt out of vaccines would put others at risk. If this bill passes it will likely result in deaths. Note the measles outbreaks that have been happening in recent years. The real tragedy of this idea is that it is more likely to be a person with a health condition who is negatively impacted by this than the likely healthy person refusing the vaccine. No one has a right to endanger someone else's life.

Voting for his law would indicate that you do not value human life. Our constitution says we should have the right to "Life, Liberty, and the Pursuit of Happiness," and this law would threaten the first of those.



January 19, 2021

Representative Karen M. Rohr  
Chair, Human Services Committee  
North Dakota Legislative Assembly  
600 East Boulevard  
Bismarck, ND 58505

Senator Judy Lee  
Vice Chair, Human Services Committee  
North Dakota Legislative Assembly  
600 East Boulevard  
Bismarck, ND 58505

Dear Chair Rohr, Vice Chair Lee, and Members of the Human Services Committee,

I am writing today on behalf of the Biotechnology Innovation Organization (BIO), a national trade association for the biotechnology industry, representing over 900 companies and academic institutions involved in the research and development of innovative healthcare, agriculture, industrial, and environmental biotechnology products. BIO membership includes vaccine developers and manufacturers who have worked closely with the public health community to support policies that help ensure access to innovation and life-saving vaccines for all individuals.

BIO and our member companies would like to express our **opposition to HB 1306, HB 1307, and HB 1320**, as these bills put North Dakotans at risk of preventable diseases.

Legislative efforts related to vaccines should focus on continuing to extend protection from these diseases and their side effects to all North Dakotans. The Legislature serves a critical function in passing laws to protect the people of North Dakota. Decisions to change the immunization laws should be held to high standards of evidence-based scientific deliberation. Prohibiting the State, employers, and schools from implementing any immunization requirements will have a detrimental effect on public health in North Dakota, particularly in the middle of a pandemic. North Dakota has experienced a high toll from the COVID-19 pandemic, particularly when cases spiked to a 16% positivity rate in November and December.<sup>1</sup> As COVID-19 vaccination begins and there is hopefully an end to the pandemic coming soon, we must remain vigilant against other infectious diseases. Removal of vaccine requirements risks outbreaks of measles,

---

<sup>1</sup> <https://www.health.nd.gov/diseases-conditions/coronavirus/north-dakota-coronavirus-cases>



pertussis, and influenza. Such outbreaks put lives at risk and are accompanied by great economic costs to the State<sup>2</sup> and society.<sup>3</sup>

HB 1305 is based upon false claims that vaccines are linked to sudden infant death syndrome (SIDS) and autism spectrum disorder (ASD). Potential links between vaccines and these conditions have been extensively studied, with no association found. In fact, studies have found that immunization may have a *protective* impact against SIDS. A meta-analysis of existing research in 2007 found that immunizations were associated with *halving* the risk of SIDS.<sup>4</sup> Similarly, a 2001 study in the United Kingdom found immunization lowered the odds of SIDS<sup>5</sup> and a 1995 study in New Zealand found unimmunized infants had a higher risk of SIDS<sup>6</sup>. Additionally, more than nine studies have been conducted to investigate any possible connection between vaccines and ASD, all finding no association.<sup>7</sup> Thimerosal, the vaccine preservative alleged to cause autism was removed from all pediatric vaccines between 1999 and 2001, yet autism rates continue to rise.<sup>8</sup> Rather than continuing to look for a connection to vaccines, research should be done investigating the actual causes of these conditions.

HB 1307 and HB 1320 would restrict the ability of employers and schools to implement vaccination requirements. North Dakota's school entry requirements allow for freedom of choice by offering exemptions based upon personal beliefs. However, the choice to delay or reject some vaccines entirely is not just a personal decision. When we choose to not receive vaccines or vaccinate our children, we put ourselves and others in our community at risk for serious disease. Putting others, such as those who are immunocompromised or too young to receive vaccines, at risk for vaccine-preventable disease arguably presents a challenge to their personal freedom to go to the store, to school, or anywhere else they come into contact with their community without the possibility of contracting a dangerous, preventable illness. All North Dakotans deserve the right to freedom from preventable infectious diseases.

Individuals understandably have concerns about the unprecedented pace of development of COVID-19 vaccines. Time has been saved through prioritization of resources toward COVID-19, novel technologies that have been more efficient, public-private collaboration, and clinical trial phases happening in parallel rather than in sequence. These vaccines enrolled the same number of individuals in clinical trials as trials for other vaccines and the FDA and CDC have maintained their high standards. Therefore, individuals should be confident that there have not been shortcuts in testing

---

<sup>2</sup> <https://www.cdc.gov/mmwr/volumes/66/wr/mm6646a3.htm>

<sup>3</sup> <https://www.worldbank.org/en/news/feature/2020/06/08/the-global-economic-outlook-during-the-covid-19-pandemic-a-changed-world#:~:text=Businesses%20might%20find%20it%20hard,by%20almost%208%25%20in%202020>

<sup>4</sup> <https://www.ncbi.nlm.nih.gov/pubmed/17400342>

<sup>5</sup> <https://www.bmj.com/content/322/7290/822.short>

<sup>6</sup> <https://adc.bmj.com/content/73/6/498>

<sup>7</sup> <https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf>

<sup>8</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>



the safety and efficacy of these vaccines and such concerns should not lead to overreaching policies that impact the use of all vaccines.

Vaccinations have led to steep decreases and eradication of many significant infectious diseases such as polio, measles, mumps, pertussis, and haemophilus influenza type B (Hib). Immunizations are our best protection against preventable disease and can help North Dakotans live longer, healthier lives.

BIO and our member companies urge the Committee to oppose HB 1306, HB 1307, and HB 1320. We stand ready to help in any discussion of legislation to strengthen immunizations and to share our knowledge of activities and initiatives from around the country.

Sincerely,

/s/

John Gregory Hoke

Director, State Government Affairs

cc: Rep. Jeff A. Hoverson  
Rep. Dwight Kiefert  
Rep. Lisa Meier  
Rep. Matthew Ruby  
Rep. Mary Schneider  
Rep. Kathy Skroch  
Rep. Bill Tveit  
Rep. Greg Westlind  
Sen. JoNell A. Bakke  
Sen. Dick Dever  
Sen. Kathy Hogan  
Sen. Tim Mathern  
Sen. Jessica Unruh-Bell

Good Morning Chairman Weisz and members of the House Human Services Committee. My name is Molly Howell and I am the Immunization Director of for the North Dakota Department of Health. I do not have testimony for HB1307 but want to let you know I am available virtually to answer questions, if needed. Thank You.

I, Melyssa Howry, of New Town, North Dakota, am in full support of HB1307. With discussions going around the country about requiring people to have the Covid-19 vaccine in order to fly, attend concerts, and even enter businesses, there has never been a more relevant time to have this conversation in our state. The reality about the Covid-19 vaccine is that it is still in experimental stages. Typically, vaccines take years, even a decade or more to become truly safety tested. And even with that, they are often not studied for long term safety. Because pharmaceutical companies are exempt from liability, and the government agencies work closely with these companies, there is no accountability to make sure that the ingredients in vaccines are truly safe and effective. Several years ago, Harvard Pilgrim conducted a study of the Vaccine Adverse Events Reporting System, and found that only 1% of vaccine injuries are reported. This means that they are generally much more dangerous than commonly thought. We cannot just expect people to broadly accept vaccines that could potentially cause serious harm, or even death. The argument of “for the greater good” is often used in this regard. But what is an acceptable casualty, when we don’t even know what that number of injuries truly is? We are already seeing several very serious problems with the Covid-19 vaccines, from both Pfizer and Moderna. Are we really supposed to trust that they have our best interest at heart? We know that the pharmaceutical industry as a whole is corrupt. They are making money off of the fact that Americans are generally unhealthy. They have already been proven as criminals through court cases about various drugs that they knew were harmful and even killing people, but they left on the market anyway. How can these same people be so evil in one aspect and so benevolent when it comes to vaccines? The truth is that they are corrupt in every aspect. Until vaccines are truly tested for safety and efficacy, there will never be complete trust in the vaccine program. To expect people to be vaccinated in order to enter businesses is preposterous, and I believe North Dakotans should have the right to be protected from such a ludicrous idea. I am extremely grateful for the legislators who sponsored this bill, and I am thoroughly proud and overjoyed to have them as our representatives. Please vote “Do Pass” on HB1307! Thank you for your time! I have attached the Harvard study I mentioned previously in regards to VAERS. I have also attached a recent article that highlights some of the Covid-19 vaccination issues that are happening currently in a few parts of the world:

1)Harvard study:

<https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

2) Covid 19 Vaccine:

<https://childrenshealthdefense.org/defender/china-health-experts-suspension-covid-vaccines-no-rway/?fbclid=IwAR3Imp8cPYTf2rZ6yktH33pJah6n0oU7yCSwrPCfrGsGIOGRfcmQqMAlac>

January 19, 2021

Testimony by: Malinda Weninger

Dear Members of the Human Services Committee:

I am writing regarding HB1307

**HB1307** – would enact a law that prohibits places of public accommodation from refusing service, goods, or access to facilities to individuals who refuse vaccination.

- **I support this bill.** I am the mother of a vaccine injured child. My daughter was injured in 2006 by the Gardasil vaccination (HPV vaccine) which came out in 2006. My daughter was one of the first inoculated for this vaccine. As time went on, many reports of injuries started coming out. This allowed me to make the connection to a mysterious sudden autoimmune illness that came upon my daughter after her 2<sup>nd</sup> and 3<sup>rd</sup> required injections. We went to many doctors and finally went to Mayo Clinic to try and figure out why my daughter's body turned into a horrific ill body with many many life altering symptoms.
- Everyone's body is made up differently and we don't know how each individual body will react. Each individual knows their bodies and their limits to chemical exposures and issues they may have from these injections, they should not be FORCED to be immunized and they need their FREEDOM of choice. ALL vaccines carry the risk of injury or death so there has to be informed consent and the right to refuse any vaccine without penalty.
- There is a reason there is a National Vaccine Injury Compensation Program that has paid out over \$ 4.5 billion in damages.
- **Individuals need to be allowed to make their own decisions when it involves THEIR body – the only thing they truly own in this world.**
- **If you received a vaccine – that is your choice – then if vaccines are so great – you are protected.**

To: Legislative Assembly of North Dakota

From: Heather Miller,  
Mandan, ND

Date: January 18, 2021

RE: Testimony in favor of HB 1307

Ladies and gentlemen, my name is Heather Miller and I am a resident of Mandan, North Dakota. I hereby give testimony about House Bill 1307 which would enact a law that prohibits places of public accommodation from refusing services, goods, or access to facilities to individuals who refuse vaccination. I support this bill.

As a mother of a vaccine-injured child, this bill is important to me because it is my heart's desire to never give my child another vaccine again. At 18 months of age, my son's world changed. It was traumatizing to me – shook me to the core. His journey of healing has been very long. I truly believe a vaccine would do my son more harm than good. I almost lost him once, and I won't chance that again!

House Bill 1307 helps people like me who don't vaccinate because we love and we want to save lives. As America works to bring diversity, equity and inclusion to our communities, House Bill 1307 needs to pass to bring equity and inclusion to all North Dakotans, no matter their vaccine preference. Please North Dakota, protect people's right of access to society regardless of vaccination status.

<b>VAERS Table of Reportable Events Following Vaccination*</b>	
<b>Vaccine/Toxoid</b>	<b>Event and interval** from vaccination</b>
Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	<ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Brachial neuritis (28 days)</li> <li>C. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>D. Vasovagal syncope (7 days)</li> <li>E. Any acute complications or sequelae (including death) of above events (interval - not applicable)</li> <li>F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Pertussis in any combination; DTaP, DTP, DTP-Hib, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	<ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Encephalopathy or encephalitis (7 days)</li> <li>C. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>D. Vasovagal syncope (7 days)</li> <li>E. Any acute complications or sequelae (including death) of above events (interval - not applicable)</li> <li>F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Measles, mumps and rubella in any combination; MMR, MMRV, MM	<ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Encephalopathy or encephalitis (15 days)</li> <li>C. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>D. Vasovagal syncope (7 days)</li> <li>E. Any acute complications or sequelae (including death) of above events (interval - not applicable)</li> <li>F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Rubella in any combination; MMR, MMRV	<ul style="list-style-type: none"> <li>A. Chronic arthritis (42 days)</li> <li>B. Any acute complications or sequelae (including death) of above event (interval - not applicable)</li> <li>C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Measles in any combination; MMR, MMRV, MM	<ul style="list-style-type: none"> <li>A. Thrombocytopenic purpura (7-30 days)</li> <li>B. Vaccine-strain measles viral infection in an immunodeficient recipient <ul style="list-style-type: none"> <li>o Vaccine-strain virus identified (interval - not applicable)</li> <li>o If strain determination is not done or if laboratory testing is inconclusive (12 months)</li> </ul> </li> <li>C. Any acute complications or sequelae (including</li> </ul>

**VAERS Table of Reportable Events Following Vaccination\***

Vaccine/Toxoid	Event and interval** from vaccination
	death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Oral Polio (OPV)	A. Paralytic polio <ul style="list-style-type: none"> <li>o in a non-immunodeficient recipient (30 days)</li> <li>o in an immunodeficient recipient (6 months)</li> <li>o in a vaccine-associated community case (interval - not applicable)</li> </ul> B. Vaccine-strain polio viral infection <ul style="list-style-type: none"> <li>o in a non-immunodeficient recipient (30 days)</li> <li>o in an immunodeficient recipient (6 months)</li> <li>o in a vaccine-associated community case (interval - not applicable)</li> </ul> C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Inactivated Polio in any combination-IPV, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of the above event (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis B in any combination- HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complications or sequelae (including death) of the above event (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
<i>Haemophilus influenzae</i> type b in any combination (conjugate)- Hib, Hib-HepB, DTaP-IPV/Hib, Hib-MenCY	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine

<b>VAERS Table of Reportable Events Following Vaccination*</b>	
<b>Vaccine/Toxoid</b>	<b>Event and interval** from vaccination</b>
	(interval - see package insert)
Varicella in any combination- VAR, MMRV	<ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Disseminated varicella vaccine-strain viral disease. <ul style="list-style-type: none"> <li>o Vaccine-strain virus identified (time interval unlimited)</li> <li>o If strain determination is not done or if laboratory testing is inconclusive (42 days)</li> </ul> </li> <li>C. Varicella vaccine-strain viral reactivation (time interval unlimited )</li> <li>D. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>E. Vasovagal syncope (7 days)</li> <li>F. Any acute complication or sequelae (including death) of above events (interval - not applicable)</li> <li>G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Rotavirus (monovalent or pentavalent) RV1, RV5	<ul style="list-style-type: none"> <li>A. Intussusception (21 days)</li> <li>B. Any acute complication or sequelae (including death) of above events (interval - not applicable)</li> <li>C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Pneumococcal conjugate(7-valent or 13-valent) PCV7, PCV13	<ul style="list-style-type: none"> <li>A. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>B. Vasovagal syncope (7 days)</li> <li>C. Any acute complication or sequelae (including death) of above events (interval - not applicable)</li> <li>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Hepatitis A in any combination- HepA, HepA-HepB	<ul style="list-style-type: none"> <li>A. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>B. Vasovagal syncope (7 days)</li> <li>C. Any acute complication or sequelae (including death) of above events (interval - not applicable)</li> <li>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Seasonal influenza--trivalent inactivated influenza, quadrivalent inactivated influenza, live attenuated	<ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>C. Vasovagal syncope (7 days)</li> </ul>

**VAERS Table of Reportable Events Following Vaccination\***

Vaccine/Toxoid	Event and interval** from vaccination
influenza-IIV, IIV3, IIV4, RIV3, ccIIV3, LAIV4	<ul style="list-style-type: none"> <li>D. Guillain-Barré Syndrome (42 days)</li> <li>E. Any acute complication or sequelae (including death) of above events (interval - not applicable)</li> <li>F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Meningococcal - MCV4, MPSV4, Hib-MenCY, MenACWY, MenB	<ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7 days)</li> <li>B. Shoulder Injury Related to Vaccine Administration. (7 days)</li> <li>C. Vasovagal syncope (7 days)</li> <li>D. Any acute complication or sequelae (including death) of above events (interval - not applicable)</li> <li>E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Human Papillomavirus (Quadrivalent, Bivalent, or 9 valent) - 9vHPV, 4vHPV, 2vHPV	<ul style="list-style-type: none"> <li>A. Anaphylaxis or anaphylactic shock (7days)</li> <li>B. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>C. Vasovagal syncope (7 days)</li> <li>D. Any acute complication or sequelae (including death) of above events (interval - not applicable)</li> <li>E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>
Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children	<ul style="list-style-type: none"> <li>A. Shoulder Injury Related to Vaccine Administration (7 days)</li> <li>B. Vasovagal syncope (7 days)</li> <li>C. Any acute complication or sequelae (including death) of above events (interval - not applicable)</li> <li>D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)</li> </ul>

\* Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.

Note that the RET differs from the Vaccine Injury Table (VIT) regarding timeframes of adverse events. Timeframes listed on the RET reflect what is required for reporting, but not what is required for compensation. To view timeframes for compensation, please see the VIT at

<b>VAERS Table of Reportable Events Following Vaccination*</b>	
<b>Vaccine/Toxoid</b>	<b>Event and interval** from vaccination</b>
<p><b><a href="https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf">https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf</a></b></p> <p>**Represents the onset interval between vaccination and the adverse event.            For a detailed explanation of terms, see the Vaccine Injury Table at  <b><a href="https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf">https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf</a></b></p>	

A list of vaccine abbreviations is located at: <https://www.cdc.gov/vaccines/terms/vacc-abbrev.html>

**Dear House Members of the Human Service Committee,**

My name is Tara Dukart and I am a business owner. I urge you to **support HB 1307**, “to prohibit public accommodations from refusing services to an individual because the individual has not been vaccinated; and to provide a penalty.”

I have been following laws pertaining to medical freedoms in other parts of the US. What has happened in states like California and New York is extremely concerning to me. I trust that you, our elected decision-makers, will be willing to secure our medical freedoms here in North Dakota.

Vaccines are not safe for everyone. All vaccines have potential side effects and risks. While some adverse events of vaccines may be mild, like pain and swelling at the injection site, some are severe and can be significantly life-altering. These risks include, but are not limited to:  
(Sources: vaers.hhs.gov and CDC.gov)

Death, SIDS, miscarriage  
anaphylaxis or anaphylactic shock  
Guillain-Barré Syndrome, transverse myelitis, paralysis  
autoimmune diseases, arthritis, gastrointestinal disorders  
myocardial infarction (heart attack)  
long-term seizures  
strokes, coma, lowered consciousness, or permanent brain damage  
pneumonia, respiratory illness, asthma, ear infections  
swelling of the brain and/or spinal cord covering  
temporary low platelet count which can cause unusual bleeding or bruising

Because vaccines are “unavoidably unsafe,” and come with potential risk, I believe vaccines should always, always be optional. Therefore, everyone should have the right to opt out of a vaccine or other health-related decision for any applicable reason including: medical, moral, ethical, religious, or philosophical concerns.

I pray that law makers in North Dakota would never require citizens to show proof of vaccination in order to buy or sell goods. Medical decisions are personal, and I believe they should remain that way. The unvaccinated population poses no true risk to the general public, including in commerce settings.

Sources will be included in additional document files. Thank you very much for your time and consideration.

Tara Dukart  
Seek First Ranch & Seek First Holistic Solutions  
Hazen, ND

# THE DANGER OF ELIMINATING VACCINE EXEMPTIONS & CURTAILING VACCINE CRITICISM

Prior to any medical procedure, the U.S. Department of Health & Human Service (“HHS”) explains that the “voluntary consent of the human subject is absolutely essential.”<sup>1</sup> **Coercion invalidates informed consent.**<sup>2</sup> Infringing this right by eliminating vaccine exemptions and curtailing criticism is unethical and un-American given the following facts:

## PHARMA HAS NO INCENTIVE TO ASSURE VACCINE SAFETY

**1. Immunity from Liability for Vaccine Harms.** By the early 1980s, pharmaceutical companies were facing crippling liability for injuries to children caused by their vaccines.<sup>3</sup> Instead of letting these market forces drive them to develop safer vaccines, Congress passed the National Childhood Vaccine Injury Act (the “**1986 Act**”) which eliminated pharmaceutical company liability for injuries caused by their vaccine products.<sup>4</sup>

**2. Pharmaceutical Company Misconduct.** Since 1986, Merck, GSK, Sanofi and Pfizer have paid billions of dollars for misconduct and injuries related to their drug products.<sup>5</sup> These same companies manufacture almost all childhood vaccines, but because of the 1986 Act, cannot similarly be held accountable for misconduct and injuries related to their vaccine products.

## HHS CONFLICTED FROM ASSURING VACCINE SAFETY

**3. HHS Must Defend Against Any Claim of Vaccine Injury.** After eliminating liability for pharmaceutical companies, the 1986 Act established the Vaccine Injury Compensation Program (“**Vaccine Court**”), part of the U.S. Court of Federal Claims, to compensate

people injured by vaccines.<sup>6</sup> Under the 1986 Act, HHS is the defendant in Vaccine Court and is legally obligated to defend against any claim that a vaccine causes injury.<sup>7</sup> There is no right to discovery in Vaccine Court and HHS is represented by the formidable resources of the U.S. Department of Justice (“**DOJ**”).<sup>8</sup> In nearly every case the injured person bears the burden to prove causation.<sup>9</sup> Despite these hurdles, since 1986, HHS has paid over \$4 billion for vaccine injuries.<sup>10</sup>

**4. HHS Incriminates Itself if it Publishes or Admits a Vaccine Can Cause a Harm.** If HHS publishes any study supporting that a vaccine causes a harm, that study will then be used against HHS in Vaccine Court.<sup>11</sup> This greatly limits HHS’s incentive to publish safety studies.

**5. CDC’s Childhood Vaccine Schedule Was Created by Pharma Insiders.** Congress has repeatedly found that the members of the FDA and CDC committees responsible for approving most of the currently licensed and recommended childhood vaccines had serious conflicts of interests with pharmaceutical companies.<sup>12</sup>

## VACCINE SAFETY: CONCERNS & LIMITATIONS

**6. HHS Fails to Perform Basic Vaccine Safety Requirements.** After eliminating the market forces that assured vaccine safety, Congress made HHS directly responsible for vaccine safety pursuant to a section of the 1986 Act entitled the “Mandate for safer childhood vaccines.”<sup>13</sup> As HHS recently

<sup>1</sup> <https://ori.hhs.gov/chapter-3-The-Protection-of-Human-Subjects-nuremberg-code-directives-human-experimentation>

<sup>2</sup> <https://www.utcomchatt.org/docs/biomedethics.pdf>

<sup>3</sup> <https://www.nap.edu/read/2138/chapter/2#2> (“The litigation costs associated with claims of damage from vaccines had forced several companies [by 1986] to end their vaccine ... programs as well as to stop producing already licensed vaccines.”)

<sup>4</sup> 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); *Brusewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”)

<sup>5</sup> <https://www.citizen.org/sites/default/files/2408.pdf>

<sup>6</sup> 42 U.S.C. § 300aa-12 (“In all proceedings brought by the filing of a petition [in Vaccine Court] the Secretary [of HHS] shall be named as the respondent.”); <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf> (HHS amended the Vaccine Court rules to make it extremely difficult to obtain compensation and “DOJ attorneys make full use of the apparently limitless resources available to them,” “pursued

aggressive defenses in compensation cases,” “establish[ed] a cadre of attorneys specializing in vaccine injury” and “an expert witness program to challenge claims.”)

<sup>7</sup> *Ibid.*

<sup>8</sup> *Ibid.*

<sup>9</sup> The 1986 Act created a Vaccine Injury Table (the “**Table**”) which was intended to permit the Vaccine Court to quickly compensate certain common vaccine injuries. 42 U.S.C. § 300aa-12. For Table injuries, the burden shifts to HHS to prove the vaccine is not the cause. 42 U.S.C. § 300aa-13. After passage of the 1986 Act, almost 90% of claims were Table claims and quickly settled. *Stevens v. Secretary of HHS, No. 99-594V (Office of Special Masters 2001)*. However, in the 1990s, HHS amended the Table such that now 98% of new claims are off-Table. <http://www.gao.gov/assets/670/667136.pdf>. As a result, injured children “must prove that the vaccine was the cause” in almost all cases. <https://www.ncbi.nlm.nih.gov/nlmcatalog/101633437>

<sup>10</sup> <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-february-2019.pdf>

<sup>11</sup> See *fn.* 6 and 9.

<sup>12</sup> <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

<sup>13</sup> 42 U.S.C. § 300aa-27

conceded in federal court, it has not performed even the basic requirements of this section, such as submitting reports to Congress on how HHS has improved vaccine safety.<sup>14</sup>

**7. Pediatric Vaccine Clinical Trials (i) Lack Placebos and (ii) Are Too Short.** The pivotal clinical trials relied upon to license childhood vaccines do not include a placebo-control group and safety review periods in these clinical trials are typically only days or months.<sup>15</sup> The safety profile for a pediatric vaccine is therefore not known before it is licensed and routinely used in children.<sup>16</sup>

**8. Post-Licensure Safety.** After licensure and use by the public, federal law requires that the package insert for each vaccine include “*only* those adverse events for which there is some basis to believe there is a *causal* relationship between the drug and the occurrence of the adverse event.”<sup>17</sup> Inserts for childhood vaccines include over one hundred serious immune, neurological and other chronic conditions that their manufacturers had a basis to believe are caused by their vaccines.<sup>18</sup>

**9. Prevalence of Vaccine Harm.** The CDC’s Vaccine Adverse Events Reporting System (“VAERS”), to which doctors and patients may *voluntarily* report adverse vaccine events, received 58,381 reports in 2018, including 412 deaths, 1,237 permanent disabilities, and 4,217 hospitalizations.<sup>19</sup> An HHS-funded three-year review by Harvard Medical School of 715,000 patients stated that “fewer than 1% of vaccine adverse events are reported” to VAERS.<sup>20</sup> This could mean there are a hundredfold more adverse vaccine events than are reported to VAERS. The CDC has nonetheless refused to mandate or automate VAERS reporting.<sup>21</sup>

**10. Children Susceptible to Vaccine Injury.** While the Institute of Medicine (“IOM”) has explained that

“most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility,” HHS and CDC have failed to conduct studies to identify children susceptible to vaccine harms while at the same time recommending vaccines for all children.<sup>22</sup>

**11. Carcinogenicity, Mutagenicity & Infertility.** Most vaccines have never been evaluated for their potential to cause cancer, mutate genes or cause infertility.<sup>23</sup>

**12. Autism.** Autism is the most controversial of the claimed vaccine injuries and the one HHS and CDC declare they have thoroughly studied. Most parents with autistic children claim vaccines (including DTaP, Hep B, Hib, PCV13, and IPV, each injected 3 times by 6 months) are a cause of their child’s autism.<sup>24</sup> The CDC tells these parents that “Vaccines Do Not Cause Autism.”<sup>25</sup> However, there is no science to support this claim for almost all vaccines. For example, reports from the IOM in 1991 and 2012, and HHS in 2014, tried but failed to identify any study to support that DTaP does not cause autism.<sup>26</sup> The same is true for Hep B, Hib, PCV 13, and IPV.<sup>27</sup> The only vaccine actually studied with regard to autism is MMR, and a Senior CDC Scientist claims the CDC did find an increased rate of autism after MMR in the only MMR/autism study ever conducted by the CDC with American children.<sup>28</sup> Moreover, HHS’s primary autism expert in Vaccine Court recently provided an affidavit explaining that vaccines can cause autism in some children.<sup>29</sup> Given the lack of studies regarding vaccines and autism, it should come as no surprise that there is a dearth of scientific studies that support the CDC’s other claims regarding vaccine safety.

**13. HHS Refuses to Conduct Vaccinated Vs. Unvaccinated Studies of Vaccine Schedule.** A true epidemic in the U.S. is the fact that 1 in 2 children have an autoimmune, developmental, neurological, or chronic disorder.<sup>30</sup> These conditions have sharply

<sup>14</sup> <http://icandecide.org/government/ICAN-HHS-Stipulated-Order-July-2018.pdf>

<sup>15</sup> <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section I)

<sup>16</sup> *Ibid.*

<sup>17</sup> <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Appendix B)

<sup>18</sup> *Ibid.*

<sup>19</sup> <https://wonder.cdc.gov/vaers.html>

<sup>20</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>21</sup> <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section III)

<sup>22</sup> <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section V)

<sup>23</sup> <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>

<sup>24</sup> <https://www.ncbi.nlm.nih.gov/pubmed/16685182>; <https://www.ncbi.nlm.nih.gov/pubmed/25398603>; <https://www.ncbi.nlm.nih.gov/pubmed/16547798>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/>

<sup>25</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>26</sup> <https://www.nap.edu/read/1815/chapter/2#7>; <https://www.nap.edu/read/13164/chapter/12?term=autism#545>; [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>27</sup> <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section VI)

<sup>28</sup> <http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf>; <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>; <https://www.c-span.org/video/?c4546421/rep-bill-posey-calling-investigation-cdcs-mmr-research-fraud>

<sup>29</sup> <http://icandecide.org/documents/zimmerman.pdf>

<sup>30</sup> <https://www.ncbi.nlm.nih.gov/pubmed/21570014>

risen in lock-step with the increases in the CDC's recommended vaccine schedule.<sup>31</sup> That schedule has risen from 7 injections of just 2 vaccines in 1986 to the current total of 50 injections of 12 different vaccines.<sup>32</sup> The need to compare health outcomes of vaccinated and unvaccinated children is urgent. In 2017, a seminal study found that babies receiving the DTP vaccine died at 10 times the rate of unvaccinated babies.<sup>33</sup> In another study, children received influenza vaccine or a saline placebo; while both groups had a similar rate of influenza, the vaccinated group had a 440% increased rate of non-influenza infections.<sup>34</sup> A recent pilot study from the School of Public Health at Jackson State University found that 33% of vaccinated preterm babies had a neurodevelopmental disorder compared to 0% of the unvaccinated preterm babies; and vaccinated children in this study had an increased risk of 290% for eczema, 390% for allergies, 420% for ADHD, 420% for autism, and 520% for learning disabilities.<sup>35</sup> Nonetheless, HHS and CDC refuse to publish any studies comparing the health outcomes between vaccinated and unvaccinated children.<sup>36</sup>

## MMR VACCINE

**14. Measles is a Mild Childhood Illness.** The mortality rate from measles declined by over 98% between 1900 and 1962 as living conditions improved in this country.<sup>37</sup> In 1962, a year before the first measles vaccine, the CDC reported a total of 408 deaths.<sup>38</sup> That amounts to 1 in 500,000 Americans at a time when measles infected nearly every American.<sup>39</sup>

**15. Eliminating Measles Has Increased Cancer Rates.** Eliminating measles has increased cancer rates. For example, the International Agency for Research on Cancer found that individuals who never had measles had a 66% increased rate of Non-Hodgkin Lymphoma

and a 233% increased rate of Hodgkin Lymphoma.<sup>40</sup> Combined, these cancers killed 20,960 Americans in 2018.<sup>41</sup> As another example, individuals who never had measles, mumps or rubella had a 50% increased rate of ovarian cancer.<sup>42</sup> In 2018, ovarian cancer killed 14,070 Americans.<sup>43</sup> Eliminating measles in this country has caused more deaths from cancer.

**16. Eliminating Measles Has Increased Heart Disease.** A 22-year prospective study of over 100,000 individuals in Japan revealed that “measles and mumps, especially in case of both infections, were associated with lower risks of mortality from atherosclerotic CVD [heart disease].”<sup>44</sup> Heart disease killed 610,000 Americans in 2018.<sup>45</sup> Eliminating our ecological relationship with measles, mumps and rubella has had serious unintended consequences.

**17. Side effects from MMR vaccine.** The MMR vaccine has serious risks. For example, the MMR vaccine causes seizures in about 1 in 640 children, five times the rate from measles, as well as “thrombocytopenic purpura,” “chronic arthritis,” and “brain damage.”<sup>46</sup> However, because the MMR was not licensed based on a placebo-controlled clinical trial and post-licensure studies are limited, there are many suspected harms the CDC has yet to confirm or rule out, such as those listed on Merck's package insert for the MMR.<sup>47</sup>

**18. Waning Immunity.** While the vaccination rate for measles in the United States has been stable over the last 20 years, what has changed is that Americans who have had measles (which confers lifetime immunity) are being replaced by those vaccinated with MMR (which does not typically confer lifetime immunity).<sup>48</sup> MMR produces no immunity in 2% to 10% of vaccinees; and 22 years after two doses of MMR approximately 33% of vaccinees are again

<sup>31</sup> <https://www.ncbi.nlm.nih.gov/pubmed/20159870>

<sup>32</sup> <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg>; <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

<sup>33</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>

<sup>34</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>35</sup> <http://www.oatext.com/pdf/JTS-3-186.pdf>; <http://www.oatext.com/pdf/JTS-3-187.pdf>

<sup>36</sup> <https://icandecide.org/hhs/ICAN-Reply.pdf> (see Section VII)

<sup>37</sup> [https://www.cdc.gov/nchs/data/vsus/vsrates1940\\_60.pdf](https://www.cdc.gov/nchs/data/vsus/vsrates1940_60.pdf);

[https://www.cdc.gov/nchs/data/vsus/VVSUS\\_1962\\_2A.pdf](https://www.cdc.gov/nchs/data/vsus/VVSUS_1962_2A.pdf)

<sup>38</sup> [https://www.cdc.gov/nchs/data/vsus/VVSUS\\_1962\\_2A.pdf](https://www.cdc.gov/nchs/data/vsus/VVSUS_1962_2A.pdf)

<sup>39</sup> *Ibid.*; <https://www.census.gov/library/publications/1962/compendia/statab/83ed.html>

<sup>40</sup> <https://www.ncbi.nlm.nih.gov/pubmed/16406019>

<sup>41</sup> <https://seer.cancer.gov/statfacts/html/nhl.html>;

<https://seer.cancer.gov/statfacts/html/hodg.html>

<sup>42</sup> <https://www.ncbi.nlm.nih.gov/pubmed/16490323>

<sup>43</sup> <https://seer.cancer.gov/statfacts/html/ovary.html>

<sup>44</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26122188>

<sup>45</sup> <https://www.cdc.gov/heartdisease/facts.htm>

<sup>46</sup> <https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf>;

<https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf>;

<https://physiciansforinformedconsent.org/measles/vrs/> (since the measles death from 1959 to 1962

was appx. 400 per 4 million cases <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/e/reported-cases.pdf> and death to seizure ratio is appx. 3.25

<https://www.cdc.gov/vaccines/pubs/pinkbook/meas.html> this amounts to 1 seizure in

3,095 measles cases).

<sup>47</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/UCM123789.pdf>

<sup>48</sup> <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/G/coverage.pdf>

potentially susceptible to measles.<sup>49</sup> The proportion after 30 years is even higher.<sup>50</sup> Yet the only focus is on children whose parents have reason to believe the MMR may cause them harm, while ignoring the efficacy issues with this vaccine.

#### OTHER VACCINES

**19. DTaP Vaccine.** According to the FDA, those vaccinated with DTaP will have fewer symptoms of pertussis, but will become infected and transmit pertussis, and “will be more susceptible to pertussis throughout their lifetimes.”<sup>51</sup> This means the children vaccinated for pertussis are more likely to catch and spread pertussis as asymptomatic carriers, while the unvaccinated are less likely to catch pertussis (and when they do will have symptoms and know to stay home).<sup>52</sup> Since pertussis is very common and more of a concern than measles, as long as children vaccinated for pertussis are permitted to attend school, children not vaccinated for measles should also be permitted to attend school. In any event, the immunity provided by DTaP for pertussis, tetanus, and diphtheria wanes within a few years.<sup>53</sup>

**20. Inactivated Polio Vaccine.** For the last 20 years, the only polio vaccine used in the U.S. is inactivated polio vaccine (“IPV”), which is injected intramuscularly, after it was determined that the oral polio vaccine can cause paralysis.<sup>54</sup> Polio is spread through fecal to oral contamination, and IPV does not prevent colonization and transmission of polio; it only potentially prevents polio from traveling to the spinal column.<sup>55</sup> Hence, those vaccinated or not vaccinated with IPV can equally become infected and transmit polio; but, it is the vaccinated who are considered less likely to have symptoms and thus more likely to spread polio.

**21. Chicken Pox Vaccine.** Children vaccinated for chicken pox can spread chicken pox virus for six weeks after vaccination.<sup>56</sup> Moreover, the immunity from this vaccine wanes and, absent natural boosting from exposure to chicken pox virus, can lead to shingles.<sup>57</sup> The increased risk of shingles from use of this vaccine is why countries, such as the United Kingdom, have not added it to their routine vaccine schedule.<sup>58</sup>

**22. Note.** There are additional efficacy and safety issues with the above vaccines and other vaccines not addressed due to space constraints. For example, aluminum adjuvant particles in vaccines, which animal studies reveal deposit in brain and bones, or the millions of snippets of human DNA cultured from the cell lines of aborted fetuses in certain vaccines.<sup>59</sup>

#### ADDITIONAL INFORMATION

The foregoing highlights a few of the vaccine safety and efficacy issues necessitating the need for informed consent for vaccination and the ability to openly criticize our vaccine policies.

At the least, the following should occur before censoring concerns regarding vaccine safety:

- a. Vaccine safety duties should be removed entirely from HHS and placed into an independent board;
- b. Pharmaceutical companies should be liable for injuries caused by their vaccine products; and
- c. The childhood vaccine schedule and each vaccine should be safety tested in a properly sized long-term placebo-controlled clinical trial.

For additional information or to arrange a presentation, please contact Cat Layton at [cat@icandecide.org](mailto:cat@icandecide.org)

<sup>49</sup> <https://www.ncbi.nlm.nih.gov/pubmed/17339511>

<sup>50</sup> Ibid.

<sup>51</sup> <https://www.ncbi.nlm.nih.gov/pubmed/24277828>; <https://www.ncbi.nlm.nih.gov/pubmed/30793754>; <https://www.ncbi.nlm.nih.gov/pubmed/29180031> (“neither DTP, nor DTaP or Tdap prevent asymptomatic infection and silent transmission of the pathogen”)

<sup>52</sup> Ibid.

<sup>53</sup> Ibid.

<sup>54</sup> <http://polioeradication.org/polio-today/polio-prevention/the-vaccines/ipv/>

<sup>55</sup> Ibid.

<sup>56</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf>

<sup>57</sup> <https://www.ncbi.nlm.nih.gov/pubmed/22659447>;

<https://www.ncbi.nlm.nih.gov/pubmed/24275643>

<sup>58</sup> <https://www.nhs.uk/common-health-questions/childrens-health/why-are-children-in-the-uk-not-vaccinated-against-chickenpox/>

<sup>59</sup> [http://vaccinepapers.org/wp-content/uploads/vaccine\\_papers\\_brochure\\_8.5x11.pdf](http://vaccinepapers.org/wp-content/uploads/vaccine_papers_brochure_8.5x11.pdf); <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>; <https://www.ncbi.nlm.nih.gov/pubmed/5949788>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC274969/>; <https://www.ncbi.nlm.nih.gov/pubmed/29108182>

HB - 1307

I appreciate being able to address the members of the House Human Services Committee regarding this matter.

I am writing in support of HB 1307.

Our God-given freedoms include the right to decide what is taken into the body, via medication or injection. Attempting to tie access to goods, rights to services, education, or travel to being vaccinated, denies our fundamental rights and takes away our responsibility over our own health. It is immoral to demand that people make medical decisions, that could have life altering consequences, based on their need of access to these services. There is no one-size-fits-all medicine, so Public accommodations should not have the right to refuse service based on differing medical decisions.

Erin J McSparron

Lisa Pulkrabek  
4795 Co Rd 82  
Mandan, ND 58554  
701-595-4264  
wadenlisa@aol.com  
Jan 19, 2021

Hello Members of the House Human Services Committee,

I am writing to you today in regards to HB1307 regarding prohibiting public accommodations from refusing service to individuals who are not "up to date" with vaccinations. I am IN FAVOR of this bill.

I do not believe that there are any known diseases that are so deadly that we cannot have any individuals that are unvaccinated against such diseases, walking about in society. To discriminate against a person due to their vaccination status is absolutely insane. How do you expect to enforce this? We have a right to medical privacy according to HIPPA laws. To force people to disclose personal medical information in order to go to school, to shop, to travel, to work or to attend entertainment and worship facilities, goes against HIPPA. We will not stand for it. I am against having to walk around with "papers" or "vaccine documentation". I am against having my medical information loaded on to my drivers license or having a digital record. This is getting very close to the mark of the beast.

Furthermore, forcing every person in the state to have the exact medicine/ treatment / vaccine / injection / preventative measure will never work. We are all different, with different allergies, diseases, conditions and medical issues. One size does not fit all with medical treatments. Mandating a vaccine for every person and punishing those who refuse to or cannot take the vaccine by allowing businesses to refuse service is not in the best interest of anyone. It will not only physically harm North Dakotans by causing vaccine injuries or death, but it will also further cause division between us. Refusing service to North Dakotans will cause patriotic, God fearing, North Dakota loving people to lose faith in the officials we elected to serve us in public office.

Again, I am in FAVOR of HB1307 PROHIBITING public accommodations from refusing service to those who are unvaccinated.

THANK YOU FOR YOUR TIME.

Lisa Pulkrabek

The Nuremberg Code was a result of the Nuremberg Military Tribunal held in August of 1947 established to try several high ranking Nazis as war criminals. Among the defendants were physicians who had either ordered or performed the torture or murder of prisoners in numerous Nazi concentration and death camps.

Since ancient times, beneficence has been a key principle of the medical profession, enshrined in the Hippocratic Oath and subsequent codes of medical ethics. Beneficence entails that physicians must always put the needs and welfare of patients first. However, until the verdict was handed down in the Nuremberg "Doctors Trial" the specific rights of human subjects of modern biomedical research were not codified. ....Encyclopedia.com

The number of people suffering serious adverse events following vaccination for the Wuhan coronavirus is 50 times higher than the number for seasonal flu shots according to independent journalist Alex Berenson. The CDC's VAERS reporting system was set to track vaccine-related injury, Most patients can expect to experience some kind of adverse reaction, but for the vast majority of patients, symptoms will be relatively mild and clear up within a couple of days. But amid a rush of reports about patient deaths, Berenson points out that the number of patients seeing serious complications per the number of doses distributed is roughly 50x higher the rate of adverse reactions caused by the flu vaccine.- This was thru December 22, 2020.

Plus the Covid Vaccine does have been mostly given to healthy people in settings where problems can be quickly treated. These problems are occurring BEFORE the rollout to older, less healthy people – and before the 2<sup>nd</sup> dose, which is known to be far more dangerous... per Alex Berenson

The data is here at <https://t.co/qOp5zS7cYB> CDC Website

"The threat of forcing or compelling people to become unwilling guinea pigs in an ongoing medical experiment is immoral on its face. But even the prospect of enforcing such mandates would entail the erection of a surveillance and tracking system that further threatens basic rights and liberties. After all, in order to determine who has been vaccinated... there will need to be a system for identifying and tracking each vaccine recipient. James Corbett"

List adverse vaccine events.

**This written testimony is in opposition to HB 1307: To prohibit public accommodations from refusing services to an individual because the individual has not been vaccinated; and to provide a penalty.**

I believe this legislation would become a gateway to the erosion of other personal freedoms granted to us by the Constitution. Imposing a financial penalty is meant to intimidate and incur hardship on anyone opposed. I stand firmly in opposition to this legislation.

Sean Thorenson

My testimony is in support of HB1307. The bottom line is Vaccines are not a one size fits all approach to health and wellness. Everyone is different. Genetics are different. DNA is different. Businesses should never be allowed to discriminate a person that is not or chooses not to be Vaccinated for any reason.

I am sharing a story about a man that received a Tdap Vaccine in order to be able to work on August 19, 2019, and his life has not been the same since. I will copy and paste snippets from his website:

[www.bravelikenick.com](http://www.bravelikenick.com)

## **TDAP**

I was administered a TDAP at my position at Darnall Army Hospital on August 19, 2019. Throughout the following week, my left leg began to feel like it was on fire, I had severe tinnitus in my right ear and I would be woken multiple times a night by my right foot cramping. Finally, I was admitted into the hospital on Friday August 23, 2019. That Sunday, I began to lose feeling and strength in my right arm. Shortly after, both legs went into severe spasms and cramps. The pain was excruciating. After this subsided, I was no longer able to lift either leg while laying. My right arm lost significant strength and sensation. I lost nearly all sensation to my penis and bladder spasms began. I also lost hearing in my right ear and had balance issues. Symptoms continued to progress. The spasms and cramping extended to most of my body. We continued to search for answers.

## **CLOSE CALL**

As symptoms continued to progress, there came a time where I didn't believe I would make it. A few days prior to this event, I said goodbye to my children and wife. I truly didn't believe I was going to survive. I was in respiratory distress, at times only taking one breath per minute. My body would spasm, then lock, and I went unconscious many times.

January 19<sup>th</sup>, 2021

Dear ND House Human Services Committee Members,

I am writing this morning to urge you to support and pass:

[HB 1307](#) that would enact a law that prohibits places of public accommodation from refusing services, goods, or access to facilities to individuals who refuse vaccination.

[HB 1320](#) that would prohibit state and local government from mandating vaccination and would prohibit making the receipt of a vaccine a condition for entry, education, employment, or services.

[HB 1306](#) that would establish an interim committee to study the interrelationship between sudden infant death syndrome, vaccines, and autism spectrum disorder in children.

I am a retired pharmacist having worked 32 years in hospital, community, and compounding pharmacies. Having done so, I have been eyewitness to vaccine injury over the years and have grave concerns over the SARS-COV2 vaccine. New pharmaceutical drugs commonly take 7-8 years to come on the market because of extensive animal and human trials done first to ensure safety of the drug and thereby ensure the pharmaceutical manufacturer will not face exorbitant damage liability. However, as you likely know, vaccine manufacturers are exempt from damage liability. Though it is amazing that this vaccine has been formulated in a short amount of time, it has not passed the test of time and trials to determine safety. I also oppose this vaccine because it is a mRNA vaccine with the possibility of being incorporated into one's genetic code. Also, the use of cell lines from aborted babies is highly problematic for religious reasons.

Last September, I was sick with what appeared to be COVID and recovered without incident. I have had numerous bouts of influenza in my lifetime which were worse. My observation has been that people with symptoms have not been treated adequately in the early stages of the disease, especially when complaining of shortness of breath. I know of MD's who successfully treat people with Vitamin C, D, and Zn, Quercetin, HCQ or Ivermectin, and Budesonide for inhalation. These treatments were vilified by the powers that be who likely stood to benefit from the emergency authorization of the vaccines. Herd immunity will happen without vaccines. The number of deaths due to COVID is dropping weekly. I would encourage you to keep that statistic before you, and not the number of cases which is determined by a test with dubious false positives. Also, the study of the 30 million people in Wuhan showed that there is not asymptomatic spread of the virus.

Finally, I believe that implementation of a laws to prevent people without the vaccine from enjoying their rights as citizens of the United States of America is unconstitutional. For most, this disease is not worse than the common flu and draconian measures to attempt to vaccinate everyone with an untested vaccine is reckless and suspect. Thank you so much for your time and consideration of my concerns.

Regards,

Maureen Bratten  
827 19<sup>th</sup> St E  
Dickinson, ND

Representative Karen M. Rohr, Chair  
Senator Judy Lee, Vice Chair  
House Human Services Committee

Emily Meissner  
701-430-7179

Tuesday, January 19th, 2021

Support for HB1307, Relating to Service without Vaccinations

The SARS-COV-2 pandemic affected and continues to affect every North Dakota citizen, either directly or indirectly. While some have seriously suffered from the illness, others have suffered from the unnecessary pressure placed on citizens to compromise personal health every day. North Dakota citizens have endured through the faulty testing measures, the extended quarantines, the threats of losing jobs or getting kicked out of public accommodations if not wearing pieces of fabric on the face, and the stress associated with losing a loved one or trying to make sure someone they care about stays healthy.

While some precautionary measures have been healthy, others have not been safe or appropriate. I personally know individuals who have been threatened by store management when not wearing masks for medical reasons. I personally know individuals who have been refused service at highly recognized stores, even though they have a medical exemption and cannot wear a mask. Medically exempt individuals have personal rights to keep personal health matters private but still get questioned constantly or kicked out of establishments that they have every right to be buying consumer goods from. Individuals in the public have turned into private investigators, with false assumed permission to dig into other citizens personal health matters. Although it is illegal to refuse service to anyone not wearing a mask for medical reasons, it commonly happens in the state.

Being forced to wear a mask to shop seems to be trivial when compared with being forced to be vaccinated in order to shop or attend a public accommodation. This is unethical and violates our 14th Amendment Constitutional rights to pursue life, liberty and property. It also violates our Constitutional 1st Amendment rights by prohibiting free exercise of religion, for those who have religious convictions about vaccinations.

Although forced vaccinations are clear violations of Constitutional rights, I believe passing a bill that explicitly states it is illegal to refuse service to individuals based on vaccination records, would be in the best interest of the public. Bringing attention to this issue will help prevent further conflict with citizens and public accomodation management, school systems, and workplaces. It would be in the best interest of the state to not set a precedent that the feelings of the collective outweigh the rights of the individual. Please support and pass HB1307. Thank you for the opportunity to testify.



January 19, 2021

Dear Legislators,

I am writing you in regards to HB 1307 and am in support of this bill. As a practicing and licensed chiropractic physician in North Dakota, I feel it is imperative that we maintain the individual freedom to pursue our own health and not be forced into any medical procedures that carry any risk. Furthermore, we are a culture that protects personal health information and there shouldn't be a single North Dakotan that is refused service due to refusal of carrying proof of performed medical services. As we can agree that I should not be judged by the color of my skin, nobody should be judged based upon what has been pushed through it.

Kind Regards,

Chad Zimmerman DC

## **In Re: House Bill 1307**

House Human Services Committee

Erica Thunder, Commissioner, North Dakota Department of Labor and Human Rights

Neutral Testimony

01/19/2021

Chairman Weisz and members of the Human Services Committee,

My name is Erica Thunder, and I serve as the Commissioner for the North Dakota Department of Labor and Human Rights. I am here today to listen into the discussion and answer questions neutrally, as HB 1307 discusses the term “public accommodations”.

The Department of Labor and Human Rights is responsible for enforcing the North Dakota Human Rights Act and the North Dakota Housing Discrimination Act. These laws prevent discrimination in employment, housing, public accommodation, public service, and credit transactions or lending. The Department accepts, hears, and investigates claims that include public accommodation.

The Department is looking for clarity as the full definition of public accommodation is not included in this Bill. The full definition of public accommodation under NDCC 14-02.4-02.14 is: "Public accommodation" means every place, establishment, or facility of whatever kind, nature, or class that caters or offers services, facilities, or goods to the general public for a fee, charge, or gratuity. "Public accommodation" does not include a bona fide private club or other place, establishment, or facility which is by its nature distinctly private; provided, however, the distinctly private place, establishment, or

facility is a "public accommodation" during the period it caters or offers services, facilities, or goods to the general public for a fee, charge, or gratuity.

Again, this section of Century Code speaks specifically to the work of the North Dakota Department of Labor and Human Rights.

I am here to testify neutrally, if so needed, and will be happy to answer any questions should the Committee ask. If I am unable to answer a question specifically for today's purposes, I will promptly work to provide an answer to the Committee.

Thank you,

*Erica Thunder*

Erica Thunder  
Commissioner  
North Dakota Department of Labor and Human Rights

I am in support of this bill due to the incomplete science of the long term health effects of vaccinations. Where there is inherent risk, there should also be choice.

These bills regarding personal health freedoms have been brought to our attention. We would hope that you would support these bills to prevent discrimination against those who choose, for many different reasons not to vaccinate.

We have a voting-age son who has a documented reaction to a childhood vaccine and currently has a medical exemption for several vaccines.

Knowing the things that can be triggered in a persons body by an immunization has caused us to be quite leery of many vaccines. We are certainly not “anti-vaxxers”, as our son and other family members have received certain other vaccines since his reaction. This term and the

negative attitude that go along with it are proof of the discrimination, shaming and bullying that already is happening to those choose to not vaccinate.

If doctors would not be so afraid to learn the truth about vaccine-triggered illnesses and be honest about them, people would have far more trust.

Ourselves and many, many people we have talked to are choosing to wait on receiving any covid vaccine until short & long term effects are known. Part of the problem is that we have already seen the denial by doctors of injuries/negative reactions. Obviously resulting in lack of trust.

The thought of mandatory vaccines and the refusing of services/

discrimination to those who refuse is absolutely appalling and I would have never believed it could happen here in the United States of America, certainly not here in North Dakota. This should not be a partisan issue in any way. All you need to do is imagine yourselves or a loved one being forced to receive any sort of medical treatment that you don't want. The idea of taking away personal rights is a dangerous path to go down. We would ask that you support these bills and stand up for the personal health freedom of North Dakota residents!

Sincerely,

Patricia and Tyrone Unruh

Sykeston, ND

I am in support of HB1307.

Prohibiting service based on vaccine status is medical discrimination and segregation plain and simple.

It is also potentially a HIPPA violation...Individuals may be medically unable to receive the vaccination or have denied the service for several other reasons, they are not required to disclose this information to anyone.

Entities determined to provide public accommodation have no right to ask medical questions and people using them should not have to provide this information.

Are we are on our way back to people using different drinking fountains, different restrooms, sitting in different parts of the bus???

Put an end to this nonsense now and send a message for future endeavors as well.

Respectfully,

Dr. Allen Rudolph

HB 1307 'No vax, no entry'

Good afternoon Chariman Weisz and committee members. My name is Rena Rustad and I live in McLean county.

When I read through this bill I was thinking to myself, 'Gosh was all that stuff I saw about immunization passports on facebook for real?' I hope not.

I am in FAVOR of preventing "public accommodation" from requiring proof of immunization from the general public.

The way I understand this bill is that it prevents every place, establishment, or facility that offers services, facilities or goods to the general public for a fee, charge or gratuity FROM requiring a proof of vaccination for a communicable disease to refuse services.

**"Communicable disease"** means an illness caused by an infectious agent or its toxins that occurs through the direct or indirect transmission of the infectious agent or its products from an infected individual or via an animal, vector or the inanimate environment to a susceptible animal or human host.

ND DOH designates 88 infectious diseases as reportable now as of January 7, 2020, including a Novel Severe Acute Respiratory illness.

This bill would prevent businesses and such from requiring a proof of Covid Shot among others before coming in to dine or whatever, perhaps attend a concert, go to symphony, attend a basketball game in a school gym, or enjoy a movie at a theater. It would prevent stadiums and event centers from requiring such documentation before entering.

ND provides for a Statement of Exemption to Immunization Law on their Certificate of Immunization so how would 'public accommodation' deal with those that have exemptions? And what about those that didn't keep up with timely vaccinations or have had a vaccine injury? It's not possible.

No, these public entities should NOT be able to require a proof of immunization. I am in FAVOR of passing this bill.

Thank you for your time and allowing me to address the committee.

(Resources 2)

Acute Flaccid Myelitis  
 Anaplasmosis  
 Anthrax **◆** **☠**  
 Arboviral infection (other)  
 Babesiosis  
 Botulism **◆** **☠**  
 Brucellosis **◆** **☠**  
 Campylobacteriosis  
*Candida auris* **◆**  
 Carbapenem-resistant organisms  
 • *Enterobacteriaceae* **◆**  
 • *Pseudomonas aeruginosa* **◆**  
 Chickenpox (varicella)  
 Chikungunya virus disease  
 Chlamydial infection  
 Cholera **◆**  
 Cluster of severe or unexplained illnesses and deaths  
 Coccidioidomycosis  
 Creutzfeldt-Jakob disease  
 Cryptosporidiosis  
 Cyclosporiasis  
 Dengue  
 Diphtheria **◆**  
 Eastern equine encephalitis **☠**  
*E. coli* (Shiga toxin-producing) **◆**  
 Ehrlichiosis  
 Foodborne/waterborne outbreaks  
 Giardiasis  
 Glanders **◆** **☠**  
 Gonorrhea  
*Haemophilus influenzae* (invasive) **◆**  
 Hantavirus **◆**  
 Hemolytic uremic syndrome  
 Hepatitis A **◆**  
 Hepatitis B

Hepatitis C\*  
 Hepatitis D  
 Hepatitis E  
 HIV/AIDS infection\*\*  
 Influenza  
 • Pediatric deaths  
 • Seasonal  
 • Suspect novel, PCR influenza A unsubtypable **◆**  
 Jamestown Canyon virus disease  
 Laboratory incidents with possible release of category A agents or novel influenza virus **☠**  
 La Crosse encephalitis  
 Legionellosis  
 Leptospirosis  
 Listeriosis **◆**  
 Lyme disease  
 Malaria **◆**  
 Measles (rubeola) **◆**  
 Melioidosis **◆** **☠**  
 Meningococcal disease (invasive) **◆**  
 Mumps **◆**  
 Nipah virus infections **◆** **☠**  
 Nosocomial outbreaks  
 Novel severe acute respiratory illness **◆** **☠**  
 Pertussis  
 Plague **◆** **☠**  
 Poliomyelitis **◆**  
 Powassan virus disease  
 Pregnancy in person infected with:  
 • Hepatitis B  
 • HIV  
 Q fever **◆** **☠**

Rabies  
 • Animal  
 • Human **◆**  
 Rocky Mountain spotted fever  
 Rubella **◆**  
 Salmonellosis **◆**  
 Scabies outbreaks in institutions  
 Shigellosis **◆**  
 Smallpox **◆** **☠**  
*Staphylococcus aureus*  
 • Vancomycin-resistant and intermediate resistant (VRSA and VISA) – any site **◆**  
*Staphylococcus enterotoxin B* intoxication **◆** **☠**  
 St. Louis encephalitis  
*Streptococcus pneumoniae* infection (invasive) **◆**  
 Syphilis  
 Tetanus  
 Tickborne disease (other)  
 Trichinosis  
 Tuberculosis\*\*\*  
 • Disease **◆**  
 • Infection  
 Tularemia **◆** **☠**  
 Typhoid fever **◆**  
 Unexplained or emerging critical illness/death  
 Vibriosis **◆**  
 Viral hemorrhagic fevers **◆** **☠**  
 Weapons of Mass Destruction suspected event **☠**  
 Western equine encephalitis  
 West Nile virus  
 Yellow fever **◆**  
 Zika virus

◆ Send isolate or sample to North Dakota Department of Health Division of Microbiology.

☠ This is a Select Agent when confirmed. Notify the Division of Microbiology at 701-328-6272. Report any possible lab exposures.

\*Hepatitis C: All positive/reactive test results, hepatitis C genotypes, all hepatitis C nucleic acid test results (including nondetectable)

\*\*HIV/AIDS: Any positive/reactive test results, gene sequencing and drug resistance patterns, all HIV nucleic acid test results (including nondetectable), all CD4 test results

\*\*\*TB: All positive PPD & IGRA results. All results for AFB Smears, cultures and rapid methodologies performed when *M. tuberculosis* complex is suspected.

**How to Report:** • Secure website: [www.ndhealth.gov/disease/reportcard/](http://www.ndhealth.gov/disease/reportcard/) • Telephone: 701-328-2378 or 800-472-2180 • Secure Fax: 701-328-0355 • Electronic laboratory reporting: [www.ndhealth.gov/disease/ELR/](http://www.ndhealth.gov/disease/ELR/)



**CERTIFICATE OF IMMUNIZATION**  
**NORTH DAKOTA DEPARTMENT OF HEALTH**  
 SFN 16038 (Revised 01-2018)

Division of Disease Control  
 2635 East Main Ave. PO Box 5520  
 Bismarck, ND 58506-5520  
 800.472.2180 or 701.328.3386

Child's Name (Last, First, Middle Initial):	Date of Birth:
Parent's Name:	Telephone Number:

Vaccine Type	Exemption Type*	Enter Month/Day/Year for Each Immunization Given					
Hepatitis B	Hepatitis B						
Rotavirus	Rotavirus						
Hib	<i>Haemophilus influenzae</i> type B						
PCV	Pneumococcal conjugate						
DTP/DTaP/DT	Diphtheria-Tetanus-Pertussis						
IPV/OPV	Polio						
MMR	Measles-Mumps-Rubella						
Varicella	Chickenpox						
Hepatitis A	Hepatitis A						
Td/Tdap	Tetanus-Diphtheria (and Pertussis)						
MCV4	Meningococcal ACYW-135						
HPV	Human Papillomavirus						
Men B	Meningococcal B						
Other							

*To the best of my knowledge, this person has received the above-indicated immunizations on the above dates.*

Physician, Nurse, Local/State Health:	Title:	Date:
---------------------------------------	--------	-------

**If additional doses are added after initial signature, please initial dose and sign below.**

Update signature #1:		
Physician, Nurse, Local/State Health:	Title:	Date:

Update signature #2:		
Physician, Nurse, Local/State Health:	Title:	Date:

My child has not met the minimum requirements for his/her age. I agree to resume immunizations within 30 days from the date I was notified (today's date noted below) and to submit a signed Certificate of Immunization.

Parent/Guardian Signature:	Date:
----------------------------	-------

**Statement of Exemption to Immunization Law**

**In the event of an outbreak, exempted persons may be subject to exclusion from school or childcare facility.**

**Medical (Med) Exemption:** (Indicate vaccine above, requires physician signature) The physical condition of the above-named person is such that immunization would endanger life or health or is medically contraindicated due to other medical conditions.

**History of Disease (HD) Exemption:** (Indicate vaccine above, requires physician signature) To the best of my knowledge, the above named person has had prior infection as indicated by prior diagnosis or laboratory confirmation.

Physician Signature:	Date:
----------------------	-------

**Religious (Rel), Philosophical/Moral (PBE) Exemption:** (Indicate vaccine above, requires parental signature)

Parent/Guardian Signature:	Date:
----------------------------	-------

\* Medical =Med, History of Disease = HD, Religious = Rel, Philosophical/Moral = PBE

HB 1307

Good Afternoon Chairman Weisz and committee members. Thank you for your attention to my testimony on HB 1307.

My name is Tiffanie Fettig, I am lifelong resident of Minot, ND. I am a business owner and parent of 3 children, one of which has multiple medical conditions.

I am writing today to encourage you to pass HB 1307.

As a business owner of a privately held ND company, I do NOT believe it is in my best interest now or in the future, for me or my employees to have to determine if we can provide service to a customer based on whether they have received and/or kept up on a vaccination that may or may not be recommended for their particular medical situation. I also do not believe it would be just for a company to be able to decide that they will not supply me with product if I have not received certain vaccinations or immunizations.

As I mentioned in my introduction, I am also a mother of 3 children, one of which has multiple medical conditions. Due to my daughter's diagnosed medical conditions, her doctor has already stated that the covid and some other specific vaccines could be life threatening for her and she should NOT receive it. Please understand that I am not promoting that people should not vaccinate. I am simply stating that people need to be able to evaluate with their trusted medical consultants the best for an individual's particular situation and businesses should not be allowed to refuse service based on whether someone has been vaccinated or not.

If this bill is not passed and vaccine's are mandatory in the future, we will be coming back to the legislature, proposing bills as to how exemptions such as this should be dealt with. I believe it is in all of our best interest to allow doctors to communicate/regulate who should receive the vaccine and who should not. I do not believe it is in the best interest of the ND people to allow businesses to determine that they are not going to allow my daughter to go to a concert or fly on a plane, or eat in their restaurant because she did not receive the vaccine as it was medically advised she should not.

As a consumer and a parent, I also believe it is unfair for businesses to be able to decimate whether they will allow me in their restaurant, in their theater, or on their plane.

On a personal note, I believe that it is absolutely absurd that there is even talk of mandating vaccinations for a virus that has a 99% survival rate. In the case of my daughter, the vaccine could be more detrimental to her health than the illness itself.

If you believe that mandatory vaccine's are farfetched and this bill is not necessary, please consider the following:

A person that desires to shop at Menards today is refused service if they do not wear a mask, they have a "no mask, no sale" policy. It does not matter if you have a written medical exemption, if you don't wear a mask, they will refuse to allow you to purchase products from

them. If you think businesses like those won't adapt the "no vaccine, no sale policy", I think you are incorrect. Businesses such as Menards are clearly laying out the path they will most likely take.

One of my daughter's is currently in college. The college states that they do not require covid testing except ...

- If you leave campus for the weekend
- If you go home for Thanksgiving or Christmas, etc and want to come back
- If you are a collegiate athlete
- If you live in a dorm
- If you want to eat in the dining center
- And the list goes on ...

I do not agree with the statement that they do not require covid testing. I do not believe you can actually be an on campus college student and not be subject to testing according to their exemptions as listed above.

It is my belief that unless we stand up and say no now, our liberties will continue to be stripped just like in the above 2 examples.

I encourage a DO PASS on this bill to protect the rights of ND citizens.

Thank you for your consideration.

House Human Services  
Robin Weisz, Chairman  
January 19, 2021

Testimony by April Heinz  
RE: HOUSE BILL NO. 1307

My name is April Heinz and I am in favor of HB 1307. Immunizations are not for everyone. Each individual has a choice to get immunizations or not. It is the individual's choice, not anyone else's, nor is it anyone else's business to know if someone has the vaccine or not! To deny someone access to goods and services just because they didn't get a vaccine is discrimination and absolutely ridiculous.

I also agree there should be a penalty to those that violate this bill. Seeing this in the agenda to even be discussed is disturbing.

Thank you for your attention to this matter.

April Heinz

1-19-21

To whom it may concern,

This is a letter submitted to my employer regarding my application being denied to have an exemption from the flu vaccination this winter. I was denied an exemption 2 times, as I appealed their decision. Following my third attempt at filing for an exemption (see letter below), based on having adequate personal protective equipment being worn from covid-19 precautions, I was granted the exemption but not indefinitely. I was scheduled to work on a Saturday and Sunday, December 12-13, and was told if I had not received the exemption, I would not be able to return to work. They informed me on Friday, December 11, 2020 that I would be able to continue to work. I continue to work at Altru Health System and feel that I should not be mandated to have any vaccination in my workplace that has possible risk of "serious injury or death."

Sincerely,

Erica Hanson

November 23, 2020

To whom it may concern,

This does not make any sense to me. In the command center update I received on Friday it states,

"The COVID-19 vaccine will not be mandatory for employees. We have educational resources available for employees to read covering how a vaccine is developed, approved and manufactured."

Why is the flu vaccine mandatory with no exception for my personal views but not the covid virus vaccine? I don't understand why I can't have a reasonable accommodation made for me to still do my job. Why can't I have a reasonable accommodation, like the accommodation of wearing a facemask, while working with patients? If this is a method of preventing transmission of viruses, why can I utilize this method to prevent the spread of flu instead of getting a vaccination?

I ask Altru Health System to again reconsider their decision and make a reasonable accommodation to allow me to continue to work for this healthcare system.

Sincerely,

Erica Hanson

November 20 Denial letter

Erica:

I just wanted to inform you that after review of your flu shot exempt request by the review board, your exempt from the flu shot was not approved.

xxxx

This was my 2<sup>nd</sup> appeal letter

November 2, 2020

To whom it may concern,

I received notification that Altru health System has denied my request for an exemption from the flu shot this year. This email is an appeal to your decision. In Altru's email it states, "A determination has been made that those articles do not present evidence strong enough to make a change in policy. Your exemption has been denied at this time." I did not request a change in Altru's flu shot policy, I asked for a personal exemption from the flu shot. I should have a right to decide what I put in my body. In the list of side effects on the flu vaccination information sheet (VIS) from the CDC it states, "As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death." I have a right to decide if I accept the "very remote chance of death." I have a right to decide if I accept "Other serious injury" to my body. There are so many unknowns in the corona virus world we are in today that have me greatly concerned for what I choose to put in my body. I have attached additional research to provide additional evidence why I should be allowed to have an exemption from the flu vaccination.

(1) JAMA found 106,000 deaths in the US related to adverse effects of medication and it is likely that many others were not reported accurately as stated by my personal beliefs with medical error in the next link below: [https://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-primary-care-policy-center/Publications\\_PDFs/A154.pdf](https://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-primary-care-policy-center/Publications_PDFs/A154.pdf)

(2) Medical error-the third leading cause of death in the US. If a person develops a life-threatening side effect from a vaccination would it get reported as such? I have personal testimony to one of my children having a severe allergic reaction to vaccinations and

yet Altru Health systems doctors stated to me and my husband, "There is no way to know for certain this is a result of his vaccination." Again, the VIS states, "Remote chance...death." : <https://www.bmj.com/content/353/bmj.i2139>

(3) "Seasonal influenza vaccines provide limited protection against divergent influenza strains. Therefore, the development of a universal influenza vaccine is a top priority for the NIH." <https://pubmed.ncbi.nlm.nih.gov/33092070/>

(4) <https://www.cdc.gov/flu/vaccines-work/effectiveness-studies.htm> 9-60% flu vaccination efficacy "yet I should assume remote risk of death"

(5)"forms of immunity may lessen disease severity but are insufficient to prevent epidemic spread " <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1600-065X.2010.00974.x?fbclid=IwAR02J76-7RhsXhRSu6Uk7miCTqOiCjNXI9xZ8Cir96QtmB6sp50CJZByyMQ>

(6) What price is my health being bought for? I previously provided an article about money controlling decision making that may affect my health. Here is another article to support my concerns. "\$4 billion global influenza vaccine market" <https://www.genengnews.com/topics/translational-medicine/novartis-selling-flu-vaccine-business-to-csl-for-275m/#:~:text=Novartis%20is%20selling%20its%20influenza,set%20to%20close%20next%20year.>

<https://www.cnn.com/2015/10/19/the-16-billion-business-of-flu.html>

I should question if WHO is making decisions in my best interest when the 2 greatest financial contributors are Warren Buffet and Bill

Gates. <https://www.politico.eu/article/bill-gates-who-most-powerful-doctor/>

(7)This article found a "Positive association between COVID-19 deaths and influenza vaccination rates in elderly people worldwide." While there are other research articles that state the opposite, it should cause all of us to question if we actually know how COVID-19 and the flu shot are working together. If I have concerns with having a flu shot possibly causing or correlating to decrease tolerance to COVID-19 why would I get the flu shot this year? <https://peerj.com/articles/10112/>

(8)Throughout the history of vaccines, there have been ingredients in them that have been found to be harmful to our health. One of my own children has toxic levels of aluminum in his hair follicles that our medical doctor believes to have come from vaccinations. <https://www.fda.gov/vaccines-blood-biologics/safety-availability->

[biologics/thimerosal-and-vaccines?fbclid=IwAR3QsL9ZqDjPnGPeiN0s0hgVqE2pGq23w3lTgDRq9Zn8X0wy0EhDUlc3WvU](https://pubmed.ncbi.nlm.nih.gov/34411111/)

(9) Influenza vaccination was associated with an increased risk of developing influenza-like illnesses (ILI)- what does this look like with our current pandemic? I don't want to put something in my body that has even a small chance of making covid-19 worse than it may be. This article also addresses antiviral resistance. We have a virus running rampant in our world, is antiviral resistance something to be concerned with? This article also addresses the live virus risks (mist) to the population that does not vaccinate versus the use of harmful chemicals that are not even listed in the vaccination ingredients (more studies to follow regarding this statement). The influenza virus strains change and according to the CDC they determined that immunization with the 2003-2004 influenza vaccine offered negligible population protection. Again, I ask, "Should I assume a remote chance of death" for something that "offers negligible population protection" since we won't know until after the flu season is over is our vaccination was for the correct strain? <https://www.jpands.org/vol11no3/geier.pdf?fbclid=IwAR34zk-bfM2czYPE6Vts9X2uP3RaUtyyAc0GGyKdr4UMnuk8g1pafLmXfU>

(10) This is an article where ingredients in vaccinations were studied and what was not listed in the ingredient lists that was actually in the vaccinations. This study was published 3 years ago, if pharmaceutical companies were not disclosing their entire ingredient list 3 years ago, why would I trust them today? <https://medcraveonline.com/IJVV/IJVV-04-00072.pdf>

This is a list of ingredients in vaccines as of Feb 2020 per the CDC: <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>

(11) Vaccine insert states numerous reasons to question safety and efficacy with vaccine: <https://www.fda.gov/media/83072/download>

(12) This article states reduced effectiveness with recurrent vaccinations as well as more aerosol shedding compared to those that were unvaccinated. <https://www.pnas.org/content/115/5/1081>

(13) Flu shot may blunt effectiveness of vaccine through antibody interference. <http://www.cmaj.ca/content/187/6/E180>

(14) Facts about Vaccine injuries reported <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6500451/>

(15) This study found that only 1% of vaccine injuries are actually reported. [https://drive.google.com/file/d/1pAyZOnPgcd0ZcrMwUi8cNcZovftFK\\_YN/view?fbclid=IwAR2QaRoD08bAZhNmlfxCi801oXSkytFy15RypospNTqRa3mARLZNFUK-8qw](https://drive.google.com/file/d/1pAyZOnPgcd0ZcrMwUi8cNcZovftFK_YN/view?fbclid=IwAR2QaRoD08bAZhNmlfxCi801oXSkytFy15RypospNTqRa3mARLZNFUK-8qw)

(16) The national vaccine compensation injury link: Why is there an organization that even has to exist like this. If there is risk in vaccinations shouldn't I have a right to not take them? When my child had a huge side effect from having a vaccination, I signed a paper authorizing Altru to give him the vaccination so they would not be held accountable if something happened to him. Did I understand there was risk? Yes. Did I let him get the vaccination? Yes. On my shoulders as his parent. This year, I say NO to the flu vaccine as I fear the risk of complications from covid 19 as well as not trusting the ingredients fully being disclosed to me. Will a medical organization test the covid vaccine on me without my consent? If so, my Altru Employee health wouldn't protect me, help me because I signed a paper saying I assume the risk of injury. The vaccine compensation organization wouldn't help me either because I signed a paper saying I assume the risk of injury. Therefore, it is my right to request and be honored an exemption from the flu vaccination. <https://www.hrsa.gov/vaccine-compensation/index.html>.

(17) A few years ago, when I was pregnant with one of my children, I filed for an exemption from the flu shot as I had one but could not find the paperwork indicating I had it. Employee health stated that I had to get a second shot or would not be able to work until after delivery and therefore complying with Altru's policy. I elected to take a leave of absence in order to protect my baby with the unknown possibility of causing harm from having 2 shots. Again, Altru did not consider my or my babies best interest, only if I was following your policy. This article states there are reported cases of miscarriage that are connected to flu shots. [https://www.jeremyrhammond.com/2019/05/14/the-cdcs-criminal-recommendation-for-a-flu-shot-during-pregnancy/?utm\\_source=ActiveCampaign&utm\\_medium=email&utm\\_content=The%20Ignorance%20of%20Doctors%20\(Part%20II\)&utm\\_campaign=The%20Ignorance%20of%20Doctor](https://www.jeremyrhammond.com/2019/05/14/the-cdcs-criminal-recommendation-for-a-flu-shot-during-pregnancy/?utm_source=ActiveCampaign&utm_medium=email&utm_content=The%20Ignorance%20of%20Doctors%20(Part%20II)&utm_campaign=The%20Ignorance%20of%20Doctor)

(18) This article indicates there are many unknowns to vaccinations, again with the current state of health concerns I feel my concerns should be respected. <https://childrenshealthdefense.org/news/most-of-you-think-we-know-what-our-vaccines-are-doing-we-dont/?fbclid=IwAR1vKLaelBqa07RTOcVv2IMT7BHTAnkcPfkFLD-hBxjJcGjtl6cYNU1PT2E>

(19) Sleep problems have began to occur in my life. Is this a result of hormonal changes or is the a possibility that it could be related to annual compliance with Altru's Influenza virus policy? These studies address my sleep concerns. <https://www.ncbi.nlm.nih.gov/pubmed/24485154> <https://n.neurology.org/content/80/14/1276>

(20) This article address concerns with increased risk of non-influenza respiratory viral infections associated with receipts of the inactivated influenza vaccine. So, we have covid-19 a non-influenza respiratory viral infection present in our society, shouldn't I be concerned? <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

(21) Unvaccinated children are the healthiest according to this doctor and his research. If that applies to children, does that apply to adults as well? <https://thestaracademy.co.za/former-vaccine-bully-board-certified-pediatrician-now-claims-unvaccinated-children-are-healthiest/>

<https://www.youtube.com/watch?v=8RwoGibCKhc>

(22) Do health care organizations or insurance companies profit from vaccinations? Why push vaccinations? Does Altru get a kickback of some sort for their percentage of compliance to the influenza vaccination? "Systems of Care and Contracted Groups are eligible to receive an additional 10% of their Medicare Advantage base payment based on individual providers' performance. To receive this bonus, 50% of the providers affiliated to the SOCs or contracted groups must achieve an overall aggregated Star rating of 4.5 Stars or above for their Medicare Advantage performance. " Is Altru being bought by incentives? [https://www.bcbsri.com/sites/default/files/portal\\_files/providers/2020-PCP-Quality-Incentive-Program-FINAL.pdf](https://www.bcbsri.com/sites/default/files/portal_files/providers/2020-PCP-Quality-Incentive-Program-FINAL.pdf)

<https://nursesagainstmandatoryvaccines.wordpress.com/2014/11/17/employee-vaccination-rates-are-tied-to-government-funding-and-reimbursement/>

(23) This article address antibiotic overuse. Many vaccinations have antibiotics in them (neomycin, kanamycin, polymyxin B, and gentamicin) further contributing to the antibiotic resistance problems we have in our society. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/>

Here is the link from above from the CDC with vaccine ingredients that you can look up to verify my statement as well as the article

above: <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>

(24) Evidence for “consistent high-level protection is elusive,” the researchers concluded. Although vaccination was found to provide modest protection from infection in young healthy adults who rarely have complications of flu, the authors found that “evidence for protection in adults 65 years of age and older [who represent over 90% of deaths from flu] . . . is lacking.”

<https://www.bmj.com/content/345/bmj.e7856.full>

(25) Vaccines for preventing influenza in healthy

adults: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001269.pub4/epdf>

I fear that this will not change your decision. As stated previously, I have worked for Altru for 15 years, much of that time in a flex position. I value my position and feel I am of benefit to my fellow therapy team both at the hospital and rehab. I am dependable, reliable, and good at what I do. I bring fresh eyes and hands to the patients I serve and am therefore very valuable to all the patients that I have served over the 15 years I have worked here. I have seen people with illness work through physical impairments, family issues, addiction problems, etc. and be able to live a life they didn't know they could have again. I remember them and value their lives, their choices, their decisions, even when I don't agree. Isn't that what we are taught in our sensitivity training, we need to value each person's differences? I am different, I am unique, I have choices that should be respected. I have concern with the covid-19 pandemic and what risks I may have to endure from me having the influenza vaccination put into my body. If Altru Health System does not choose to respect my decision to have an exemption from the flu vaccination, you will have to terminate my position, as I don't feel I am doing anything wrong. I hope that through my research above and through your sensitivity training that you can find a way to respect my decision.

Sincerely,

Erica Hanson, PT  
Physical Therapist

# VACCINE SAFETY

## Introduction to Vaccine Safety Science & Policy in the United States

---



Published: October 2, 2017 (Version 1.0)

Address for correspondence: [whitepaper@icandecide.org](mailto:whitepaper@icandecide.org)

---

This white paper provides an introduction to vaccine safety science and policy in the United States.

Section “I” discusses how Congress granted pharmaceutical companies immunity from liability for vaccine injuries and transferred all responsibility for vaccine safety to the United States Department of Health & Human Services (HHS) and its agencies, including the Food & Drug Administration (FDA), the Centers for Disease Control (CDC) and the National Institutes of Health (NIH).

Section “II” discusses how most pediatric vaccines were licensed based on inadequate clinical trials, including follow-up periods too brief to capture adverse outcomes, and illegitimate placebos (e.g., other vaccines).

Section “III” discusses the CDC’s deficient post-licensure vaccine safety surveillance.

Section “IV” discusses the conflicts of interest at HHS regarding vaccine safety, including the issues resulting from placing HHS in charge of vaccine safety and the conflicting duty of promoting and defending vaccines against any claim of injury.

Until a frank conversation is possible regarding vaccine safety, children susceptible to vaccine injury will not be protected from such injury. Nor will children injured by vaccines be able to access the services they need. We can do better in protecting and serving children who are susceptible or succumb to serious injuries from vaccination.

The first step in avoiding vaccine injuries and helping those already harmed is understanding the state of vaccine safety science and policy in America. This paper provides this understanding and highlights areas in need of improvement.

## I. Who is responsible for vaccine safety?

---

Unlike nearly every other company in America, pharmaceutical companies have almost no liability for injuries caused by their vaccine products. How did this happen? As

explained by the Institute of Medicine (IOM)<sup>1</sup>, by 1986, the “litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine

---

<sup>1</sup> In 2016, the IOM formally changed its name to the National Academies of Sciences, Engineering, and Medicine.

research and development programs as well as to stop producing already licensed vaccines.”<sup>2</sup> Instead of letting market forces compel vaccine makers to create safer vaccines, Congress granted pharmaceutical companies financial immunity from injuries caused by vaccines recommended by the CDC.<sup>3</sup> Congress did so by passing the National Childhood Vaccine Injury Act (the **1986 Act**).<sup>4</sup>

By granting immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the market forces that are generally relied upon to assure the safety of all other products. As the 1986 Act expressly provides: “No person may bring a civil action ... against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”<sup>5</sup>

The 1986 Act even shields vaccine makers from liability where it is clear and unmistakable that the vaccine in question could have been designed safer.<sup>6</sup> As recently explained in a U.S. Supreme Court opinion:

*[N]o one—neither the FDA nor any other federal agency, nor state and federal juries—ensures that vaccine manufacturers adequately take account of scientific and technological advancements. This concern is especially acute with respect to vaccines that have already been*

*released and marketed to the public. Manufacturers ... will often have little or no incentive to improve the designs of vaccines that are already generating significant profit margins.*<sup>7</sup>

Recognizing that the 1986 Act eliminated the incentive for vaccine makers to assure the safety of their vaccine products, the 1986 Act explicitly places this responsibility in the hands of the United States Department of Health & Human Services (**HHS**).<sup>8</sup>

As provided in the 1986 Act, HHS is responsible for “research ... to prevent adverse reactions to vaccines,” “develop[ing] the techniques needed to produce safe ... vaccines,” “safety ... testing of vaccines,” “monitoring ... adverse effects of vaccines,” and “shall make or assure improvements in ... the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, ... and research on vaccines in order to reduce the risks of adverse reactions to vaccines.”<sup>9</sup>

Since passage of the 1986 Act, the number of required pediatric vaccines has grown rapidly. In 1983, the CDC’s childhood vaccine schedule included 11 injections of 4 vaccines.<sup>10</sup> As of 2017, the CDC’s childhood vaccine schedule includes 56 injections of 30 different vaccines.<sup>11</sup>

---

<sup>2</sup> <https://www.nap.edu/read/2138/chapter/2#2>

<sup>3</sup> 42 U.S.C. § 300aa-1 et seq.

<sup>4</sup> Ibid.

<sup>5</sup> 42 U.S.C. § 300aa-11

<sup>6</sup> *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011)

<sup>7</sup> Ibid.

<sup>8</sup> 42 U.S.C. § 300aa-2; 42 U.S.C. § 300aa-27

<sup>9</sup> Ibid.

<sup>10</sup> [https://www.cdc.gov/vaccines/schedules/images/schedule\\_1983s.jpg](https://www.cdc.gov/vaccines/schedules/images/schedule_1983s.jpg)

<sup>11</sup> [https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adol\\_escent.html](https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adol_escent.html) (note that the influenza vaccine is different every year)

CDC Childhood Immunization Schedule <sup>12</sup>		
1986	2017	
DTP (2 months)	Influenza (pregnancy)	Influenza (18 months)
Polio (2 months)	TDaP (pregnancy)	Influenza (2 years)
DTP (4 months)	Hepatitis B (one day)	Influenza (3 years)
Polio (4 months)	Hepatitis B (one month)	Influenza (4 years)
DTP (6 months)	DTaP (2 months)	DTaP (4 years)
MMR (15 months)	Polio (2 months)	Polio (4 years)
DTP (18 months)	Hib (2 months)	MMR (4 years)
Polio (18 months)	PCV (2 months)	Varicella (4 years)
DTP (4 years)	Rotavirus (2 months)	Influenza (5 years)
Polio (4 years)	DTaP (4 months)	Influenza (6 years)
Tetanus (14 years)	Polio (4 months)	Influenza (7 years)
	Hib (4 months)	Influenza (8 years)
	PCV (4 months)	Influenza (9 years)
	Rotavirus (4 months)	Influenza (10 years)
	DTaP (6 months)	HPV (11 years)
	Polio (6 months)	Men (11 years)
	Hepatitis B (6 months)	TDaP (11 years)
	Hib (6 months)	Influenza (11 years)
	PCV (6 months)	HPV (11 ½ years)
	Rotavirus (6 months)	Influenza (12 years)
	Influenza (6 months)	HPV (12 years)
	MMR (12 months)	Influenza (13 years)
	Varicella (12 months)	Influenza (14 years)
	Hib (12 months)	Influenza (15 years)
	Hepatitis A (12 months)	Men (16 years)
	PCV (12 months)	Influenza (16 years)
	DTaP (15 months)	Influenza (17 years)
	Hepatitis A (18 months)	Influenza (18 years)

It is only when the CDC adds a vaccine to its recommended vaccine schedule that the manufacturer is granted immunity from

liability for vaccine injuries. And due to a federal funding scheme, CDC recommended vaccines are then made compulsory to American children under state laws and subsidized by the Federal government for children unable to afford the vaccine.<sup>13</sup>

The end result is that under the 1986 Act, every pediatric vaccine recommended by the CDC creates for its manufacturer a liability-free captive market of 78 million children with guaranteed payment. This incentive structure is unequal in the marketplace and eliminates the normal market forces driving product safety. Hence the 1986 Act transferred essentially all responsibility for vaccine safety from the pharmaceutical companies to HHS.

## II. Pre-Licensure Vaccine Safety Review

HHS, through the FDA, licenses all vaccines used by the American public.

All non-vaccine drugs licensed by the FDA undergo long-term multi-year double-blind safety studies during which the rate of adverse reactions in the group receiving the drug under review is compared to the rate of adverse reactions in a group receiving an inert placebo, such as a sugar pill or saline injection.

For example: Enbrel’s pre-licensure trials followed subjects up to 80 months and

controls received a saline injection.<sup>14</sup> Lipitor’s pre-licensure trials lasted a median of 4.8 years and controls received a sugar pill.<sup>15</sup> Botox’s pre-licensure trials lasted a median of 51 weeks and controls received a saline injection.<sup>16</sup> And even with these long-term studies, drugs are still often recalled.

While most drugs, like the ones above, are given to sick adults, pediatric vaccines are typically given universally to babies and toddlers. And while pharmaceutical companies remain liable for injuries caused by their

<sup>12</sup> The rapid growth of CDC’s vaccine schedule is expected to accelerate since there were 271 new vaccines under development in 2013 and far more currently under development. <http://www.phrma.org/press-release/medicines-in-development-vaccines> (listing 2,300 trials in search for “vaccines” between 2013 and 2017)

<sup>13</sup> See Section IV below.

<sup>14</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/103795s5503lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf)

<sup>15</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020702s0561lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s0561lbl.pdf)

<sup>16</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/103000s5302lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf)

non-vaccine drugs, as discussed above, they have no liability for injuries caused by their vaccines. One would therefore expect that pre-licensure safety testing for vaccines would be more rigorous than that conducted for drugs.

Unfortunately, unlike all non-vaccine drugs licensed by the FDA, vaccines are *not* required to undergo long-term double-blind inert-placebo controlled trials to assess safety. In fact, not a single one of the clinical trials for vaccines given to babies and toddlers had a control group receiving an inert placebo. Further, most pediatric vaccines currently on the market have been approved based on studies with inadequate follow-up periods of only a few days or weeks.

For example, there are two Hepatitis B vaccines licensed for one day old babies in the United States – one manufactured by Merck and the other by GlaxoSmithKline. Merck’s Hepatitis B vaccine was licensed by the FDA after trials which solicited adverse reactions for *only five days* after vaccination.<sup>17</sup> Similarly, GlaxoSmithKline’s Hepatitis B vaccine was licensed by the FDA after trials which solicited adverse reactions for *only four days* after vaccination.<sup>18</sup>

Follow-up periods of 4 or 5 days are not nearly long enough to detect possible adverse effects such as autoimmune or neurological disorders, seizures, or death. Worse is that since neither of these clinical trials used a control group, it was impossible to scientifically determine if any adverse

reaction in the limited four or five day safety review period was even caused by the Hepatitis B vaccine being evaluated.

Similarly, the HiB vaccines manufactured by Merck and GlaxoSmithKline were licensed by the FDA based on trials in which adverse reactions were monitored for only three days and four days, respectively, after vaccination.<sup>19</sup> The only stand-alone polio vaccine in the United States was licensed after a mere 48-hour follow-up period.<sup>20</sup>

Even more amazing is that unlike every drug licensed by the FDA, the control groups in these vaccine trials did not receive an inert placebo.<sup>21</sup> Rather, the control group was given one or more previously licensed vaccines as the “placebo.”<sup>22</sup> This means each new vaccine need only be roughly as safe as one (or in some cases numerous) previously licensed vaccines. Such flawed and unscientific study designs cannot establish the actual safety profile of any vaccine. The real adverse event rate for a vaccine can only be determined by comparing subjects receiving the vaccine with those receiving an inert placebo. Yet, this study design, required for every drug, is never required before or after licensing a vaccine.

It is unacceptable that the FDA licensing process for vaccines fails to assess the safety profile of each vaccine. It is also unacceptable that the FDA does not require the use of inert placebo controls to assure the integrity of even the minimal safety review conducted. As HHS’s own paid experts, the

<sup>17</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>

<sup>18</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>

<sup>19</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf>

<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf>

<sup>20</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf>

<sup>21</sup> Ibid. (prior two footnotes)

<sup>22</sup> Ibid.

IOM, explains: “Because [vaccine] trials are primarily ... for determination of efficacy,

conclusions about vaccine safety derived from these trials are limited.”<sup>23</sup>

### III. Post-Licensure Surveillance of Vaccine Safety & the Known and Unknown Risks of Vaccination

---

HHS also fails to conduct proper post-licensure monitoring and studies of vaccine safety.

#### 1. CDC Blocks Automation of Vaccine Adverse Events Reporting

---

The paucity of pre-licensure safety reviews for vaccines (see discussion above) leaves the assessment of adverse reactions to the post-licensing period when they are being administered to children in the “real world.”

In order to capture adverse events that may arise from vaccination in the “real world,” the 1986 Act established the Vaccine Adverse Events Reporting System (VAERS) operated by HHS and co-sponsored by the CDC and FDA.<sup>24</sup> VAERS is a passive, not mandatory, reporting system.<sup>25</sup> Anyone, including health care providers, on a voluntary basis, may report adverse vaccine reactions to VAERS.<sup>26</sup> HHS compiles these adverse reaction reports in VAERS and the CDC uses VAERS as a “safety signal detection and hypothesis generating system” to identify potential injuries caused by vaccines.<sup>27</sup>

In 2016, VAERS received 59,117 reports of adverse reactions following vaccination including 432 deaths, 1,091 permanent disabilities, 4,132 hospitalizations, and 10,284 emergency room visits.<sup>28</sup>

A problem with VAERS is that it is a passive reporting system, relying on voluntary, rather than mandatory, reporting.<sup>29</sup> As such, numerous reviews of VAERS have found that only a tiny fraction of vaccine adverse events are reported. For example, an HHS-funded review of vaccine adverse events over a three-year period by Harvard Medical School involving 715,000 patients found that “fewer than 1% of vaccine adverse events are reported.”<sup>30</sup> A U.S. House Report similarly stated: “Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events.”<sup>31</sup>

Assuming VAERS captures 1 percent of adverse events (which is more than is estimated), then the number of adverse events reported to VAERS in 2016 would reflect for that year 5,911,700 adverse events, 43,200 deaths, 109,100 permanent disabilities, 413,200 hospitalizations, and 1,028,400 emergency

---

<sup>23</sup> <https://www.nap.edu/read/13563/chapter/4>

<sup>24</sup> <https://wonder.cdc.gov/vaers.html>

<sup>25</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/>

<sup>26</sup> Ibid.

<sup>27</sup> Ibid.

<sup>28</sup> <https://wonder.cdc.gov/vaers.html>

<sup>29</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/>

<sup>30</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>31</sup> <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>

room visits. If accurate, these figures are very troubling.

Of course, these figures are merely estimates. It would be far better if adverse events reports were automatically created and submitted to VAERS to avoid the issue of underreporting. Automated reporting would provide invaluable information that could clarify which vaccines might cause which harms and to whom, potentially allowing us to avoid these injuries and deaths.

The idea of automating adverse event reporting to VAERS is not new or even difficult to achieve.<sup>32</sup> The Agency for Healthcare Research and Quality, an agency within HHS, sought to do exactly that in 2007 when it provided an approximately \$1 million grant to automate VAERS reporting at Harvard Pilgrim Health Care.<sup>33</sup> The result was the successful automation of adverse event reports at Harvard Pilgrim:

*Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions ... were identified.*<sup>34</sup>

These results should have been startling to HHS since they show that over only a three-year period, there were 35,570 reportable reactions in just 376,452 vaccine recipients. Given HHS's statutory mandate to assure safer vaccines, it should have rushed forward with automating VAERS reporting. However, this is not what happened.

<sup>32</sup> <https://healthit.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system>

<sup>33</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>34</sup> Ibid.

After automating adverse event reports at Harvard Pilgrim, the developers of this system asked the CDC to take the final step of linking VAERS with the Harvard Pilgrim system so that these reports could be automatically transmitted into VAERS. Instead, the CDC refused to cooperate. As the Harvard grant recipients explained:

*Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.*<sup>35</sup>

After three years and spending \$1 million of taxpayers' money, the CDC refused to even communicate with the HHS' Harvard Medical School grant recipients.

While HHS generally strongly supports automating public health surveillance systems, when it comes to vaccine safety, the CDC has only supported projects that would limit VAERS to passive surveillance.<sup>36</sup> Automation would improve safety and address many of the long-standing issues and limitations raised by CDC regarding VAERS.<sup>37</sup>

Capturing "fewer than 1% of vaccine adverse events" thirty years after the passage of the 1986 Act is unacceptable – and potentially deadly.

<sup>35</sup> Ibid.

<sup>36</sup> [http://www.ajpmonline.org/article/S0749-3797\(12\)00249-8/pdf](http://www.ajpmonline.org/article/S0749-3797(12)00249-8/pdf); <https://www.ncbi.nlm.nih.gov/pubmed/26209838>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/>

<sup>37</sup> Ibid.

## 2. CDC Ignores IOM's Calls to Identify Injuries Caused by Vaccines

---

The IOM was formed in 1863 by congressional charter, to “provide expert advice on some of the most pressing challenges facing the nation and the world.”<sup>38</sup> The IOM further claims its “members are among the world's most distinguished scientists, engineers, physicians, and researchers; more than 300 members are Nobel laureates.”<sup>39</sup>

Under the 1986 Act, the IOM was charged with issuing reports on injuries from vaccination. In 1991, the IOM examined 22 commonly reported serious injuries following the DTP vaccine.<sup>40</sup> The IOM concluded the scientific literature supported a causal relationship between the DTP vaccine and 6 of these injuries: acute encephalopathy, chronic arthritis, acute arthritis, shock and unusual shock-like state, anaphylaxis, and protracted inconsolable crying.<sup>41</sup>

While this picture was troubling enough, equally concerning was that the IOM found that the scientific literature was insufficient to conclude whether or not the DTP vaccine can cause 12 other serious injuries commonly reported from this vaccine:

*Aseptic meningitis (serious inflammation of the brain); Chronic neurologic damage; Learning disabilities and attention-deficit disorder; Hemolytic anemia; Juvenile diabetes; Guillain-Barre syndrome;*

*Erythema multiforme; Autism; Peripheral mononeuropathy (nerve damage); Radiculoneuritis and other neuropathies; Thrombocytopenia; Thrombocytopenic purpura*<sup>42</sup>

These commonly reported serious injuries *could* be caused by this vaccine – the IOM just couldn't determine one way or another due to a lack of science.

The IOM lamented that it “encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines.”<sup>43</sup> The IOM also remarked on the poor design of the few vaccine studies that had been conducted, stating these “studies are too small or have inadequate length of follow-up to have a reasonable chance of detecting true adverse reactions.”<sup>44</sup> Moreover, the IOM reported that “existing surveillance systems of vaccine injury have limited capacity to provide persuasive evidence of causation.”<sup>45</sup>

The IOM thus cautioned in its 1991 report that: “If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.”<sup>46</sup>

As charged under the 1986 Act, the IOM issued another report in 1994 entitled *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causation*.<sup>47</sup> This second IOM Report examined the scientific literature for evidence that could either prove or disprove a causal link between 54

---

<sup>38</sup> <http://www.national-academies.org/about/whoweare/index.html>

<sup>39</sup> Ibid.

<sup>40</sup> <https://www.nap.edu/read/1815/chapter/2#7>

<sup>41</sup> Ibid.

<sup>42</sup> Ibid.

<sup>43</sup> <https://www.nap.edu/read/1815/chapter/2#8>

<sup>44</sup> <https://www.nap.edu/read/1815/chapter/9>

<sup>45</sup> Ibid.

<sup>46</sup> Ibid.

<sup>47</sup> <https://www.nap.edu/read/2138/chapter/1>

commonly reported serious injuries and vaccination for diphtheria, tetanus, measles, mumps, polio, hepatitis B, and Hib.<sup>48</sup>

For this Report, the IOM located sufficient science to support a causal connection between these vaccines and 12 injuries, including death, anaphylaxis, thrombocytopenia, and Guillain-Barre syndrome.<sup>49</sup>

Again, as with the IOM Report from 1991, for “the majority of vaccine-adverse event pairs the evidence was considered inadequate to accept or reject causality.”<sup>50</sup> The problem that basic scientific studies had not been done continued to persist. The IOM could not determine whether there was a causal connection between vaccination and 38 of the most common serious injuries parents reported their children experienced following these vaccines, including:

*Demyelinating diseases of the central nervous system, Sterility, Arthritis, Neuropathy, Residual seizure disorder, Transverse myelitis, Sensorineural deafness, Optic neuritis, Aseptic meningitis, Insulin-dependent diabetes mellitus, SIDS*<sup>51</sup>

This means that of the 54 vaccine-injury pairs studied, there was sufficient science to find a causal relationship of harm for 12, and to reject a relationship for 4.<sup>52</sup> But for the remaining 38, there was insufficient science to reach any conclusion.<sup>53</sup>

As in 1991, this IOM Report from 1994 again stated: “The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meeting indicated that many parents and physicians share this concern.”<sup>54</sup>

Another acute concern raised by the IOM in 1994 was the potential risks posed by combining vaccines. The IOM noted that this subject simply had not been studied: “The committee was able to identify little information pertaining to the risk of serious adverse events following administration of multiple vaccines simultaneously. This is an issue of increasing concern as more vaccines and vaccine combinations are developed for routine use.”<sup>55</sup>

In 2011, HHS paid the IOM to conduct another assessment regarding vaccine safety.<sup>56</sup> This Report, entitled *Adverse Effects of Vaccines: Evidence and Causality*, was the culmination of the largest review by the IOM regarding vaccine safety since the IOM’s reports from 1991 and 1994.<sup>57</sup>

This third IOM Report reviewed the 158 most common vaccine injuries claimed to have occurred from vaccination for varicella, hepatitis B, tetanus, measles, mumps, and/or rubella.<sup>58</sup> The IOM located science which “convincingly supports a causal relationship” for 14 of these serious injuries, including pneumonia, meningitis, hepatitis, MIBE (deadly brain inflammation a year after vaccination), febrile seizures, and

<sup>48</sup> <https://www.nap.edu/read/2138/chapter/2#12>

<sup>49</sup> <https://www.nap.edu/read/2138/chapter/2#12>

<sup>50</sup> <https://www.nap.edu/read/2138/chapter/1#vi>

<sup>51</sup> <https://www.nap.edu/read/2138/chapter/2#12>

<sup>52</sup> Ibid.

<sup>53</sup> Ibid.

<sup>54</sup> <https://www.nap.edu/read/2138/chapter/12>

<sup>55</sup> <https://www.nap.edu/read/2138/chapter/12#307>

<sup>56</sup> <https://www.nap.edu/read/13164/chapter/2#2>

<sup>57</sup> Ibid.

<sup>58</sup> Ibid.

anaphylaxis.<sup>59</sup> The review found sufficient evidence to support “acceptance of a causal relationship” for 4 additional serious injuries.<sup>60</sup>

The IOM, however, found the scientific literature was insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

*Encephalitis (brain inflammation), Encephalopathy (gradual degeneration of brain function, including memory, cognitive ability, concentration, lethargy, and eventually consciousness), Infantile Spasms, Afebrile Seizures, Seizures, Cerebellar Ataxia (inflammation of and/or damage to the cerebellum), Ataxia (the loss of full control of bodily movements), Acute Disseminated Encephalomyelitis (brief but widespread attack of inflammation in the brain and spinal cord that damages myelin – the protective covering of nerve fibers), Transverse Myelitis (neurological disorder caused by inflammation across both sides of one level, or segment, of the spinal cord that typically results in permanent impairments), Optic Neuritis (inflammation of the optic nerve and symptoms are usually unilateral, with eye pain and partial or complete vision loss), Neuromyelitis Optica (body’s immune system over time repeatedly mistakenly attacks healthy cells and proteins in the body, most often those in the spinal cord and eyes resulting in permanent disability), Multiple Sclerosis, Guillain-Barre Syndrome (body’s immune system attacks part of the peripheral nervous system), Chronic Inflammatory*

*Demyelinating Polyneuropathy (auto-immune inflammatory disorder of the peripheral nervous system resulting in loss of nerve axons), Brachial Neuritis (auto-immune reaction against nerve fibers of the brachial plexus), Amyotrophic Lateral Sclerosis (rapidly progressive, invariably fatal neurological disease that attacks the nerve cells responsible for controlling voluntary muscles), Small Fiber Neuropathy (damage to the small unmyelinated peripheral nerve fibers), Chronic Urticaria (chronic hives), Erythema Nodosum (skin inflammation in the fatty layer of skin), Systemic Lupus Erythematosus (autoimmune disease in which the body’s immune system mistakenly attacks healthy tissue), Polyarteritis Nodosa (inflammation resulting in injury to organ systems), Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Arthralgia (joint pain), Autoimmune Hepatitis, Stroke, Chronic Headache, Fibromyalgia, Sudden Infant Death Syndrome, Hearing Loss, Thrombocytopenia, Immune Thrombocytopenic Purpura<sup>61</sup>*

Thus, out of the 158 most common serious injuries reported to have been caused by the vaccines under review, the evidence “convincingly supports a causal relationship” for 14, “favors acceptance of a causal relationship” for 4, and “favors rejection of a causal relationship” for only 5 of them.<sup>62</sup> For the remaining 135 vaccine-injury pairs, over 86 percent of those reviewed, the IOM found

<sup>59</sup> <https://www.nap.edu/read/13164/chapter/2#3>

<sup>60</sup> Ibid.

<sup>61</sup> Ibid.

<sup>62</sup> Ibid.

that the science simply had not been performed.<sup>63</sup>

### 3. CDC Ignores IOM’s Calls to Identify Children Susceptible to Vaccine Injury

Compounding the lack of adequate science to simply ascertain whether the most commonly reported serious adverse reactions following vaccination are caused by vaccines, the IOM Reports discussed above have consistently acknowledged there is individual susceptibility to serious vaccine injuries.

The IOM has also acknowledged that research on such susceptibility must be done on an individual basis, considering a child’s personal genome, behaviors, microbiome, intercurrent illness, and present and past environmental exposure.<sup>64</sup> Unfortunately, HHS has not conducted this research.

In 1994, the IOM, building on concerns raised in its 1991 Report, stated: “The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not.”<sup>65</sup> The IOM urged that “research should be encouraged to elucidate the factors that put certain people at risk.”<sup>66</sup>

Yet, seventeen years later, in 2011, the IOM acknowledged this research had still not been done:

*Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines*

*have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact as suggested graphically in Figure 3-1.*

*Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine. ... [M]uch work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients.*

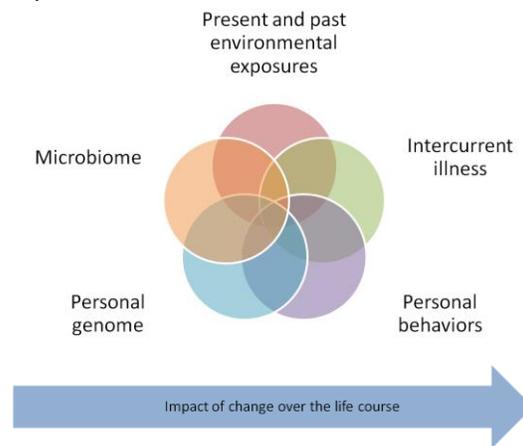


FIGURE 3-1 Present and past environmental exposures.<sup>67</sup>

In 2013, HHS commissioned the IOM to review the safety of the entire vaccine schedule.<sup>68</sup> The IOM again explained that while “most children who experience an adverse reaction to immunization have preexisting susceptibility,” the IOM:

<sup>63</sup> Ibid.

<sup>64</sup> <https://www.nap.edu/read/13164/chapter/5#82>

<sup>65</sup> <https://www.nap.edu/read/2138/chapter/12#307>. See also <https://www.nap.edu/read/1815/chapter/9>

<sup>66</sup> Ibid.

<sup>67</sup> <https://www.nap.edu/read/13164/chapter/5#82>

<sup>68</sup> <https://www.nap.edu/read/13563/chapter/1>

*found that evidence assessing outcomes in sub populations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes.*<sup>69</sup>

HHS had failed to even define the terminology for the study of susceptible subpopulations; hence IOM admonished HHS to “develop a framework that clarifies and standardizes definitions of ... populations that are potentially susceptible to adverse events.”<sup>70</sup> While every vaccine brand is the same, it is plain that every child is different.

The IOM correctly points out in 2011 that given the “widespread use of vaccines” and “state mandates requiring vaccination of children ... it is essential that safety concerns receive assiduous attention.”<sup>71</sup> This is the same call for diligent attention that the IOM made in 1991 and 1994. Unfortunately, all of these calls for action have gone unheeded. The critical scientific inquiry to identify individuals susceptible to serious vaccine injury has simply never commenced.

Since the IOM’s first call for this science in 1991, HHS has spent tens of billions promoting and purchasing vaccines, and

vaccine makers have accumulated hundreds of billions in vaccine revenue.<sup>72</sup> Yet, during this time, no material funds have been allocated to identify susceptible subpopulations, let alone what injuries are caused by vaccines.<sup>73</sup>

#### **4. CDC Views Vaccine Safety as a Public Relations Issue**

---

The CDC, unfortunately, has treated vaccine safety as a public relations issue rather than a public health imperative. For example, the CDC claims on its website that “Vaccines Do Not Cause Autism” even though this broad claim is plainly not supported by the scientific literature.<sup>74</sup>

Indeed, as part of the IOM’s 2011 review of vaccine safety, it was asked by HHS whether there is a causal relationship between autism and the DTaP vaccine administered to children at two, four, six, and fifteen months of age.<sup>75</sup> The IOM could not locate a single study supporting that DTaP does not cause autism.<sup>76</sup> The IOM therefore concluded: “The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.”<sup>77</sup> The IOM’s full explanation for this finding is as follows:

---

<sup>69</sup> <https://www.nap.edu/read/13563/chapter/9#130>

<sup>70</sup> Ibid.

<sup>71</sup> <https://www.nap.edu/read/13164/chapter/3#28>

<sup>72</sup> <https://www.hhs.gov/about/budget/index.html#previous>; <https://www.statista.com/statistics/265102/revenues-in-the-global-vaccine-market/>; <https://www.ft.com/content/93374f4a-e538-11e5-a09b-1f8b0d268c39>

<sup>73</sup> For example, while in 2016 vaccine makers reported over \$33 billion from vaccine sales and the CDC reported spending over

\$5 billion promoting and purchasing vaccines (Ibid.), the CDC Immunization Safety Office’s budget is apparently only around \$20 million. [http://www.ajpmonline.org/article/S0749-3797\(15\)00314-1/pdf](http://www.ajpmonline.org/article/S0749-3797(15)00314-1/pdf)

<sup>74</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>75</sup> <https://www.nap.edu/read/13164/chapter/2#2>

<sup>76</sup> <https://www.nap.edu/read/13164/chapter/12#545>

<sup>77</sup> Ibid.

## AUTISM

### Epidemiologic Evidence

The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

### Weight of Epidemiologic Evidence

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.

### Mechanistic Evidence

The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.

### Weight of Mechanistic Evidence

The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism as lacking.

### Causality Conclusion

Conclusion 10.6: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.<sup>78</sup>

It is troubling that the only study the IOM could locate regarding whether DTaP causes autism, (Geier and Geier, 2004), concluded there *was* an association between DTaP and autism.<sup>79</sup> No research has been published since 2011 that could change the IOM's conclusion. Based on the foregoing, the CDC cannot validly make the blanket assertion that "Vaccines Do Not Cause Autism."

As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines – all of which HHS recommends babies receive by one year of age.<sup>80</sup>

Instead, HHS's claim that "Vaccines Do Not Cause Autism" relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.<sup>81</sup> Putting aside the controversy surrounding these studies, studies which focus on only one vaccine and one ingredient while ignoring the entire balance of the CDC's pediatric vaccine schedule cannot support the

<sup>78</sup> Ibid.

<sup>79</sup> Ibid. Ironically, this study was disregarded "because it provided data from a passive surveillance system [VAERS] and lacked an unvaccinated comparison population," which would be true of any study using VAERS data.

<sup>80</sup> <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

<sup>81</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

CDC's overarching declaration that "Vaccines Do Not Cause Autism."

As for the MMR vaccine, the CDC's senior scientist for its seminal MMR-autism study has recently revealed that the CDC concealed an association between MMR and autism. Dr. William Thompson has been a scientist at CDC for nearly two decades and is the CDC's Senior Scientist on dozens of the CDC's peer-reviewed publications, including the core group of the CDC's vaccine-autism safety studies.<sup>82</sup>

Dr. Thompson recently provided a statement through his attorney that the CDC "omitted statistically significant information" showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.<sup>83</sup>

Dr. Thompson, in a recorded phone call in 2014, described how the CDC concealed a finding indicating that healthy children who received the MMR vaccine may be eight times more likely to develop autism than those without the vaccine.<sup>84</sup> He stated: "Oh my God, I can't believe we did what we did. But we did. It's all there. It's all there. I have handwritten notes."<sup>85</sup> Dr. Thompson stated that "If I were forced to testify or something like that, I'm not gonna lie ... I basically have stopped lying."<sup>86</sup> Expressing contrition for concealing the MMR-autism association, Dr. Thompson stated:

*I have great shame now when I meet families with kids with autism because I*

*have been part of the problem ... the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway there's still a lot of shame with that. ... I am completely ashamed of what I did.<sup>87</sup>*

Dr. Thompson also provided the following statement explaining the CDC's concealment of the autism-MMR association with regard to African-American males:

*My primary job duties while working in the immunization safety branch from 2000 to 2006, were to later co-lead three major vaccine safety studies. ... We hypothesized that if we found statistically significant effects at either 18 or 36 month thresholds, we would conclude that vaccinating children early with MMR vaccine could lead to autism-like characteristics or features. We all met and finalized the study protocol and analysis plan ... [and after implementing this plan we found] the adjusted race effect statistical significance was huge.*

*All the authors and I [therefore] met and decided ... to exclude reporting any race effects. The co-authors scheduled a meeting to destroy documents related to the study. The remaining four co-authors all met and brought a big garbage can into the meeting room, and reviewed and went through all the hardcopy documents that we had thought we should discard, and put them into a huge garbage can. However,*

<sup>82</sup> <https://www.ncbi.nlm.nih.gov/pubmed/?term=Thompson+WW%5BAuthor%5D>

<sup>83</sup> <http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf>

<sup>84</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

<sup>85</sup> Ibid.

<sup>86</sup> Ibid.

<sup>87</sup> Ibid.

*because I assumed it was illegal and would violate both FOIA and DOJ requests, I kept hardcopies of all documents in my office, and I retain all associated computer files. I believe we intentionally withheld controversial findings from the final draft of the Pediatrics paper.*<sup>88</sup>

Hence, for the only vaccine (MMR) actually studied by the CDC with regard to autism, it appears the CDC concealed an association between that vaccine and autism.

When the former Director of the National Institutes of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: “You can’t say that.”<sup>89</sup> When asked again, Dr. Healy explained: “The more you delve into it – if you look at the basic science – if you look at the research that’s been done, in animals – if you also look at some of these individual cases – and, if you look at the evidence that there is no link - what I come away with is: *The question has not been answered.*”<sup>90</sup>

Former NIH Director Dr. Healy goes on to explain:

*This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine. ... A susceptible group does not*

*mean that vaccines are not good. What a susceptible group will tell us is that maybe there is a group of individuals, or a group of children, that shouldn’t have a particular vaccine or shouldn’t have vaccine on the same schedule. ...*

*I think the government, or certain health officials in the government, are - have been too quick to dismiss the concerns of these families without studying the population that got sick. I haven’t seen major studies that focus on - three hundred kids, who got autistic symptoms within a period of a few weeks of a vaccine.*

*I think that the public health officials have been too quick to dismiss the hypothesis as irrational, without sufficient studies of causation. I think that they often have been too quick to dismiss studies in the animal laboratory, either in mice, in primates, that do show some concerns with regard to certain vaccines. ...*

*The reason why they didn’t want to look for those susceptibility groups was because they’re afraid if they found them – however big or small they were – that that would scare the public away. First of all, I think the public’s smarter than that; the public values vaccines. But, more importantly, I don’t think you should ever turn your back on any scientific hypothesis because you’re afraid of what it might show!*<sup>91</sup>

The CDC’s claim that “Vaccines Do Not Cause Autism” also fails to address the

<sup>88</sup> <https://www.c-span.org/video/?c4546453/senator-posey-calls-investigation-cdc-fraud>

<sup>89</sup> <http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/>

<sup>90</sup> Ibid.

<sup>91</sup> Ibid.

science supporting a link between vaccines and autism.<sup>92</sup> For example, the CDC has not addressed a study which found a 300% increased rate of autism among newborns receiving the hepatitis B vaccine at birth compared to those that did not.<sup>93</sup> Nor a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.<sup>94</sup> There is also a persuasive body of science supporting a connection between aluminum adjuvants in vaccines and autism which the CDC has, despite request, failed to directly or persuasively address.<sup>95</sup>

The CDC also failed to address the fact that a review of vaccine injuries compensated by HHS, through the vaccine injury compensation program established by the 1986 Act, “found eighty-three cases of autism among those compensated for vaccine-induced brain damage.”<sup>96</sup>

The CDC ignores all the foregoing and continues to rely on its prior MMR-autism studies which, even putting aside Dr. Thompson’s claims of concealment, are not applicable to any of the 25 doses of seven vaccines the CDC advised doctors to inject into babies during the first year of life.<sup>97</sup>

The critical need for the CDC to properly engage in vaccine safety science regarding autism is made even more vital by the fact that vaccine makers are immune from liability for vaccine injury and vaccines are not

safety-tested prior to licensure to assess whether they cause autism. Without proper *long-term* safety studies comparing those receiving the vaccine to a true placebo group, it is impossible to know prior to licensure whether these products cause autism. There are also no follow-up studies which compare vaccinated to unvaccinated individuals and hence no supportable basis to claim that vaccines do not cause any cases of autism. For the CDC to make this claim, it must demonstrate that a child receiving the entire vaccine schedule is at no greater risk of becoming autistic than a child that is unvaccinated. No such study has ever been done.

The IOM Report referenced above has confirmed that the CDC cannot make this claim even for children receiving only the DTaP, let alone the entire vaccine schedule. It is thus plain that the CDC cannot validly claim that “Vaccines Do Not Cause Autism.” The truth is, the CDC, at best, does not know.

## **5. CDC & IOM Ignore Massive Body of Science Supporting Vaccine Injuries**

---

While the 2011 IOM Report has 75 pages of citations to peer-reviewed sources, there are far more peer-reviewed articles documenting vaccine injuries apparently not even considered by the 2011 IOM Report. Resources for references to these citations can be provided upon request.

---

<sup>92</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>93</sup> [http://hisunim.org.il/images/documents/scientific\\_literature/Gallagher\\_Goodman\\_HepB\\_2010.pdf](http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf)

<sup>94</sup> [http://www.cmsri.org/wp-content/uploads/2017/05/Mawson\\_StudyHealthOutcomes5.8.2017.pdf](http://www.cmsri.org/wp-content/uploads/2017/05/Mawson_StudyHealthOutcomes5.8.2017.pdf)

<sup>95</sup> [http://vaccine-safety.s3.amazonaws.com/WhitePaper-Alum\\_AdjuvantAutism.pdf](http://vaccine-safety.s3.amazonaws.com/WhitePaper-Alum_AdjuvantAutism.pdf)

<sup>96</sup> <http://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=peir>

<sup>97</sup> Further, studies of MMR and autism are simply erroneous because of healthy user bias, which has been emphasized as a serious source of error in epidemiological vaccine safety studies by the CDC’s own scientists. <https://www.ncbi.nlm.nih.gov/pubmed/1415136>

A major theme among these peer-reviewed vaccine papers is the connection between vaccination and chronic disease, mainly autoimmunity and immune mediated neurological disorders and injuries. As detailed above, in the last 30 years, the CDC's childhood vaccine schedule has rapidly increased from 11 injections of 4 vaccines in 1986 to 56 injections of 30 vaccines in 2017. This upsurge has occurred in lock step with the precipitous increase in childhood chronic illness and developmental disabilities which have, during this same period, risen among American children from 12.8% to 54%.<sup>98</sup>

Many of the same disorders that have sharply risen during this period, including neurological and autoimmune disorders, are associated with vaccination as reflected in VAERS<sup>99</sup>, manufacturer inserts for vaccines<sup>100</sup>, and claims in the Vaccine Injury Compensation Program<sup>101</sup>.

The causal mechanisms of these disorders are increasingly understood, and increasingly implicate vaccine exposure during early development.<sup>102</sup> For example, it is now known that early life immune activation can cause autism, mental illnesses, and immune disorders.<sup>103</sup> Vaccines and vaccine adjuvants (particularly in cases of adverse reactions) can cause the types of immune activation known to cause these disorders later in life.<sup>104</sup> Accordingly, there is an urgent and long-overdue need for higher quality vaccine safety research looking at long term neurological and immune outcomes.

Nonetheless, the 2011 IOM Report makes it clear that little has been ruled out with regard to what injures are caused by vaccines. In 2013, the IOM was again engaged by HHS to review the safety of the entire vaccine schedule on a population level.<sup>105</sup> The "committee's literature searches and review were intended to identify health outcomes associated with some aspect of the childhood immunization schedule."<sup>106</sup> "Allergy and asthma, autoimmunity, autism, other neurodevelopmental disorders (e.g., learning disabilities, tics, behavioral disorders, and intellectual disability), seizures, and epilepsy were included as search terms."<sup>107</sup>

Instead of answers, the IOM found that no studies had been conducted to validly assess the safety of the entire vaccine schedule or even portions of the vaccine schedule:

*[F]ew studies have comprehensively assessed the association between the entire immunization schedule or variations in the overall schedule and categories of health outcomes, and no study ... compared the differences in health outcomes ... between entirely unimmunized populations of children and fully immunized children. Experts who addressed the committee pointed not to a body of evidence that had been overlooked but rather to the fact that existing research has not been designed to test the entire immunization schedule. ...*

<sup>98</sup> <https://www.ncbi.nlm.nih.gov/pubmed/20159870>

<sup>99</sup> <https://wonder.cdc.gov/vaers.html>

<sup>100</sup> <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>; See also Section III(7) below.

<sup>101</sup> <http://www.uscfc.uscourts.gov/aggregator/sources/7>; See also Section IV(4) below.

<sup>102</sup> <https://www.ncbi.nlm.nih.gov/pubmed/27540164>

<sup>103</sup> <https://www.ncbi.nlm.nih.gov/pubmed/25311587>

<sup>104</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26531688>;

<https://www.ncbi.nlm.nih.gov/pubmed/27908630>

<sup>105</sup> <https://www.nap.edu/read/13563/chapter/1>

<sup>106</sup> <https://www.nap.edu/read/13563/chapter/2#5>

<sup>107</sup> Ibid.

*[Also,] studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted.*<sup>108</sup>

While most of the 78 million children in America follow the CDC's childhood vaccine schedule, currently at 56 injections, no science has been done to confirm the safety of this schedule.<sup>109</sup> Even more alarming is that the IOM acknowledges that science does not yet even know "if there is a relationship between short-term adverse events following vaccination and long-term health issues."<sup>110</sup>

Due to the lack of science regarding the safety of the CDC vaccine schedule, the best the IOM could do was conclude: "There is no evidence that the schedule is not safe."<sup>111</sup> Left unsaid, but equally true: There is no evidence that the schedule is safe.

## 6. CDC Refuses to Conduct Vaccinated vs. Unvaccinated Study

---

The best and most efficient way to answer a large portion of the questions raised regarding vaccine safety would be a long-term, properly powered (*i.e.*, sized) study comparing the overall health outcomes of vaccinated and completely unvaccinated children. Parents and safety advocacy groups

have been demanding for decades that HHS perform such a study. Even the CDC's internal vaccine committee recognizes that assessing "adverse events require more detailed epidemiologic studies to compare the incidence of the event among vaccinees to the incidence among unvaccinated persons."<sup>112</sup>

HHS has nonetheless consistently refused to study health outcomes of the completely unvaccinated. There have been, however, small-scale studies performed outside of HHS comparing vaccinated with completely unvaccinated children. And these smaller studies have consistently reported that the unvaccinated have much better health outcomes.

Dr. Peter Aaby is renowned for studying and promoting vaccines in Africa with over 300 published studies.<sup>113</sup> In 2017, he published a study finding children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated.<sup>114</sup> Dr. Aaby's study therefore concluded that: "All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis."<sup>115</sup> More disturbing is that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.<sup>116</sup> This indicated that while DTP

increasingly recognized problem in vaccine safety studies is that subjects are typically not well-matched. People with pre-existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. Dr. Aaby's study was one of the few specifically designed to avoid this error.

---

<sup>108</sup> Ibid.

<sup>109</sup> Ibid.

<sup>110</sup> <https://www.nap.edu/read/13563/chapter/5#45>

<sup>111</sup> <https://www.nap.edu/read/13563/chapter/2#12>

<sup>112</sup> <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm>

<sup>113</sup> <https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D>

<sup>114</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>

Dr. Aaby's study was more reliable than other vaccine safety studies because the subjects were accurately matched. An

<sup>115</sup> Ibid.

<sup>116</sup> Ibid.

reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.<sup>117</sup>

It is equally troubling that Dr. Aaby's study was based on data that had been collecting dust for over 30 years.<sup>118</sup> This begs the question: what other serious vaccine injuries are we missing because of neglect to conduct proper vaccine safety science?

A pilot study comparing 650 vaccinated and unvaccinated homeschooled children in the United States provides a glimpse of the potential scope of vaccine harm.<sup>119</sup> The study found that, compared to completely-unvaccinated children, fully-vaccinated children had an increased risk of 390% for allergies, 420% for ADHD, 420% for autism, 290% for eczema, 520% for learning disabilities, and 370% for any neuro-developmental delay.<sup>120</sup> Fully-vaccinated pre-term infants had an increased risk of 1,450% for a neurodevelopmental disorder, which includes a learning disability, ADHD or autism, compared to completely unvaccinated preterm infants.<sup>121</sup>

Another recent study compared children receiving the flu shot with those receiving a saline injection in a prospective randomized double-blind study.<sup>122</sup> Both groups had the same rate of influenza but the group receiving the flu shot had a 440% increased rate of non-influenza infection.<sup>123</sup>

Like the DTP study, the flu vaccine increased susceptibility to other infections.

As a final example, the CDC in 2001 unwittingly conducted a narrow vaccinated versus unvaccinated study comparing children receiving the Hepatitis B vaccine during the first month of life versus those who did not.<sup>124</sup> The results of this study were never released by the CDC, and an abstract of the study was only recently obtained under a FOIA request.<sup>125</sup> Children vaccinated with Hepatitis B vaccine in the first month of life, compared to children receiving no vaccines in the first month of life, had an increased risk of 829% for ADHD, 762% for autism, 638% for ADD, 565% for tics, 498% for sleep disorders, and 206% for speech delays.<sup>126</sup>

The foregoing limited studies should have raised alarm bells at the CDC regarding the urgency of a proper vaccinated versus unvaccinated study that stakeholders have been demanding the CDC perform for over 20 years. The IOM has even confirmed such a study can be conducted using the CDC's VSD, a database of health records for almost ten million individuals maintained by the CDC.<sup>127</sup> As explained by the IOM: "It is possible to make this comparison [between vaccinated and unvaccinated children] through analyses of patient information contained in large databases such as VSD."<sup>128</sup> Such a retrospective epidemiological study would be quick, cheap and efficient; CDC could literally

---

<sup>117</sup> Ibid.

<sup>118</sup> Ibid.

<sup>119</sup> <http://www.oatext.com/pdf/JTS-3-186.pdf>

<sup>120</sup> Ibid.

<sup>121</sup> <http://www.oatext.com/pdf/JTS-3-187.pdf>

<sup>122</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>123</sup> Ibid.

<sup>124</sup> [http://vaccine-safety.s3.amazonaws.com/CDC\\_FOIA\\_Response\\_UnpublishedStudy.pdf](http://vaccine-safety.s3.amazonaws.com/CDC_FOIA_Response_UnpublishedStudy.pdf) The CDC's study abstract discusses comparing thimerosal exposure by one month of age.

Since the only vaccine recommended by one month of age was Hepatitis B, and since only thimerosal containing Hepatitis B vaccine was available at the time of this study, this study primarily compared children receiving Hepatitis B with children that did not receive this vaccine.

<sup>125</sup> Ibid.

<sup>126</sup> Ibid.

<sup>127</sup> <https://www.nap.edu/read/13563/chapter/2#13>

<sup>128</sup> Ibid.

conduct this study using the VSD in a matter of minutes. Yet it has never, as far as the public knows, been done.<sup>129</sup>

Every year tens of millions of American children are compelled to receive pediatric vaccines. Yet a large-scale study with completely-unvaccinated controls has never been performed to assess the long-term safety of the CDC's recommended vaccine schedule.<sup>130</sup> When vaccine makers are generating over \$33 billion in vaccine revenue annually and the CDC is spending over \$5 billion annually to promote and purchase vaccines, there is no justification for not performing this study.<sup>131</sup>

## 7. CDC Ignores Vaccine Manufacturer Disclosures of Potential Adverse Reactions

---

Vaccine makers are required by law to report to the FDA complaints they receive from consumers of serious adverse reactions from their vaccines.<sup>132</sup> A partial list of these serious adverse reactions is detailed below. While studies have been conducted for a few of these to confirm whether they are in fact caused by vaccines, the CDC has failed to conduct such studies for most of them.

Meningitis (*acute inflammation of protective membranes covering the brain and spinal cord*); Thrombocytopenia (*low blood platelet count which can result from autoimmune action*); Stevens-Johnson's Syndrome (*severe autoimmune reaction in which the top layer of skin is burned off and dies*); Alopecia Areata (*autoimmune skin disease resulting in the loss of hair on the scalp and elsewhere on the body*); Arthritis (*painful and disabling autoimmune disease that includes joint pain, swelling and progressive stiffness in the fingers, arms, legs and wrists*); Rhinitis (*irritation and inflammation of nasal mucous membranes impacting ability to breathe properly*); Insomnia; Lupus Erythematosus (*autoimmune disease in which immune system attacks healthy tissue, including skin, joint, kidney, brain, and other organs*); Hypotension (*abnormally low blood pressure*); Guillian-Barre Syndrome (*autoimmune disease that attacks the nerves in the legs, upper body, arms and/or face*); Polyarteritis Nodosa (*systemic vasculitis that affect medium-sized and small muscular arteries resulting in ruptures and other damage*); Encephalitis (*inflammation of the brain, which can result in permanent injury*); Bell's Palsy (*disfiguring paralysis or weakness on one side of the face*); Radiculopathy (*compressed or pinched nerve*); Myelitis (*inflammation of spinal cord that can involve nerve pain, paralysis and incontinence*); Multiple Sclerosis (*immune system attacks nerve fibers, causing them to deteriorate*); Optic Neuritis (*inflammation*

---

<sup>129</sup> The CDC's inaction does not appear to be mere neglect since CDC Senior Scientist, Dr. Thompson, recently stated that a proper large scale vaccine safety study "needs to be done" but that the CDC is "not doing what they should be doing because they're afraid to look for things that might be associated." <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio> Dr. Thompson even explained that they have the data to conduct such a study and that "we're insane to be sitting on this data and not have an independent group" conduct this study but that it will not happen because "they don't really want people to know that this data exists." Ibid.

<sup>130</sup> In fact, due to the CDC's refusal to act, bills have been proposed in Congress to require such a study, but, the political clout for passage could not be mustered. See, e.g., H.R. 1757 (2013) and H.R. 1636 (2015) ("to conduct or support a comprehensive study comparing total health outcomes ... in vaccinated populations in the United States with such outcomes in unvaccinated populations in the United States").

<sup>131</sup> <https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf>; <https://www.bccresearch.com/market-research/pharmaceuticals/vaccine-technologies-markets-report-phm014f.html>

<sup>132</sup> [21 C.F.R. § 600.80\(c\)](#)

*causing eye pain and partial or complete vision loss); Aplastic anemia (damage to the bone marrow which slows or shuts down the production of new blood cells); Aseptic Meningitis (acute inflammation of the brain and spinal cord which can lead to death); Henoch-Schonlein purpura (abnormal immune response resulting in inflammation of microscopic blood vessels which can result in multiple organ damage); Myalgia (muscle pain that can become chronic); Radial nerve and recurrent nerve paralysis (nerve injury to the radial nerve that can cause weakness or difficulty moving the wrist, hand or fingers); Encephalopathy with EEG disturbances (damage or malfunction of the brain with severity ranging from altered mental status to dementia, seizures and coma); Grand Mal Convulsion (loss of consciousness and violent muscle contractions); Sudden Infant Death Syndrome (sudden death of infant in good health); Diabetes mellitus (chronic, lifelong condition effecting ability to use*

*energy found in food); Pancreatitis (pancreas attacks its own digestive enzymes); Encephalomyelitis (inflammation of the brain and spinal cord); Transverse myelitis (autoimmunity causing inflamed spinal cord which may result in paralysis); Pneumonitis (inflammation of lung tissue); Ocular Palsies (damage to the nerve of the eye that controls eye movement); Ataxia (brain damage resulting loss of full control of bodily movement, impaired speech, eye movement, and swallowing); Retrobulbar Neuritis (inflammation and damage to the optic nerve between the back of the eye and the brain); Epididymitis (inflammation testicle tube which can lead to abscess formation, testicular pain, painful urination, tissue death, and decreased functionality of gonads); Orchitis (inflammation of one or more testicles that can cause infertility, testicular atrophy, pain, and severe pain); Nerve Deafness (hearing loss from damage to the nerve that runs from the ear to the brain).<sup>133</sup>*

## IV. CONFLICTS OF INTEREST IN VACCINE SAFETY

---

The 1986 Act created a system in which vaccines are licensed, recommended, encouraged, subsidized, and defended by HHS (the **Vaccine Program**).

The lack of evidence supporting vaccine safety is partially the result of the 1986 Act's unfortunate scheme which places the same agency, HHS, in charge of two conflicting duties. On the one hand, HHS is responsible for vaccine safety. On the other hand, HHS is simultaneously required to promote vaccine uptake and defend against any claim that vaccines cause any harm.

Regrettably, it appears that HHS has chosen to focus almost entirely on its vaccine promotion and defense responsibilities to such a degree that it has essentially abandoned its vaccine safety responsibility.

The Vaccine Program has transformed what should be a government watchdog over the pharmaceutical industry with regard to vaccines into an industry partner, with the same interests of promoting and literally defending, with the Department of Justice (**DOJ**) as its defense firm, against any claim of

---

<sup>133</sup> See vaccine products inserts at <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>

vaccine injury. The result – as reflected in scathing reports by Congress and the HHS Inspector General – is that the Vaccine Program is fraught with pervasive conflicts of interests both structurally and literally with pharmaceutical company insiders.

Usually, when a government watchdog becomes ineffective or conflicted, consumers turn to the last line of recourse against harm caused by a product: class action and product liability attorneys. But in the case of vaccines, even they have been neutered because of the immunity from financial liability given to pharmaceutical companies for harms caused by their vaccines.

The Vaccine Program created by the 1986 Act has unfortunately resulted in a complete lack of accountability for vaccine safety.

## 1. HHS Licenses Vaccines

---

The introduction of a new vaccine begins with its licensure by the FDA. A committee at the FDA, the Vaccines and Related Biological Products Advisory Committee (VRBPAC), “advises the FDA on whether or not to license new vaccines for commercial use.”<sup>134</sup> In reality this committee effectively decides whether a new vaccine gets licensed since its recommendations for licensure are almost always accepted by the FDA. Unfortunately, the members of this board are often pharmaceutical insiders and, as discussed in Section II above, they license vaccines with virtually no safety data.

By the year 2000, most pediatric vaccines on the CDC’s vaccine schedule were already licensed by the FDA. That same year, the U.S. House of Representatives’ Committee on Government Reform (the **Committee**) issued a report revealing serious conflicts of interest in the VRBPAC.<sup>135</sup> The Committee “determined that conflict of interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings.”<sup>136</sup> The Committee further explained that:

*Perhaps one of the major problems contributing to the overall influence of the pharmaceutical industry over the vaccine approval and recommendation process may be the loose standards that are used by the agency in determining whether a conflict actually exists. In many cases, significant conflicts of interest are not deemed to be conflicts at all.*<sup>137</sup>

For instance, the Committee found that “3 out of 5 FDA advisory committee [VRBPAC] members who voted to approve the rotavirus vaccine in December 1997 [then the most recently approved vaccine by the VRBPAC] had financial ties to pharmaceutical companies that were developing different versions of the vaccine.”<sup>138</sup>

Among these five VRBPAC members present and voting to license the rotavirus vaccine: one member’s employer had a \$9,586,000 contract for a rotavirus vaccine;

---

<sup>134</sup> <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

<sup>135</sup> <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

<sup>136</sup> Ibid.

<sup>137</sup> Ibid.

<sup>138</sup> Ibid.

another member was the principal investigator for a grant from Merck for the development of a rotavirus vaccine; two other members received almost \$1,000,000 from vaccine manufacturers toward vaccine development; and even the “consumer advocate” member (an ardent vaccine supporter) had received honoraria, in addition to travel expenses, from Merck.<sup>139</sup>

These members voted to approve this pediatric vaccine even though a temporary voting member raised the following concern: “I would ask the FDA to work with the sponsor to further quantitate what these serious side effects are – specifically the adverse effects, driven in particular by febrile illness – is inducing hospitalizations and what is that level of access. I still don’t feel like I have a good grasp of that at this point.”<sup>140</sup>

Regarding the VRBPAC, the Committee concluded: “The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry.”<sup>141</sup> Hence, even putting aside the astonishing lack of safety review prior to licensure, extensive conflicts were found to pervade the HHS committee that largely determined whether to license the pediatric vaccines currently on the market.

## 2. HHS Recommends Vaccines

---

After a pediatric vaccine is licensed with virtually no safety data by an HHS

committee rife with conflicts of interest, another HHS committee, the CDC’s Advisory Committee on Immunization Practices (ACIP), decides whether to recommend the vaccine for all children in America.

ACIP is the only federal entity to make vaccination recommendations and these recommendations are consistently approved by the CDC.<sup>142</sup> A recommendation by ACIP “for routine use of a vaccine is tantamount to a Federal mandate for vaccine use.”<sup>143</sup> This is because “HHS regulations require that all grants for childhood immunizations are subject to the States’ implementation of procedures to ensure routine vaccination ... [and] vigorous enforcement of school immunization laws.”<sup>144</sup>

ACIP-recommended vaccines are also subsidized by the federal government.<sup>145</sup> In fact, 41% of the entire childhood vaccine market is purchased through ACIP resolutions.<sup>146</sup> This currently amounts to over \$4 billion paid to vaccine makers by the CDC, accounting for a third of the CDC’s current budget.<sup>147</sup>

Putting all this together: as a result of the 1986 Act, **when the ACIP votes to recommend a pediatric vaccine for general use, the pharmaceutical industry is handed a liability-free, captive market of 78 million children with guaranteed payment.** It is not surprising that with this economic incentive,

without needing additional Congressional appropriations. As pointed out by the CDC: “It is unusual that a federal advisory committee has the power and authority to add benefits to an entitlement program.” It is also noteworthy that another 11% of the pediatric vaccine market is purchased through other Congressional appropriations and another 5% from state and local government funding.)

<sup>147</sup> <https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf>

---

<sup>139</sup> Ibid.

<sup>140</sup> Ibid.

<sup>141</sup> Ibid.

<sup>142</sup> Ibid.

<sup>143</sup> Ibid.

<sup>144</sup> Ibid.

<sup>145</sup> <https://doi.org/10.1086/420748>

<sup>146</sup> Ibid. (Once ACIP votes to add a vaccine to the Vaccine for Children program, payment is provided to vaccine makers

the vaccine market has catapulted from \$170 million in 1982 to over \$33 billion in 2016.<sup>148</sup>

Given these economic incentives, it is obvious that the ACIP should be scrupulously shielded from even an apparent – let alone actual – conflict of interest with vaccine makers. Unfortunately, government reports have found the exact opposite.

The ACIP is comprised of 15 voting members that are *not* federal government employees. Fourteen of these voting members must be medical professionals in the area of immunization.<sup>149</sup> There are also eight non-voting members who represent federal agencies with responsibility for immunization programs and an additional 26 non-voting members of liaison organizations, many of which receive financial support from vaccine makers.<sup>150</sup> As the U.S. House Committee on Government Reform concluded:

*The absence of any consumer advocates on the ACIP has resulted in an advisory committee that is inherently not 'fairly balanced.'*<sup>151</sup>

Far worse than the structural conflicts in ACIP's composition are the actual conflicts of interests of its members. These conflicts have been highlighted by multiple government reports but due to gridlock and disparate influence on Congress by pharmaceutical companies, Congress has never moved to fix the issues and conflicts it has identified.

One investigation by the U.S. House Committee on Government Reform resulted in a June 15, 2000 report entitled *Conflicts of Interest in Vaccine Policy Making*.<sup>152</sup> The Committee found that ACIP members routinely fail to disclose conflicts with vaccine manufacturers.<sup>153</sup> Moreover, as a matter of routine, “[t]he CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts, for the entire year.”<sup>154</sup> In the congressional inquiry, legal counsel for the ACIP *conceded* that even when serious conflicts are identified, “we generally give them [waivers] to everyone ... we give them out freely.”<sup>155</sup> The Committee on Government Reform was troubled:

*The CDC's policy of issuing annual waivers creates an environment where people do not take the conflict of interest issue as seriously as they should. This policy, in concert with sloppy monitoring of the completeness of members' financial disclosure statements, allows for a clubby environment where ethical concerns are downplayed.*<sup>156</sup>

As an example of this “clubby environment,” the Committee found: “Members of the ACIP are allowed to vote on a recommendation for one company's vaccine even if they have

<sup>148</sup> <https://www.bccresearch.com/market-research/pharmaceuticals/vaccine-technologies-markets-report-phm014f.html>;

<https://www.ncbi.nlm.nih.gov/books/NBK216815/>

<sup>149</sup> <https://www.cdc.gov/vaccines/acip/committee/downloads/nominations.pdf>

<sup>150</sup> <https://www.cdc.gov/vaccines/acip/committee/acip-charter-2016.pdf>

<sup>151</sup> <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

<sup>152</sup> Ibid.

<sup>153</sup> Ibid.

<sup>154</sup> Ibid.

<sup>155</sup> Ibid.

<sup>156</sup> Ibid.

financial ties to a competing firm developing a similar vaccine.”<sup>157</sup>

Highlighting these conflict issues, the Committee drew focus on the vaccine most recently approved by the ACIP, a rotavirus vaccine, and whatever conflicts they could identify for the eight members of the ACIP that voted to approve that vaccine for routine pediatric use.<sup>158</sup> The Committee’s findings were damning: (1) The chairman served on Merck’s Immunization Advisory Board; (2) another member, who shared the patent on a rotavirus vaccine, had a \$350,000 grant from Merck to develop the vaccine, and was a consultant for Merck; (3) another member was under contract with the Merck Vaccine Division and received funds from various vaccine makers including Pasteur, and was a principal investigator for SmithKline; (4) another member received a salary and other payments from Merck; (5) another member participated in vaccine studies with Merck, Wyeth, and SmithKline; and (6) another member received grants from Merck and SmithKline.<sup>159</sup>

The Committee was deeply troubled that these members were nonetheless allowed to vote to recommend a pediatric vaccine for universal use.<sup>160</sup>

The Committee was further concerned by its finding that “ACIP liaison representatives have numerous ties to vaccine manufacturers.”<sup>161</sup> The Committee found that these liaison members, through whom third-party organizations are permitted to provide

opinions regarding a vaccine under review, “provide more than just the opinions.”<sup>162</sup> The Committee found them “more like” a voting member of ACIP “than an advisory representative.”<sup>163</sup> The advice of these liaison representatives “is solicited frequently by CDC personnel on issues where their organization has a financial interest.”<sup>164</sup>

The ACIP also routinely forms subcommittees (called “working groups”) which convene behind closed doors and whose recommendations are typically rubber stamped by the ACIP.<sup>165</sup> The Committee was troubled by extensive and routine use of working groups since the participants in these working groups often had conflicts which would have prohibited them from voting during an actual ACIP meeting.<sup>166</sup> The Committee explained: “The ACIP’s prolific use of working groups to draft vaccine policy recommendations outside the specter of public scrutiny opens the door to undue special interest access.”<sup>167</sup> Regarding the ACIP’s most recent working group recommending approval of a vaccine, the Committee found:

*The working group has ten members, seven of whom have identifiable conflicts of interest with vaccine manufacturers or vaccine interest groups. The group’s meetings were held in private with no minutes or records of the proceedings taken. It appears that members who were not allowed to vote because of conflicts of interest ... were allowed to work*

---

<sup>157</sup> Ibid.

<sup>158</sup> Ibid.

<sup>159</sup> Ibid.

<sup>160</sup> Ibid.

<sup>161</sup> Ibid.

<sup>162</sup> Ibid.

<sup>163</sup> Ibid.

<sup>164</sup> Ibid.

<sup>165</sup> Ibid.

<sup>166</sup> Ibid.

<sup>167</sup> Ibid.

*extensively on the recommendation for a long period of time in the working group.*<sup>168</sup>

The Committee's damning overall conclusion was that ACIP's process for recommending a vaccine reflected "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."<sup>169</sup>

After the Committee's scathing report in 2000, one would expect nothing less than drastic reform of ACIP – something that would differentiate it from a biased and self-interested pharmaceutical company board so that the interests of American children are placed ahead of the companies with the resources to influence government. This expectation unfortunately has not been fulfilled.

Indeed, in December 2009, the HHS Office of Inspector General issued another report after an extensive review of the conflicts of CDC's advisory committee members, known as Special Government Employee (SGEs), with the first among these committees being the ACIP.<sup>170</sup> The Inspector General found that the "CDC had a systemic lack of oversight of the ethics program for SGEs."<sup>171</sup> For example, the Inspector General found that: "Most of the experts who served on advisory panels in 2007 to evaluate vaccines for flu and cervical cancer had potential conflicts that were never resolved."<sup>172</sup>

The Inspector General reached this conclusion after reviewing the conflict forms, Form 450's, filed by SGEs at the CDC. CDC "must obtain from SGEs" a completed Form 450, which includes "assets, sources of income, and non-income-earning activities."<sup>173</sup> Then, "[b]efore permitting SGEs to participate in committee meetings, CDC must review these forms and certify them to indicate that they are complete and that it has identified and resolved all conflicts of interest."<sup>174</sup> Reviewing CDC's compliance with these requirements, the Inspector General found that nothing had changed in the years since the scathing Congressional Committee on Government Reform report in 2000.<sup>175</sup>

Indeed, the Inspector General found that "CDC certified OGE Forms 450 with at least one omission in 2007 for 97 percent ... of SGEs."<sup>176</sup> Almost all of these "had more than one type of omission."<sup>177</sup> Compounding this problem, the Inspector General found that "58 percent ... of SGEs had at least one potential conflict of interest that CDC did not identify."<sup>178</sup> Splicing down this 58% of unidentified conflicts, 40% involved employment or grants, 13% involved equity ownership, and 5% involved consulting.<sup>179</sup>

These conflicts are serious, and the CDC "did not inform the SGEs that they would violate the criminal conflict-of-interest statute if they participated in committee work regarding particular matters affecting their specific employers' financial interests."<sup>180</sup>

---

<sup>168</sup> Ibid.

<sup>169</sup> Ibid.

<sup>170</sup> <https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf>

<sup>171</sup> Ibid.

<sup>172</sup> <http://www.nytimes.com/2009/12/18/health/policy/18cdc.html?mcubz=0>

<sup>173</sup> <https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf>

<sup>174</sup> Ibid.

<sup>175</sup> Ibid.

<sup>176</sup> Ibid.

<sup>177</sup> Ibid.

<sup>178</sup> Ibid.

<sup>179</sup> Ibid.

<sup>180</sup> Ibid.

The Inspector General further concluded that even when the CDC actually identified a conflict, the CDC improperly granted broad waivers despite already being castigated for this improper practice in 2000.<sup>181</sup> Even worse, “32 percent ... of SGEs with certified forms had at least one potential conflict of interest that CDC identified but did not resolve.”<sup>182</sup> Amazingly, 13 percent of SGEs were allowed to participate in committee meetings without even having a Form 450 on file.<sup>183</sup>

In sum, even after the blistering 2000 Committee on Government Reform report, and numerous damning Congressional hearings before that committee regarding CDC’s conflicts with vaccine makers, little changed.<sup>184</sup> Instead of resolving and avoiding these conflicts, the “incestuous relationship” between the CDC and vaccine makers has apparently become even more hardened and enmeshed.<sup>185</sup>

Since an ACIP vote to recommend a vaccine hands a vaccine maker a liability-free market of 78 million American children with guaranteed payment, an ACIP vote must be completely insulated from any influence by pharmaceutical companies. Instead, the ACIP and its working groups, are inundated with conflicts of interest and ties to these companies.

### 3. HHS Promotes Vaccines

---

Not only is the process for licensing and recommending vaccines riddled with conflicts, so is HHS’s process for promoting vaccines.

While the CDC states on its website – not less than 130 times – that “CDC does not accept commercial support,” this is simply not true.<sup>186</sup> For example, in reviewing this very issue, the British Medical Journal, which it asserts is “one of the world’s most influential and widely read medical journals,” reported in 2015:

*The CDC’s image as an independent watchdog over the public health has given it enormous prestige, and its recommendations are occasionally enforced by law. Despite the agency’s disclaimer, the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking.*<sup>187</sup>

Explaining the concern with CDC receiving industry funding, the Journal described this as “classic stealth marketing, in which industry puts their message in the mouths of a trusted third party [here the CDC].”<sup>188</sup> The Journal quoted a methodologist and emeritus professor of medicine at UCLA stating, “Most of us were shocked to learn the CDC takes

---

<sup>181</sup> Ibid.

<sup>182</sup> Ibid.

<sup>183</sup> Ibid.

<sup>184</sup> Compare <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf> with Ibid.

<sup>185</sup> [https://cdn.voiceamerica.com/health/010278/arranga\\_040814.mp3](https://cdn.voiceamerica.com/health/010278/arranga_040814.mp3)

<sup>186</sup> <https://search.cdc.gov/search?query=%22cdc+does+not+accept+commercial+support%22&utf8=%E2%9C%93&affiliate=cdc-main>

<sup>187</sup> <http://vapors.org.uk/wp-content/uploads/2015/05/CDC-Industry-Funding.pdf>

<sup>188</sup> Ibid.

funding from industry,” adding that, “it is outrageous that industry apparently is allowed to punish the CDC if the agency conducts research that has the potential to cut into profits.”<sup>189</sup>

As another example, Congress expressly created a private foundation, the “CDC Foundation,” through which private entities, such as pharmaceutical companies, can support programs at the CDC, endow positions at the CDC, and even place individuals to work at the CDC, paid through “private funding.”<sup>190</sup>

Since 1995 the CDC Foundation has raised \$620 million to pay for 824 programs at the CDC.<sup>191</sup> In 2015 alone, the CDC Foundation raised \$157 million for privately funded programs at the CDC, which then obtain the stamp of legitimacy of the CDC.<sup>192</sup> Merck, for example, funded an \$832,916 program through the CDC Foundation to “expand CDC’s ... viral hepatitis prevention and vaccination activities.”<sup>193</sup> As a result, the CDC is reliant on the CDC Foundation for the continued funding of these projects, and even for the services of the staff placed at the CDC by the CDC Foundation, since the CDC is only permitted to use these funds as expressly directed by the CDC Foundation.<sup>194</sup> This foundation even funds and thus directs CDC “management training courses.”<sup>195</sup>

Worse, the promotion track for CDC management extends into vaccine makers.

The most prominent example is former CDC Director Dr. Julie Gerberding who headed the CDC from 2002 to 2009. Dr. Gerberding oversaw several controversial studies regarding vaccines produced by Merck, including notably the MMR vaccine, which sought to silence those calling for an increase in the safety profile of those vaccines. When she left the CDC she was rewarded with the position of President of Merck Vaccines in 2010 with a reported estimated \$2.5 million annual salary and lucrative stock options.<sup>196</sup>

In contrast, the few CDC officials who have attempted to blow the whistle on how vaccine safety research is conducted and treated at the CDC have become targets of character assassination. For example, following revelations of Dr. Thompson’s statements regarding the CDC’s improper conduct<sup>197</sup> (some of which was discussed above), he soon found himself marginalized and publicly maligned, despite the CDC’s prior reliance on him for over a decade to produce most of its core vaccine safety science.<sup>198</sup>

As Congressman Bill Posey explained in 2014 after investigating the CDC’s approach to vaccine safety: the CDC and vaccine industry’s “media network [will] twist the truth to disparage, to malign, to vilify, to denigrate anybody who wants any kind of accountability” and added that his review of CDC emails discussing vaccine safety “will make you absolutely sick to your stomach.”<sup>199</sup>

---

<sup>189</sup> Ibid.

<sup>190</sup> [42 U.S.C.A. §§ 280e-11\(h\)\(1\), \(2\)](#)

<sup>191</sup> <http://www.cdcfoundation.org/FY2015>

<sup>192</sup> Ibid.

<sup>193</sup> Ibid.

<sup>194</sup> [42 U.S.C.A. § 280e-11\(h\)\(2\)\(a\), \(7\)\(b\)](#)

<sup>195</sup> <https://www.cdcfoundation.org/sites/default/files/upload/pdf/CDCF-Form990-2014.pdf>

<sup>196</sup> <https://www.sec.gov/cgi-bin/own-disp?action=getowner&CIK=0001628884>

<sup>197</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

<sup>198</sup> <https://www.ncbi.nlm.nih.gov/pubmed/?term=Thompson+WW%5BAuthor%5D>

<sup>199</sup> <https://cdn.voiceamerica.com/health/010278/arranga040814.mp3>

#### 4. HHS Defends Vaccines

---

After HHS licenses, effectively mandates, and promotes a vaccine to 78 million American children with virtually no safety data, *this very same government agency is mandated to defend against any claim that the vaccine caused harm.* There is no other product where the very agency responsible to regulate a product and assure its safety is statutorily required to defend against any claim it causes harm.

The Vaccine Injury Compensation Program (**VICP** or **Vaccine Court**) is effectively the only legal recourse in America to obtain compensation for a pediatric vaccine injury.<sup>200</sup> The injured must file a claim in the VICP and litigate against HHS and the DOJ in a quasi-judicial process filed under seal where the injured child effectively cannot obtain documents from or depose vaccine makers to prove how the vaccine caused injury.<sup>201</sup> There is no jury, nor even a judge; special masters play the role of trial judges, with the final say.<sup>202</sup> DOJ and HHS have the government's vast resources while the injured must secure a private attorney.<sup>203</sup> Moreover, an injured child's damages are limited to \$250,000 for death and pain and suffering.<sup>204</sup>

Worst of all, despite these limitations, the injured child must *still* almost always prove "causation" – the biological mechanism by which the vaccine caused the claimed injury. Requiring an injured child to prove causation adds insult to injury because, sadly, had HHS conducted the vaccine safety science it demands as proof in the VICP before

licensing a vaccine, the child's injury may have been avoided altogether.

There is a disconnect in requiring a child receiving a compulsory pharmaceutical product to medically prove how the vaccine caused his or her injury, where the science to understand vaccine injuries is not being done by the government agency tasked with this job.<sup>205</sup> As confirmed by the IOM, HHS has not conducted the basic science needed to even determine whether commonly claimed vaccine injuries are caused by vaccines.<sup>206</sup> It has failed to conduct even one properly sized study comparing vaccinated to unvaccinated children, despite all the resources at its disposal.<sup>207</sup> It therefore may not be surprising that the Federal Circuit Court of Appeals found, medical science is "a field bereft of complete and direct proof of how vaccines affect the human body."<sup>208</sup>

The Committee on Government Reform explained the devastating consequences suffered by families when children are injured by a vaccine:

*Every year, a number of children are seriously injured by adverse reactions to vaccines. When such a tragedy befalls a family, they are faced with devastating emotional and financial consequences. As the devastation of adverse reactions can lead to paralysis, permanent disability and death, families without adequate insurance can face enormous expenses, including*

---

<sup>200</sup> [42 U.S.C. § 300aa-10 et seq.](#)

<sup>201</sup> [42 U.S.C. § 300aa-12](#)

<sup>202</sup> *Ibid.*

<sup>203</sup> [42 U.S.C. § 300aa-15](#)

<sup>204</sup> *Ibid.*

<sup>205</sup> See Sections II and III above.

<sup>206</sup> See Section III(2) above.

<sup>207</sup> See Section III(6) above.

<sup>208</sup> [Althen v. Secretary of Health and Human Services, 418 F.3d 1274 \(Fed. Cir. 2005\)](#)

*residential care, therapy, medical equipment, and drugs.*<sup>209</sup>

Yet it is left to the injured child to prove the physiological mechanics by which the vaccine caused injury.<sup>210</sup>

Moreover, Congress left HHS with the authority to set the rules for the VICP and so HHS has used this authority to shortcut its defense of claims for vaccine injuries by changing the rules in its favor. Indeed, the 1986 Act created a Vaccine Injury Table (the **Table**) which quickly compensated certain common injuries associated with each vaccine.<sup>211</sup> If the petitioner suffered an injury on the Table, the burden would shift to HHS to prove the vaccine did not cause the injury.<sup>212</sup> After passage of the 1986 Act, almost 90 percent of claims were Table claims and were quickly settled.<sup>213</sup> Soon after, in 1995 and 1997, HHS amended the Table such that 98% of new claims are off-Table.<sup>214</sup> This change greatly increased the difficulty of obtaining compensation for vaccine injuries.

While HHS changes the VICP rules in its favor, the Committee on Government Reform found “DOJ attorneys make full use of the apparently limitless resources available to them,” “pursued aggressive defenses in

compensation cases,” and “establish[ed] a cadre of attorneys specializing in vaccine injury” and “an expert witness program to challenge claims.”<sup>215</sup> The Committee even noted a VICP decision which stated:

*In the special master’s view, [HHS’s] counsel’s abrasive, tenacious, obstreperous litigation tactics were inappropriate in a program that is intended to be less adversarial; and hindered greatly a fair, expeditious resolution of the case. In addition, counsel lacks simply tact and compassion. Quite frankly; the special master is embarrassed that [HHS’s] counsel and ... life care planner represented the United States Government in this case.*<sup>216</sup>

The length of time it has taken to adjudicate claims has also multiplied such that over half of claims now take over five years.<sup>217</sup>

Even with all the foregoing barriers to obtaining compensation for a vaccine injury – notably requiring injured children to prove causation and capping damages for pain and suffering and death at \$250,000 – the VICP has paid over \$2.1 billion dollars for vaccine injury claims since 2007 and over \$3.7 billion since 1986.<sup>218</sup> Just a few of the serious vaccine injuries for which the VICP has paid include:

<sup>209</sup> <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>

<sup>210</sup> Further compounding the above issues, babies are unable to describe their symptoms which may explain why most VICP claims are filed by adults. Most adults bring claims for injury after a single flu shot. ([https://www.hrsa.gov/vaccinecompensation/data/vicpmonthlyreporttemplate8\\_1\\_17.pdf](https://www.hrsa.gov/vaccinecompensation/data/vicpmonthlyreporttemplate8_1_17.pdf)) In contrast, babies receive between five and seven injections of numerous vaccine doses at two months, four months, six months, etc. (See Section I above.) If babies could talk, they may be able to explain why they are crying inconsolably, have decreased activity/lethargy, drowsiness, irritability, fussiness, and loss of appetite – reactions that are considered “normal” side effects of vaccination. (See vaccine product inserts at <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm>

<093833.htm>) But since babies can’t talk, the symptoms which would explain a neurological injury, for example, are not knowable until later in life when it is too late to assert a claim.

<sup>211</sup> <https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf>

<sup>212</sup> 42 U.S.C. § 300aa-13

<sup>213</sup> *Stevens v. Secretary of the Department of Health & Human Services*, No. 99-594V (Office of Special Masters 2001)

<sup>214</sup> <http://www.gao.gov/assets/670/667136.pdf>

<sup>215</sup> <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>

<sup>216</sup> *Ibid.*

<sup>217</sup> <http://www.gao.gov/assets/670/667136.pdf>

<sup>218</sup> [https://www.hrsa.gov/vaccinecompensation/data/vicpmonthlyreporttemplate8\\_1\\_17.pdf](https://www.hrsa.gov/vaccinecompensation/data/vicpmonthlyreporttemplate8_1_17.pdf); 42 U.S.C.A. § 300aa-15(a)(2), (4)

*Guillain-Barre Syndrome, Transverse Myelitis, Encephalopathy (disease altering brain function), Seizure Disorder, Death, Brachial Neuritis, CIDP (inflammation damaging the brain and spinal cord), Acute Disseminated Encephalomyelitis, Premature Ovarian Failure, Bell's Palsy, Idiopathic Thrombocytopenic Purpura (ITP) (autoimmune disease of the blood), Juvenile Diabetes, Rheumatoid Arthritis, Multiple Sclerosis, Fibromyalgia, Infantile Spasms, Anaphylaxis, Ocular Myasthenia Gravis (autoimmune condition causing visual impairments), Hypoxic Seizure*<sup>219</sup>

Recognizing the depths of the foregoing issues and conflicts, in 2006 a bipartisan group of seven congressmen proposed a bill to create an entirely new government agency solely devoted to vaccine safety.<sup>220</sup> The primary sponsor of this bill explained the need for this bill as follows:

*Federal agencies charged with overseeing vaccine safety research have failed. They have failed to provide sufficient resources for vaccine safety research. They have failed to fund extramural research. And, they have failed to free themselves from conflicts of interest that serve to undermine public confidence in the safety of vaccines.*

*The American public deserves better and increasingly parents and the public at large are demanding better.*

*I'm a physician. ... When I first began working on this issue about seven years ago, I was shocked at the dearth of resources dedicated to vaccine safety research. ...*

*When I first tasked my staff with investigating this issue we got a lot of confused responses from federal agencies. The FDA told us to check in with the CDC, saying CDC did most of the vaccine safety research. The CDC referred us over to the NIH. Then, the NIH referred us back to the CDC. ...*

*Several issues relating to vaccine safety have persisted for years. The response from public health agencies has been largely defensive from the outset and the studies plagued by conflicts of interest. ...*

*Presently, vaccine safety research is an in-house function conducted predominantly by the CDC – the very agency that makes vaccine*

<sup>219</sup> See, e.g., *Kuperus v. Sec'y of the HHS*, No. 01-0060V, 2003 U.S. Claims LEXIS 397 (Fed. Cl. Oct. 23, 2003) (Acute Disseminated Encephalitis from DTaP); *Lerwick v. Sec'y of HHS*, No. 06-847V, 2010 U.S. Claims LEXIS 398 (Fed. Cl. May 26, 2010) (Acute Disseminated Encephalitis from DTaP); *Price v. Sec'y of HHS*, No. 11-442V, 2015 U.S. Claims LEXIS 1554 (Fed. Cl. Oct. 29, 2015) (Anaphylaxis from DTaP); *Rodriguez v. Sec'y of the HHS*, No. 06-559V, 2007 U.S. Claims LEXIS 685 (Fed. Cl. Sep. 14, 2007) (Death from DTaP); *Harry Tembenis & Gina Tembenis v. Sec'y of HHS*, No. 03-2820V, 2010 U.S. Claims LEXIS 950 (Fed. Cl. Nov. 29, 2010) (Death from DTaP); *Agresti v. Sec'y of HHS*, No. 05-0752V, 2009 U.S. Claims LEXIS 517 (Fed. Cl. Mar. 17, 2009) (Encephalopathy from DTaP); *Corzine v. Sec'y of the HHS*, No.

[01-230V](#), 2004 U.S. Claims LEXIS 116 (Fed. Cl. Apr. 23, 2004) (Hypoxic seizure leading to Death from DTaP); *Loving v. Sec'y of HHS*, No. 02-469V, 2013 U.S. Claims LEXIS 1570 (Fed. Cl. Sep. 20, 2013) (Infantile Spasms and Seizure Disorder from DTaP); *Herrell v. Sec'y of the HHS*, No. 08-123V, 2009 U.S. Claims LEXIS 577 (Fed. Cl. Jan. 6, 2009) (Idopathic Thrombocytopenic Purpura from MMR); *Zatuchni v. Sec'y of HHS (In re Snyder)*, No. 94-58V, 2006 U.S. Claims LEXIS 127 (Fed. Cl. May 10, 2006) (Fibromyalgia leading to death from MMR); *Francis v. Sec'y of the HHS*, No. 99-520V, 2007 U.S. Claims LEXIS 172 (Fed. Cl. May 23, 2007) (Ocular Myasthenia Gravis from Varicella).

<sup>220</sup> <https://www.congress.gov/bill/109th-congress/house-bill/5887>

*recommendations and promotes their uptake. This should not be.*<sup>221</sup>

This bill did not get out of committee, a fact which likely reflects the ratio of over 1,000 pharma lobbyists in Washington D.C. to virtually no vaccine safety lobbyists.

Many parents, doctors and scientists, as well as politicians, are legitimately concerned about the process whereby vaccines are licensed, recommended, promoted and defended by the same department. This is not because of any conspiracy, or belief in an insidious intent. Rather, the problem is with the structural conflicts and incentive scheme this system creates. There is no incentive for research to

uncover which long-term chronic conditions, including which immune and neurological disorders – which *can* clearly result from the current vaccination schedule – are caused by vaccines. Even worse is the disincentive to uncover susceptible populations to vaccine injury. The burden of judging whether a vaccine will seriously injure a child therefore falls on the child's parents. But unless parents can identify with scientific accuracy how a vaccine will injure their child, parents cannot obtain a medical exemption from vaccinating their child. Worse, when a child is injured, the burden again falls on the parent to prove how the vaccine injured their child. This system is inherently unfair and unjust.

## CONCLUSION

---

We can do better. With hundreds of vaccines in the pipeline we must do better. Children susceptible to vaccine injury are as deserving of protection as any other child. Avoiding injury to these children is not only a moral and ethical duty, but will, in fact, strengthen the Vaccine Program. Every parent that does not witness their child suffer a serious reaction after vaccination, such as a seizure or paralysis, is another parent that will not add their voice to the growing chorus of parents opposed to the Vaccine Program due to safety concerns.

These parents and their kindred doctors, scientists and politicians, are also in fact correct that the system for vaccine safety is broken. While we know that vaccines can

cause serious adverse reactions, the studies to quantify the rate at which it causes these harms have never been done. While we know that certain children are predisposed to serious injury from vaccines, the studies to identify which children are so disposed have never been done. While we know that valid pre-licensure safety trials take years and must use an inert placebo control, such pre-licensure safety trials are never done for any vaccine. While we know that post-licensure surveillance of vaccines captures less than one percent of adverse reactions, the CDC refused to cooperate to automate VAERS reporting.

In the zeal to protect the Vaccine Program the primary objective of protecting every child to the greatest extent possible from

---

<sup>221</sup> [http://vaccine-safety.s3.amazonaws.com/Weldon\\_Statement\\_Vaccine\\_Safety\\_final.pdf](http://vaccine-safety.s3.amazonaws.com/Weldon_Statement_Vaccine_Safety_final.pdf)

harm has been lost. Every child susceptible to a vaccine injury or injured by a vaccine deserves better.

The good news is that fixing this system is not complicated and would require a tiny fraction of the resources already devoted to the Vaccine Program. The quickest solution would be to repeal the 1986 Act and let normal market forces drive vaccine safety. Alternatively, the following actions would immediately correct many of the issues identified in this white-paper:

### **Reduce Conflicts**

1. Prohibit any conflict waivers for members of HHS's vaccine committees.<sup>222</sup>
2. Prohibit HHS vaccine committee members or employees from accepting any compensation from a vaccine maker for twenty years.
3. Require that vaccine safety advocates comprise at least half of HHS's vaccine committees.

### **Increase Safety Profile**

4. Conduct prospective double-blind saline-placebo controlled studies of each vaccine recommended by the CDC as well as the entire CDC vaccine schedule.
5. Conduct properly sized and controlled retrospective and prospective safety studies

comparing total health outcomes between vaccinated children and completely unvaccinated children.

6. Create a vaccine safety agency independent of HHS with a budget equal to 50% of HHS's budget for promoting and purchasing vaccines.
7. Automate creation and transmission of adverse reactions reports at hospital/clinic to VAERS.

---

<sup>222</sup> HHS's vaccine committees include the Advisory Committee on Immunization Practices (ACIP), the Vaccine and Related

Biological Products Advisory Committee (VRBPAC), the National Vaccine Advisory Committee (NVAC), and the Advisory Commission on Childhood Vaccines (ACCV).

## APPENDIX: Vaccine Ingredients

---

Most pediatric vaccines do not contain live viruses.<sup>223</sup> For example, (i) polio vaccine (IPV) only contains a killed virus, (ii) hepatitis b vaccine contains a portion of a killed virus, and (iii) diphtheria vaccine contains only a modified toxin released by the diphtheria bacteria.<sup>224</sup> These pieces of killed bacteria or virus or modified toxins are commonly referred to as “antigens.” An injection of antigen alone, with nothing more, produces a weak immune response insufficient for creating long-term immunity.<sup>225</sup>

Therefore, many vaccines also contain an “adjuvant,” an immune-stimulating substance that increase the immune response to the antigen, so that immunity is created. Aluminum compounds are by far the most commonly used adjuvants in vaccines. They are made of particles of aluminum hydroxide, aluminum phosphate or aluminum sulfate, or mixtures thereof.<sup>226</sup>

It is universally accepted that aluminum is a potent neurotoxin, and toxic to all life.<sup>227</sup> Accordingly, the FDA has established strict limits for aluminum in intravenous feeding solutions (.000005 grams per kg body weight per day). Exposure in infants exceeding this limit causes long term cognitive impairment.<sup>228</sup>

A significant safety problem with aluminum adjuvants is that, because they are made of microscopic particles, they can travel into the brain.<sup>229</sup> Once in the brain, aluminum adjuvants cause long term chronic inflammation.<sup>230</sup>

Inflammation in the brain is a cause of neurodevelopmental disorders (e.g. autism) and mental illnesses (e.g. schizophrenia).<sup>231</sup> The resulting mental illness can occur years or decades after the inflammation starts.<sup>232</sup>

Exposure to aluminum adjuvants has increased dramatically in the last 50 years, in parallel with the increasing incidence of neurodevelopmental disorders in children.<sup>233</sup>

Some vaccines also contain other biological matter, both intended and unintended.<sup>234</sup> These include cell lines from aborted human fetuses and biological material from animal tissue.<sup>235</sup> Before being killed in the vaccine manufacturing process, the virus, disease, or toxin (against which the vaccine is supposed to protect) is grown on these human and biological mediums.<sup>236</sup>

Human cell portions in vaccines disclosed by the CDC include “human albumin, human diploid cell cultures (WI-38), human embryonic lung cultures, WI-38 human diploid lung fibroblasts, MRC-5 (human diploid) cells, MRC-5 cells, residual components of MRC-5 cells including DNA and protein, [and] recombinant human albumin.”<sup>237</sup> These human cell portions also include billions of strands of human DNA from these aborted fetal cells lines that are of a length capable of inserting themselves into DNA to which they are exposed.<sup>238</sup>

<sup>223</sup> <https://www.vaccines.gov/basics/types/index.html>

<sup>224</sup> Ibid.

<sup>225</sup> <https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html>

<sup>226</sup> Ibid.

<sup>227</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2940082>;  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2819810/>;  
<https://www.ncbi.nlm.nih.gov/pubmed/23932735>

<sup>228</sup> <https://www.ncbi.nlm.nih.gov/pubmed/9164811>

<sup>229</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23557144>

<sup>230</sup> <https://www.ncbi.nlm.nih.gov/pubmed/27908630>;

<https://www.ncbi.nlm.nih.gov/pubmed/19740540>

<sup>231</sup> <https://www.ncbi.nlm.nih.gov/pubmed/27540164>;

<https://www.ncbi.nlm.nih.gov/pubmed/25311587>

<sup>232</sup> Ibid.

<sup>233</sup> <https://www.cdc.gov/vaccines/schedules/past.html>;

<https://www.ncbi.nlm.nih.gov/pubmed/20159870>

<sup>234</sup> <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf>

<sup>235</sup> Ibid.

<sup>236</sup> Ibid.

<sup>237</sup> Ibid.

<sup>238</sup> <http://soundchoice.org/research/dna-fragments-research/>;

<http://soundchoice.org/wp-content/uploads/2012/08/DNA>

The CDC's list of ingredients for the vaccines also includes the following animal parts:

*monkey kidney cells, vero (monkey kidney) cells, embryonic guinea pig cell cultures, lactose, chick embryo cell culture, bovine calf serum, bovine serum albumin, calf serum protein, fetal bovine serum*<sup>239</sup>

These fragments of cultured human tissue and animal tissue, which have also been found to include various monkey, retro and other unintended viruses, are injected into the muscle tissue of babies and children, along with the adjuvant intended to generate a sustained immune response to the biological matter in the vaccine.<sup>240</sup>

---

[Contaminants in Vaccines Can Integrate Into Childrens Genes.pdf](#)

<sup>239</sup> <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf>

<sup>240</sup> <https://www.fda.gov/biologicsbloodvaccines/scienceresearch/biologicsresearchareas/ucm127327.htm>; <https://www.ncbi.nlm.nih.gov/pubmed/20375174>. Vaccines also contain, among other ingredients, the following: *2-phenoxethanol, complex*

*fermentation medium, detergent, 5rdimethyl 1-beta-cyclodextrin, Eagle MEM modified medium, enzymes, formaldehyde, gelatin, glutaraldehyde, hemin chloride, hydrolyzed galtin, lactalbumin hydrolysate, Medium 199, Minimum Essential Medium, modified Mueller's growth medium, modified Stainer-Scholte liquid medium, neomycin, neomycin sulfate, phenol polymyxin B, polymyxin B sulfate, polysorbate 80, soy peptone, Stainer-Scholte medium, streptomycin, yeast, yeast protein*

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

INSTITUTE FOR AUTISM SCIENCE AND THE  
INFORMED CONSENT ACTION NETWORK,

Plaintiffs,

-against-

CENTERS FOR DISEASE CONTROL  
AND PREVENTION,

Defendant.

**COMPLAINT**

The above-captioned Plaintiffs, through their undersigned counsel, as for their Complaint against the above-captioned Defendant allege as follows:

**INTRODUCTION**

1. In 1986, Congress passed the National Childhood Vaccine Injury Act, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the “**1986 Act**”), which virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccines. 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”).

2. By granting pharmaceutical companies immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the market forces relied upon to assure the safety of these often mandatory consumer products. Recognizing that it eliminated the financial

incentive for pharmaceutical companies to assure the safety of their vaccine products, Congress placed the responsibility for vaccine safety in the hands of HHS and its agencies pursuant to 42 U.S.C. § 300aa-27(a) (“Mandate for safer childhood vaccines”) which provides, *inter alia*, that the Secretary of HHS “shall ... make or assure improvements in, and otherwise use the authorities of the Secretary with respect to ... research on vaccines, in order to reduce the risks of adverse reactions to vaccines.”

3. The Plaintiffs and their affiliates are nonprofit groups involved in supporting families with autism spectrum disorder (“**autism**”), as well as supporting research into identifying the potential causes of autism in order to better understand how to treat and prevent autism (the “**Autism Groups**”).

4. In the past decade, no claim regarding vaccination has received more attention and publicity than the claim that vaccines cause autism. Likewise, federal health authorities claim to have studied the link between vaccines and autism more thoroughly than any other type of injury that parents claim are caused by vaccination. Federal health authorities assert that they carefully and methodically studied the issue and that the studies clearly and definitively support that vaccines do not cause autism.

5. Reflecting this conclusion, the Center for Disease Control and Prevention (“**CDC**”) unequivocally asserts on its website that “Vaccines Do Not Cause Autism”:



Various CDC department heads have also testified before Congress and declared on national news outlets that vaccines do not cause autism.

6. Despite these unequivocal assertions by the CDC, numerous peer-reviewed articles report that a majority of parents of children with autism have and continue to report one or more vaccines as a cause of their child's autism, including DTaP, Hepatitis B, Hib, PCV13, and IPV. Each of these vaccines are injected into babies three times during the first 6 months of life.

7. In order to provide assurance to parents of children with autism that their child's condition was not caused by one or more vaccines, the Autism Groups wanted to post the studies the CDC relied upon to assert that vaccines do not cause autism. Given the CDC's clear and unequivocal statements on this issue and its assertions that the science supporting this conclusion is robust, the Autism Groups expected to be able to identify numerous studies establishing that none of the vaccines, especially those given to babies, cause autism.

8. The Autism Groups, which include many doctors and scientists, engaged in research to identify these studies. However, as detailed below, the more research the Autism Groups conducted, the more apparent it appeared that these studies do not exist. Ultimately, the Autism Groups were unable to identify studies supporting the CDC's claim that vaccines do not cause autism with regard to any of the vaccines administered during the first six months of life pursuant to the CDC's childhood vaccine schedule.

9. The Autism Groups therefore submitted a request pursuant to the Freedom of Information Act ("FOIA") requesting the studies that CDC relies upon to claim that the DTaP vaccine, which is injected into babies at 2, 4, and 6 months of age, does not cause autism. The CDC failed to produce a single study to support that DTaP vaccines do not cause autism.

10. The Autism Groups also submitted a FOIA request to the CDC for the studies it relies upon to claim that the Hepatitis B vaccine (injected into babies at birth and then at 1 and 6 months of age), Hib vaccine (injected at 2, 4, and 6 months of age), PCV13 vaccine (injected at 2, 4 and 6 months of age), and IPV vaccine (injected at 2, 4 and 6 months of age) do not cause autism. The CDC also failed to provide a single study to support that any of these vaccines do not cause autism.

11. Given the CDC's broad and unequivocal assertions that "Vaccines Do Not Cause Autism" and that a robust body of science supports this conclusion, the Autism Groups seek copies of the studies which support this conclusion; or they want clear confirmation from the CDC that there are no studies which support that DTaP, Hepatitis B, Hib, PCV13, and IPV do not cause autism. If these studies do exist, they should be readily available to the CDC.

12. The Autism Groups sincerely hope that through this action the CDC will produce studies showing that DTaP, Hep B, Hib, PCV13, and IPV do not cause autism. However, given the history described below, they are concerned that the CDC probably has no such studies. If that is the case, the CDC should have to admit this fact and allow the public to weigh in on whether further proof is necessary before their government makes the unequivocal claim that "Vaccines Do Not Cause Autism."

13. The Autism Groups therefore bring this action seeking an order directing the CDC to provide a clear response to their FOIA requests in which the CDC must either admit it has no studies responsive to their requests or produce studies which are responsive to their requests.

#### **PARTIES**

14. Plaintiff, Institute for Autism Science, is a not-for-profit organization with an office located in Villa Park, California.

15. Plaintiff, Informed Consent Action Network, is a not-for-profit organization with an office located at 140 Broadway, 46th Floor, New York, New York 10005.

16. There are other autism groups that have expressed strong support for the instant FOIA requests and action but did not participate due to concern that their corporate and health authority sponsors would terminate their funding.

17. Defendant, the Centers for Disease Control and Prevention (“CDC”), is an agency within the Executive Branch of the United States Government, organized within HHS. The CDC is an agency within the meaning of 5 U.S.C. §552(f).

### **JURISDICTION AND VENUE**

18. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(a).

### **BACKGROUND & FACTS**

19. The CDC affirmatively asserts to the American public that “Vaccines Do Not Cause Autism” and has asserted this to the public for many years. The Autism Groups seek to obtain copies of the studies which support this claim; or alternatively, they are entitled to confirmation that there are no studies to support the claim for any of the vaccines injected into children during the first six months of life. If the studies do exist, which appears doubtful given what the Autism Groups have uncovered as detailed below, the Autism Groups would like to disseminate these studies to assure the members of their groups and the public that vaccines do not cause autism. If these studies do not exist, the Autism Groups are entitled to a clear “no responsive documents” response from the CDC.

**I. National Childhood Vaccine Injury Act of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34.)**

20. Product liability attorneys provide a critical check in ensuring that unsafe products are improved or eliminated from the market through civil lawsuits. By the mid-1980s, pharmaceutical companies were facing crippling liability from their vaccine products due to lawsuits brought by parents whose children were injured by these products.<sup>1</sup> As the United States Supreme Court explained: “by the mid-1980’s ... the remaining manufacturer [of diphtheria, tetanus and pertussis vaccine] estimated that its potential tort liability exceeded its annual sales by a factor of 200.” *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 227 (2011).

21. Instead of letting the usual market forces drive pharmaceutical companies to develop safer vaccines, Congress passed the National Childhood Vaccine Injury Act, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the “**1986 Act**”), in 1986, which virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccine products.<sup>2</sup>

22. Since 1983, the childhood vaccine schedule has gone from 7 injections of just 2 vaccines (DTP & MMR) to 50 injections of 12 vaccines (Hep B, DTaP, Hib, PCV13, IPV, IIV, MMR, VAR, Hep A, Men, Tdap & HPV).<sup>3</sup> During that time, with a liability-free captive market of over 60 million children, vaccine sales in the U.S. have grown from just a few hundred million

---

<sup>1</sup> (Institute of Medicine, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, at 2 (1994)) (By 1986 the “litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines,” and the remaining pharmaceutical companies producing vaccines threatened to withdraw from the vaccine market.)

<sup>2</sup> 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death.”); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“we hold that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”).

<sup>3</sup> <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg>; <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>.

dollars around 1986 to over \$35 billion in 2017.<sup>4</sup> A copy of the CDC's childhood vaccine schedule from 1983 is attached as **Exhibit A** and a copy of the CDC's childhood vaccine schedule from 2019 is attached as **Exhibit B**.

23. By granting manufacturers immunity from actual or potential liability for injuries caused by vaccines, Congress eliminated the market forces relied upon to assure the safety of these products. Recognizing that it eliminated the incentive for pharmaceutical companies to assure the safety of their vaccine products, Congress made the Secretary of HHS directly responsible for vaccine safety under the 1986 Act.

24. HHS' mandate to assure the safety of vaccines is codified at 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines" (the "**Mandate**") and provides:

- (a) **General rule.** In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall — (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.
- (b) **Task force.** (1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control. (2) The Director of the National Institutes of Health shall serve as chairman of the task force. (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the

---

<sup>4</sup> <https://files.eric.ed.gov/fulltext/ED255480.pdf>; <https://www.bccresearch.com/market-research/pharmaceuticals/global-markets-for-vaccine-technologies-phm014g.html>

Secretary concerning implementation of the requirements of subsection (a).

- (c) **Report.** Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

25. The requirements of the Mandate however, are only effective if HHS implements them. HHS has unfortunately failed to fulfill even its basic duties under the Mandate. The Task Force required by part “b” of the Mandate was disbanded in 1998, and HHS has not prepared or filed a single biennial vaccine safety report for Congress as required by part “c” of the Mandate. *Informed Consent Action Network v. United States Department of Health and Human Services*, 18-cv-03215-JMF, (Doc # 18) (S.D.N.Y, July 9, 2018). HHS has similarly failed to fulfill the far more difficult work required by part “a” of the Mandate to actually assure and improve vaccine safety. This failure is apparent from a recent letter exchange with HHS in which it was unable to support most of its vaccine safety claims with any data or studies.<sup>5</sup>

26. Nevertheless, there are other parts of the 1986 Act that HHS has vigorously fulfilled, specifically its obligations to (i) increase vaccine uptake and (ii) defend against legal claims that a vaccine caused an injury.

27. As for vaccine uptake, HHS spends over \$5 billion annually promoting and purchasing vaccines.<sup>6</sup> It also maintains extensive programs working with manufacturers, state and local officials, and advocacy groups to assist in mandating vaccines, eliminating exemptions, and otherwise increasing vaccine uptake.

---

<sup>5</sup> <https://www.icandecide.org/ican-vs-hhs-the-great-vaccine-debate/>

<sup>6</sup> <https://www.hhs.gov/about/budget/index.html>

28. As for defending claims of vaccine injury in court, the 1986 Act established the Vaccine Injury Compensation Program (“**Vaccine Court**”), which is part of the U.S. Court of Federal Claims. Congress intended for the Vaccine Court to serve as a way to compensate people injured by vaccines.<sup>7</sup> If an individual is injured by a vaccine, he or she must bring a claim in the Vaccine Court. HHS is the respondent in Vaccine Court and is legally obligated to defend against any claim that a vaccine causes injury. 42 U.S.C. § 300aa-12 (“In all proceedings brought by the filing of a petition [in Vaccine Court] the Secretary [of HHS] shall be named as the respondent.”) Hence, HHS, while responsible for vaccine safety, is simultaneously responsible for the conflicting duty of defending against claims of vaccine injuries.

29. In the Vaccine Court, HHS is represented by the formidable resources of the U.S. Department of Justice (“**DOJ**”) and vigorously defends against any claim that a vaccine causes injury. *See, e.g.*, <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf> (“DOJ attorneys make full use of the apparently limitless resources available to them,” “pursued aggressive defenses in compensation cases,” “establish[ed] a cadre of attorneys specializing in vaccine injury” and “an expert witness program to challenge claims.”)

30. Any studies or assertion by HHS or its agencies (including the CDC) which reflect that a vaccine that is already on the market causes a harm can and will be used against HHS in Vaccine Court to establish liability.

31. It is therefore critical that the safety of these vaccine products be established prior to licensure, but as the U.S. House Committee on Government Reform has found, the “overwhelming majority of members” of the CDC and FDA’s vaccine committees had conflicts of interest because of “substantial ties to the pharmaceutical industry,” and that these committees reflect “a system

---

<sup>7</sup> <https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters>

where government officials make crucial decisions affecting American children without the advice and consent of the governed.”<sup>8</sup>

## **II. FOIA Request for Studies Supporting that DTaP Vaccine Does Not Cause Autism**

32. The DTaP vaccine is intended to develop antibodies to certain antigens from the pertussis bacteria as well as certain toxins sometimes released by the diphtheria bacteria and tetanus bacteria.

33. Pursuant to the CDC’s childhood vaccine schedule, the DTaP vaccine is to be injected intramuscularly when a baby is 2-months, 4-months, 6-months, and 15-months of age. The two standalone DTaP vaccines currently licensed in the United States are Daptacel, manufactured and sold by Sanofi, and Infanrix, manufactured and sold by GSK.<sup>9</sup> Neither vaccine was licensed based on a placebo controlled clinical trial.<sup>10</sup> Moreover, the safety review period during these trials for these products was 28 days and six months, respectively.<sup>11</sup> Given the lack of a placebo control and the short safety review periods, these vaccines were never assessed prior to licensure for whether they could cause autism.

34. Since it was unknown prior to licensure whether these products can cause autism, there has been a long history of Congress and the scientific community requesting an answer to the question of whether the pertussis vaccines cause autism. However, as detailed below, the Autism Groups have learned that those requests have gone unanswered.

---

<sup>8</sup> <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

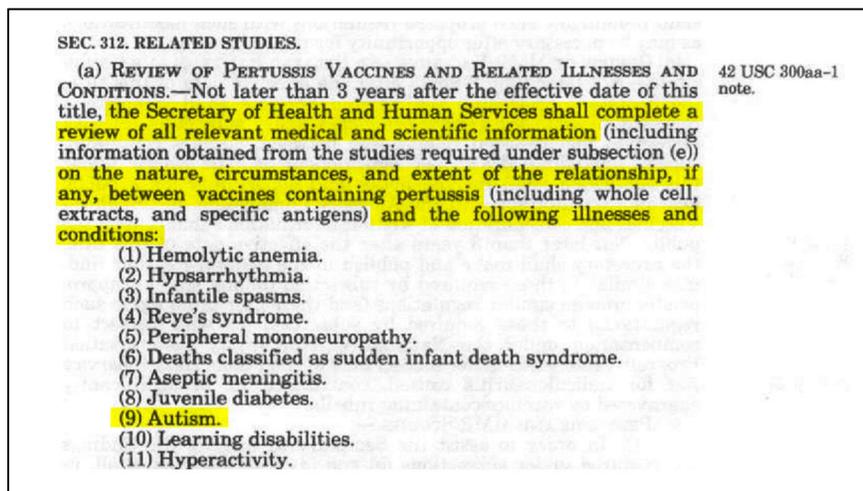
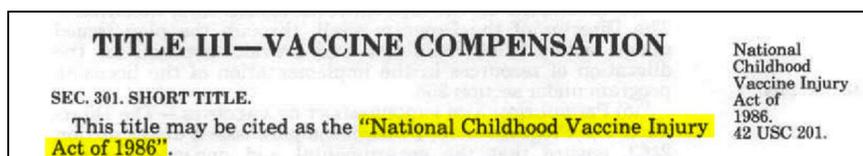
<sup>9</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM124514.pdf>;  
<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM103037.pdf>

<sup>10</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM124514.pdf>;  
<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM103037.pdf>

<sup>11</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM124514.pdf>;  
<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM103037.pdf>

a. **In 1986, Congress Directed HHS to Review Whether Pertussis Vaccines Cause Autism**

35. The concern that pertussis-containing vaccines could cause immune and brain dysfunction, including autism, was identified as a research priority in the 1986 Act.<sup>12</sup> Thus, Congress directed HHS to review the scientific evidence for whether pertussis-containing vaccines can cause, among other conditions, autism.<sup>13</sup>



36. In implementing the foregoing congressional directive, HHS commissioned the Institute of Medicine ("IOM") in 1989 to identify any and all medical and scientific literature addressing whether pertussis-containing vaccines can cause autism.<sup>14</sup> The IOM conducted this review and issued its report in 1991.<sup>15</sup> In that report, the IOM explained that it could not find any

<sup>12</sup> <https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf>

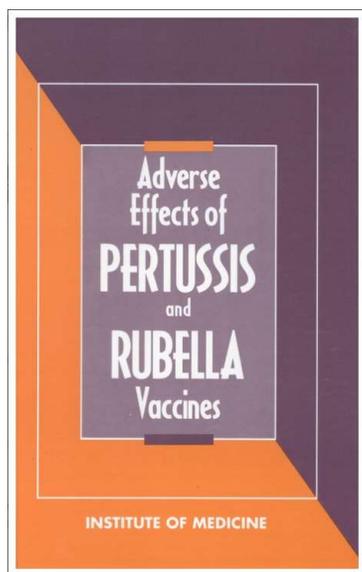
<sup>13</sup> <https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf>

<sup>14</sup> <https://www.nap.edu/read/1815/chapter/1#v>

<sup>15</sup> <https://www.nap.edu/read/1815/chapter/1>

evidence to support the claim that pertussis-containing vaccines do not cause autism.<sup>16</sup> As explained by the IOM, this is because no studies “were identified that address the question of a relation between vaccination with DPT or its pertussis component and autism.”<sup>17</sup>

37. The following is a summary chart of the conclusions from the 1991 IOM report:



**TABLE 1-2 Summary of Conclusions by Adverse Event for DPT<sup>a</sup> and RA 27/3 MMR<sup>b</sup> Vaccines**

Conclusion	Adverse Events Reviewed	
	DPT Vaccine	RA 27/3 Rubella Vaccine
1. No evidence bearing on a causal relation <sup>c</sup>	Autism	
2. Evidence insufficient to indicate a causal relation <sup>d</sup>	Aseptic meningitis Chronic neurologic damage Erythema multiforme or other rash Guillain-Barré syndrome Hemolytic anemia Juvenile diabetes Learning disabilities and attention-deficit disorder Peripheral mononeuropathy Thrombocytopenia	Radiculoneuritis and other neuropathies Thrombocytopenic purpura
3. Evidence does not indicate a causal relation <sup>e</sup>	Infantile spasms Hypsarrhythmia Reye syndrome Sudden infant death syndrome	
4. Evidence is consistent with a causal relation <sup>f</sup>	Acute encephalopathy <sup>g</sup> Shock and “unusual shock-like state”	Chronic arthritis
5. Evidence indicates a causal relation <sup>h</sup>	Anaphylaxis Protracted, inconsolable crying	Acute arthritis

38. Due to this and other shortcomings identified in the IOM’s report, the IOM committee explained in its 1991 report:

In the course of its review, the committee found many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. ... If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.<sup>18</sup>

**b. In 2012, The IOM Again Reviewed Whether Pertussis Vaccines, including DTaP, Cause Autism**

39. Nearly twenty years later in 2012, the CDC and its sister agency, the Health Resources and Services Administration (“HRSA”), commissioned the IOM to assess the evidence

<sup>16</sup> <https://www.nap.edu/read/1815/chapter/2#7>

<sup>17</sup> <https://www.nap.edu/read/1815/chapter/7?term=autism#152>

<sup>18</sup> <https://www.nap.edu/read/1815/chapter/9>

bearing on whether pertussis-containing vaccines, including DTaP, cause autism, as this remained, according to the CDC and HRSA, one of the most commonly claimed injuries from this vaccine.<sup>19</sup>

40. The IOM convened a committee of experts to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines, which was composed of individuals with expertise in pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law.<sup>20</sup>

41. The CDC and HRSA presented a list of commonly claimed specific adverse events for the IOM to review, including asking the IOM to review whether there was any evidence, one way or another, regarding a potential causal relationship between DTaP vaccine and autism.<sup>21</sup>

42. Despite the intervening decades between the 1991 report and the 2012 report, the IOM's response to the CDC and HRSA remained unchanged. The IOM could not locate a single study supporting that DTaP does not cause autism. The IOM therefore concluded: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism."<sup>22</sup>

43. The following is the IOM's full explanation for this finding in its report:

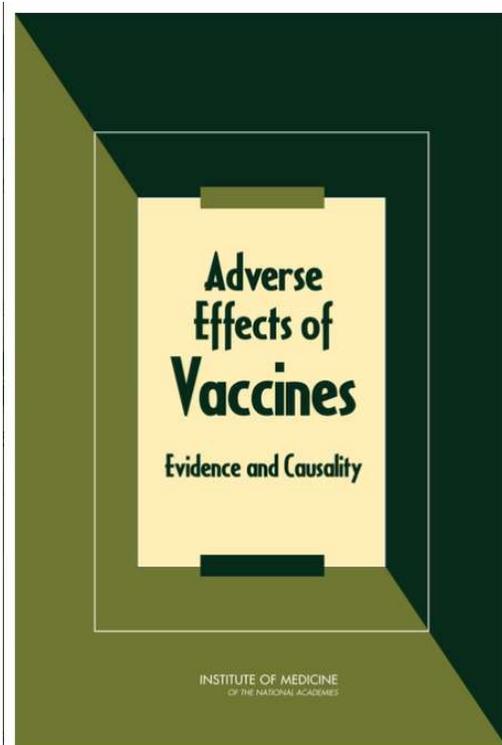
---

<sup>19</sup> <https://www.nap.edu/read/13164/chapter/2#2>

<sup>20</sup> <https://www.nap.edu/read/13164/chapter/1#v>

<sup>21</sup> <https://www.nap.edu/read/13164/chapter/2#2>

<sup>22</sup> <https://www.nap.edu/read/13164/chapter/12#545>



DT-, TT-, AND AP-CONTAINING VACCINES	545
<b>AUTISM</b>	
<b>Epidemiologic Evidence</b>	
The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.	
<i>Weight of Epidemiologic Evidence</i>	
<i>The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.</i>	
<b>Mechanistic Evidence</b>	
The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.	
<i>Weight of Mechanistic Evidence</i>	
<i>The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism as lacking.</i>	
<b>Causality Conclusion</b>	
<b>Conclusion 10.6: The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.</b>	

44. The only study the IOM could locate regarding whether DTaP causes autism (Geier and Geier, 2004) concluded there *was* an association between DTaP and autism.<sup>23</sup>

c. **In 2014, an HHS Agency Again Reviewed Whether Pertussis Vaccines, Including DTaP, Cause Autism**

45. Just a few years after the 2012 IOM report was released, the Agency for Healthcare Research and Quality (“AHRQ”) again conducted a review searching for any study bearing on a potential causal relationship between pertussis-containing vaccines, including DTaP, and autism.<sup>24</sup> HHS has explained that this report, published in 2014, represented “the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States.”<sup>25</sup>

<sup>23</sup> <https://www.nap.edu/read/13164/chapter/12?term=autism#545>

<sup>24</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>25</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

46. As with the IOM reports from 1991 and 2012, the “comprehensive review” published by AHRQ in 2014 again concluded it could not identify a single study to support the claim that DTaP does not cause autism.<sup>26</sup>

d. **In 2017, the Director of the NIH, and the Chairman of the Interagency Autism Coordinating Committee Were Unable to Produce a Single Study to Support that DTaP Vaccine Does Not Cause Autism**

47. On May 31, 2017, the White House convened a meeting at the National Institutes of Health (“NIH”) in which HHS’s published agenda for the meeting included “Causes of autism, including genetic and environmental influences.” In attendance at that meeting were approximately a dozen individuals from the government and outside groups, including:

- Dr. Francis Collins, Director (NIH)
- Dr. Joshua Gordon, Director, National Institute of Mental Health (NIMH) and, Chairman, Interagency Autism Coordinating Committee (IACC)
- Dr. Diana Bianchi, Director, Eunice Kennedy Shriver Institute of Child Health and Human Development (NICHD)
- Dr. Linda Birnbaum, Director, National Institute of Environmental Health Sciences (NIEHS)
- Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID)
- Robert F. Kennedy Jr., Chairman, Children’s Health Defense
- Del Matthew Bigtree, President, Informed Consent Action Network

48. During this meeting, none of the directors from NIH could identify a single study which supported the claims that DTaP, nor any other vaccine given during the first six months of life, does not cause autism.

49. As a follow-up to this meeting, on June 21, 2017, Mr. Kennedy sent an email to Dr. Collins, Dr. Gordon, Dr. Bianchi, Dr. Birnbaum, and Dr. Fauci which included the following request:

As with most vaccines (other than MMR) there has not been a single study regarding whether DTaP causes autism. For example, the

---

<sup>26</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

IOM in a 2011 report stated that the IOM could not confirm whether DTaP causes autism because no science had been done on that point. Nevertheless, the HHS baldly claims that all “Vaccines Do Not Cause Autism.” (<https://www.cdc.gov/vaccinesafety/concerns/autism.html>) *Therefore, can you please explain how HHS claims that vaccines do not cause autism when it does not know whether DTaP causes autism?*

In response to this email and numerous follow-up requests, the directors from the NIH failed to produce a single study to support that DTaP or any other vaccine given during the first six months of life does not cause autism.

e. **In 2017, Scientists from Major Universities in Canada, France and the United Kingdom Studying Aluminum Adjuvants Raise Serious Concerns that DTaP and Other Aluminum Adjuvanted Vaccines May be Causing Autism**

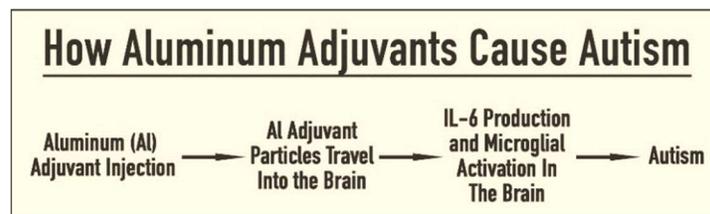
50. The DTaP vaccine contains tens of thousands of particles of aluminum hydroxide or aluminum phosphate. Aluminum hydroxide and aluminum phosphate are adjuvants used in inactivated vaccines to generate an immune response. The biological material in the DTaP vaccine bind to these aluminum adjuvant particles. Aluminum adjuvant particles cause cellular death in the area of the muscle tissue where it is injected, thereby triggering an immune response. Immune system cells that rush to that area will then carry the aluminum adjuvant particles to the lymph nodes, where antibody production occurs. Unlike biological material however, animal models reveal that the aluminum adjuvant pieces are then deposited in various bodily organs, including the brain. Aluminum adjuvant particles in the brain cause the release of, among other things, IL-6 in the brain, which is a known cause of neurological disorders including autism.

51. In June 2017, at least three scientists at major universities around the world with expertise regarding aluminum adjuvants raised a concern that aluminum adjuvants in vaccines could be contributing to neurological disorders, including autism. These letters each asserted that these scientists strongly supported the contention that aluminum adjuvants in vaccines may have

a role in the etiology of autism, and cited the peer reviewed literature supporting this contention. Copies of these three letters were provided to HHS, CDC and NIH, including a copy to Dr. Joshua Gordon, due to his position as Director of the National Institute of Mental Health (NIMH) and Chairman of the Interagency Autism Coordinating Committee. See Appendix C to **Exhibit C**.

52. Despite numerous attempts to facilitate a meeting with Dr. Gordon and these scientists, neither Dr. Gordon nor anyone else at HHS, CDC, or NIH agreed to meet with them to discuss their concerning conclusions regarding DTaP and other vaccines containing aluminum adjuvant.

53. Dr. Gordon and the other NIH directors and scientists were also provided a clear and detailed white paper which identified the peer-reviewed studies that support each step in the process for how aluminum adjuvants can cause autism. This science reflects that: injected aluminum adjuvant is taken up by immune cells (macrophages) at the injection site; these aluminum-adjuvant-loaded immune cells then travel through the lymph vessels to, among other places, the brain; the immune cells then unload their aluminum adjuvant cargo in the brain; and aluminum adjuvant in the brain causes a release of interleukin IL-6 and microglial activation, leading to autism.<sup>27</sup> Depicted in simple terms:



This white paper has not been refuted by Dr. Gordon, any other directors at NIH, or by any scientists at CDC. A copy of this review is attached as **Exhibit G**.

<sup>27</sup> <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf>

f. **On June 11, 2018, Dr. Stanley Plotkin Asked About Whether Studies Exist to Support that DTaP Vaccine Does Not Cause Autism**

54. The equivalent of the Nobel prize in vaccinology is called the “Plotkin Award.” The medical textbook for vaccinology is called “Plotkin’s Vaccines.” The gavel used at the CDC’s Advisory Committee on Immunization Practices, which is the committee that decides the CDC’s childhood immunization schedule, is called the “Stanley A. Plotkin ACIP Gavel.” Dr. Plotkin has developed vaccinations for rubella, varicella, polio, rotavirus, rabies and cytomegalovirus. Dr. Plotkin is the Founding Father of the Pediatric Infectious Diseases Society. He has published over 800 peer-reviewed articles, most of which relate to vaccinology. Dr. Plotkin has received over 50 awards and honors for his work in vaccinology, including the French Legion of Honor Medal, and is a member of the IOM.

55. On June 11, 2018, Dr. Plotkin provided testimony under oath in a litigation that had received national media attention. The following is an excerpt from that testimony:

Q What was the IOM’s conclusion in 2011 about whether [the DTaP and Tdap] vaccines can cause autism?

A I’d have to look that up, but I feel confident they do not cause autism.

Q ... This is an excerpt from the IOM’s report [from 2011], right?

A Yes.

Q ... If you take a look at that section please, was the IOM able to identify a single study supporting that DTaP and Tdap do not cause autism?

A No, they did not identify a study.

Q ... If you don't know whether DTaP or Tdap cause autism, shouldn't you wait until you do know, until you have the science to support it to then say that vaccines do not cause autism?

A Do I wait? No, I do not wait because I have to take into account the health of the child.

Q And so for that reason, you're okay with telling the parent that DTaP/Tdap does not cause autism even though the science isn't there yet to support that claim?

A Absolutely.<sup>28</sup>

---

<sup>28</sup> <https://www.youtube.com/watch?v=DFTsd042M3o>

56. There is arguably no scientist that has had a greater impact on vaccine policy at the CDC than Dr. Plotkin. A former member of the CDC's Advisory Committee on Immunization Practices, Dr. Paul Offit, explained that Dr. Plotkin "trained a generation of scientists" involved in vaccine policy and advocacy "to think like he thinks."

g. **On September 7, 2018, one of the World's Leading Experts on Autism and Mitochondrial Disorder and HHS's Autism Expert Attests Vaccines Can Cause Autism**

57. Dr. Andrew W. Zimmerman, M.D. is a world leading expert on autism, pediatric neurology and mitochondrial disorders, and has held numerous distinguished positions in this field, including as a professor at Johns Hopkins University School of Medicine, Harvard Medical School, and the University of Massachusetts Medical School and as the Director of Medical Research at the Kennedy Krieger Institute.<sup>29</sup>

58. Dr. Zimmerman was the leading expert relied upon by HHS and DOJ in contesting claims that the MMR vaccine and thimerosal-containing vaccines cause autism in Vaccine Court, in what is known as the Autism Omnibus Proceeding ("AOP").

59. Initially, Dr. Zimmerman provided an expert report in the AOP on behalf of HHS claiming that MMR and thimerosal-containing vaccines do not cause autism. Shortly thereafter, Dr. Zimmerman explained to HHS and the DOJ that while he initially did not see any basis for how vaccines could cause autism, his opinion changed during the course of the AOP upon examining additional children, including those who had received DTaP vaccine, and concluded that vaccines had been a cause of their autism. HHS and the DOJ never alerted the other side about the change in Dr. Zimmerman's position, but rather continued to use Dr. Zimmerman's initial expert report despite the fact that he had informed them of the change in his opinion.

---

<sup>29</sup> <http://icandecide.org/documents/zimmerman.pdf>

60. Dr. Zimmerman has only recently revealed the foregoing in an affidavit, dated September 7, 2018, which provides, in relevant part:

1. I am a board certified, pediatric neurologist and former Director of Medical Research, Center for Autism and Related Disorders, Kennedy Krieger Institute, and Johns Hopkins University School of Medicine.

2. I was a Reviewer for the National Academy of Sciences 2004 report entitled IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM, which was prepared by the Immunization Safety Review Committee, at the request of the Centers for Disease Control and Prevention (CDC)...

4. In 2007, I was an expert witness for the Department of Health and Human Services in the Omnibus Autism Proceeding (O.A.P.) under the National Childhood Vaccine Injury Compensation Program.

5. With the assistance of the Department of Justice, I prepared and executed the attached expert witness opinion regarding Michelle Cedillo, on behalf of the Department of Health and Human Services ... [which] states in pertinent part as follows:

“There is no scientific basis for a connection between measles, mumps and rubella (MMR) vaccine or mercury (Hg) Intoxication and autism. ...”

6. On Friday June 15th 2007 ... I spoke with DOJ attorneys... to clarify my written expert opinion.

7. I clarified that my written expert opinion regarding Michelle Cedillo was a case specific opinion as to Michelle Cedillo. My written expert opinion regarding Michelle Cedillo was not intended to be a blanket statement as to all children and all medical science.

8. *I explained that I was of the opinion that there were exceptions in which vaccinations could cause autism.*

9. More specifically, I explained that in a subset of children with an underlying mitochondrial dysfunction, vaccine induced fever and immune stimulation that exceeded metabolic energy reserves could, and in at least one of my patients, did cause regressive encephalopathy with features of autism spectrum disorder.

10. I explained that my opinion regarding exceptions in which vaccines could cause autism was based upon advances in science, medicine, and clinical research of one of my patients in particular.

...

12. Shortly after I clarified my opinions with the DOJ attorneys, I was contacted by one of the junior DOJ attorneys and informed that I would no longer be needed as an expert witness on behalf of H.H.S.

(emphasis added.)

61. A copy of Dr. Zimmerman’s affidavit is attached as **Exhibit F**.

**h. December 31, 2018, HHS Letter Exchange with ICAN**

62. On October 12, 2017, Plaintiff Informed Consent Action Network sent a letter to HHS regarding vaccine safety subscribed to by over 55 organizations, whose members exceed 5 million Americans. A copy of this letter is attached as **Exhibit C**. This letter, in relevant part, provided:

As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines ....<sup>30</sup>

Instead, HHS’s claim that “Vaccines Do Not Cause Autism” relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.<sup>31</sup> ...

As for the MMR vaccine, the CDC’s own Senior Scientist, Dr. William Thompson<sup>32</sup>, recently provided a statement through his attorney that the CDC “omitted statistically significant information” showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.<sup>33</sup> Dr. Thompson, in a recorded phone call, stated the following regarding concealing this association: “Oh my God, I can’t believe we did what we

---

<sup>30</sup> <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

<sup>31</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>32</sup> Dr. Thompson has been a scientist at CDC for nearly two generations and a senior scientist on over a dozen CDC publications at the core of many of CDC’s vaccine safety claims. <https://www.ncbi.nlm.nih.gov/pubmed>

<sup>33</sup> <http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf>

did. But we did. It's all there. It's all there. I have handwritten notes."<sup>34</sup>  
 ...

When the former Director of the National Institute of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: "You *can't* say that."<sup>35</sup> When asked again, Dr. Healy explained: "The more you delve into it – if you look at the basic science – if you look at the research that's been done, in animals – if you also look at some of these individual cases – *and*, if you look at the evidence that there *is* no link - what I come away with is: *The question has not been answered.*"<sup>36</sup>

The CDC has also failed to address the science supporting a link between vaccines and autism.<sup>37</sup> For example, the CDC has not addressed ... a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.<sup>38</sup> There is also a persuasive body of science supporting a clear connection between aluminum adjuvants in vaccines and autism which the CDC, despite numerous requests, has failed to directly or substantively address.<sup>39</sup>

63. HHS responded to the above in a letter dated January 18, 2018. A copy of this response is attached as **Exhibit D**. HHS's response was required to be reviewed and approved by the following agencies within HHS: CDC, FDA, NIH, HRSA, and AHRQ. HHS's response responded to the above question related to vaccines and autism as follows:

Many studies have looked at whether there is a relationship between vaccines and autism spectrum disorder (ASD). These studies continue to show that vaccines do **not** cause ASD. For more information, please refer to the literature below:

- <https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf>
- <http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx>
- [http://www.jpeds.com/article/S0022-3476\(13\)00144-/pdf?ext=.pdf](http://www.jpeds.com/article/S0022-3476(13)00144-/pdf?ext=.pdf)

---

<sup>34</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

<sup>35</sup> <http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/>

<sup>36</sup> Ibid.

<sup>37</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>38</sup> <http://www.oatext.com/pdf/JTS-3-186.pdf>; <http://www.oatext.com/pdf/JTS-3-187.pdf>

<sup>39</sup> <http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf>

<http://nationalacadernies.org/HMD/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>

While there is still a lot to learn about ASD, research from public and private organizations indicate that environmental and genetic factors may increase the risk of autism, not vaccines or vaccine ingredients. HHS continues to research this issue to search for answers to better understand the risk factors and causes of this disease. Recent efforts to coordinate autism research are reflected in the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee at <https://iacc.hhs.gov/publications/strategic-plan/2017/>.

64. Upon examination of the links provided by HHS, it is clear that none of these links contain a single study which supports the claim that neither DTaP, nor any other vaccine given during the first six months of life, do not cause autism. As explained in ICAN's December 31, 2018 response (a copy of which is attached as **Exhibit E**):

HHS's response merely provides five links in response to our request for the studies supporting that pediatric vaccines do not cause autism. The content of these five links all directly reinforce and confirm the very concerns raised in our opening letter.

The *first* link is to a document entitled "Science Summary: CDC Studies on Thimerosal in Vaccines."<sup>40</sup> The studies in this document are plainly insufficient to support the claim that "vaccines do not cause autism" as they at best only address whether thimerosal causes autism.

The *second* link is to an IOM report from 2004 entitled "Immunization Safety Review: Vaccines and Autism."<sup>41</sup> This report also cannot support the CDC's claim about all vaccines because it *only* addresses the MMR vaccine and thimerosal with regard to autism. ...

The *third* link is a study which only looks at one vaccine component – antigens – comparing 'vaccinated children' with 'vaccinated children' with different antigen exposure.<sup>42</sup> This study again says nothing about whether any particular vaccine or HHS's childhood vaccine schedule causes autism. This study even concedes: "ASD with regression, in which children usually lose developmental skills during the second year of life, *could* be related to exposure in infancy, *including vaccines*."<sup>43</sup>

---

<sup>40</sup> <https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf>

<sup>41</sup> <http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx>

<sup>42</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23545349>

<sup>43</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23545349> (emphasis added)

This antigen exposure study could have compared children receiving no-antigens, meaning no vaccines, with children receiving vaccine antigens. That would finally provide real data. Instead, the study engages in yet another nonsensical whitewash review in which it compares vaccinated children with vaccinated children, with the only real difference typically being that some children received DTaP while others received DTP.<sup>44</sup> ...

This study further ignores the fact that while “antigens” (as defined in the study) in vaccines have decreased since the late 1990s, the amount of aluminum adjuvant, a neuro-and-cyto-toxic immune stimulant, used in vaccines has significantly *increased*. ...

But even putting all these limitations aside, this antigen study says nothing about whether any particular vaccine or group of vaccines cause autism, and, at best, relates to the potential connection between antigen exposure and autism (albeit in a study that, in its best light, is unreliable).

The *fourth* link HHS cites is the very IOM review from 2011 cited in our opening letter.<sup>45</sup> However, as we noted in our letter, the IOM could not identify a single study which supports the claim that DTaP does not cause autism.<sup>46</sup> ...

The *fifth* (and final) link HHS cites in its letter is the “Strategic Plan for Autism Spectrum Disorder Research” by the Interagency Autism Coordinating Committee ....<sup>47</sup> Remarkably, this 196 page strategic plan outlines dozens of research priorities, but does not once mention closing the vaccine safety science gap regarding whether DTaP, Hepatitis B, and every other vaccine given by one year of age cause autism.<sup>48</sup>

The strategy plan even explains that “neuroinflammation” may cause autism, but ignores the fact that neuroinflammation (a.k.a., encephalitis or encephalopathy) is a known reaction to numerous vaccines. ... The strategic plan also recognizes “immune dysregulation” – which again can be caused by vaccines – may cause autism.<sup>49</sup> ...

HHS has even remained silent and refused to seriously study the vaccine-autism connection despite the fact that ... Dr. Zimmerman ... on November 9, 2016 ... answered “Yes” when asked under oath: “Do other people in your field, reputable physicians in your field, hold the opinion that vaccines can cause the type of inflammatory response that can lead to

---

<sup>44</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23545349>

<sup>45</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>46</sup> <http://nationalacademies.org/HMD/Reports/2011/adverse-effects-of-vaccines-evidence-and-causality.aspx>

<sup>47</sup> [https://iacc.hhs.gov/publications/strategic-plan/2017/strategic\\_plan\\_2017.pdf](https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf)

<sup>48</sup> [https://iacc.hhs.gov/publications/strategic-plan/2017/strategic\\_plan\\_2017.pdf](https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf)

<sup>49</sup> <https://onlinelibrary.wiley.com/doi/book/10.1002/9781118663721>

a regressive autism?”<sup>50</sup> Dr. Zimmerman further testified that once HHS understands ... the causal relationship between vaccines and autism, “it will prevent the development of autism in quite a few children.”<sup>51</sup>

Dr. Zimmerman’s similarly credentialed colleague, Dr. Richard Kelley, also provided the following very revealing testimony...:

*Lawyer: Do you agree with the statement that vaccines do not cause autism?*

Dr. Kelley: No

*Lawyer: Is it generally accepted in the medical community that vaccines do not cause autism?*

Dr. Kelley: It is a common opinion.

*Lawyer: It is generally accepted in the medical field that vaccines do not cause autism?*

Dr. Kelley: I have no basis to judge that. It is most often when physicians are commenting on that they say there is no proven association.

*Lawyer: Do you know the position of the American Academy of Pediatrics about any link between vaccines and autism?*

Dr. Kelley: Yes. They also say there is no proven association.

*Lawyer: Do you agree with the position of the American Academy of Pediatrics?*

Dr. Kelley: I agree with their position as a public health measure. I don’t agree with it scientifically.

*Lawyer: You are actually arguing for a link between vaccines and autism in this case, aren’t you?*

Dr. Kelley: I am.

*Lawyer: And that is contrary to the medical literature, isn’t it?*

Dr. Kelley: It’s not contrary to the medical literature that I read. It is contrary to certain published articles by very authoritative groups who say there is no proven association in large cohort studies.

*Lawyer: Your opinion is contrary to, say, the opinion of the CDC, correct?*

Dr. Kelley: It is contrary to their conclusion. It is not contrary to their data.<sup>52</sup>

The view apparently held by HHS that “public health” demands hiding any relationship between vaccines and autism to assure high vaccine uptake, is troubling. This view (i) ignores ... that the real “public health” emergency ... is that 1 in 36 children are now diagnosed with autism<sup>53</sup>, (ii) stifles research into ... vaccines ... and autism, and (iii) forces HHS to ignore any science that does support a vaccine-autism connection.

---

<sup>50</sup> <https://books.google.com/books?isbn=1603588256>

<sup>51</sup> <https://books.google.com/books?isbn=1603588256>

<sup>52</sup> <https://books.google.com/books?isbn=1603588256>

<sup>53</sup> <https://www.cdc.gov/nchs/data/databriefs/db291.pdf>

On May 24, 2014, Dr. Thompson explained that the CDC is “paralyzed right now by anything related to autism ... .”<sup>54</sup> The reason ... may be that ... [i]f a single study conducted by HHS shows that even 1 in 5 cases of autism are caused ... by vaccines, it would result in approximately \$1.3 trillion in liability<sup>55</sup> ... and [a] decimation of HHS’s reputation ...

It is hard to imagine that HHS has not already internally used the databases at its disposal, such as VSD, to compare the autism rate between vaccinated and unvaccinated children. If the results showed no difference in the autism rates between these two groups of children, no doubt this study would have been published. ....

HHS’s approach to this issue ignores the tens of thousands of families across this country that have attested – often in videos available online – that their best judgment based on the totality of their parental experience with their child is that vaccination caused their child’s autism.

**i. Autism Groups Submit FOIA Request to CDC regarding DTaP**

65. After two decades of demands upon CDC for proof that vaccines, including DTaP, do not cause autism, the CDC at this point must know what studies, if any, it has to support its assertion that vaccines, which would include DTaP, do not cause autism. Therefore, On June 21, 2019, the Autism Groups submitted a FOIA request to CDC seeking “All studies relied upon by CDC to claim that the DTaP vaccine does not cause autism.” (the “**DTaP-Autism FOIA request**”). The CDC has failed to produce a single study responsive to this request, nor has it asserted that it does not have any responsive studies.

66. It remains difficult for the Autism Groups to believe that the CDC does not have such studies, given that the CDC’s repeated assertion that vaccines do not cause autism -- an assertion which every health authority relies upon to provide medical advice and set policy with regard to research priorities related to autism.

---

<sup>54</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

<sup>55</sup> Since approximately 3.5 million American children have autism spectrum disorder and the approximate life time cost per individual is \$1.9 million, total cost of care for just 20% of these individual is \$1.3 trillion. [www.autism-society.org/what-is/facts-and-statistics/](http://www.autism-society.org/what-is/facts-and-statistics/)

67. While it remains possible the CDC has studies that support that DTaP does not cause autism but has for some reason so far refused to produce such studies, it is far more likely that the CDC does not have those studies. Either way, the Autism Groups are entitled to know the truth.

### **III. FOIA Request for Studies Supporting that Hepatitis B Vaccines Do Not Cause Autism**

68. On July 18, 2019, the Autism Groups submitted a FOIA request to CDC requesting “All studies relied upon by CDC to claim that neither Engerix-B nor Recombivax HB do not cause autism.” (the “**Hep B-Autism FOIA Request**”.)

69. The CDC’s childhood vaccine schedule provides that every infant receive a Hepatitis B vaccine on the first day of life and at one month and six months of life. The Hepatitis B vaccines licensed for use in babies are Engerix-B, manufactured by GSK, and Recombivax HB, manufactured by Merck.

70. Prior to licensure, neither of these Hepatitis B vaccines was evaluated for whether it could cause autism; nor did either of the clinical trials relied upon to license these vaccines contain a control group. Merck’s Recombivax HB was licensed after clinical trials that solicited adverse reactions for only five days after vaccination, and GSK’s Engerix-B was licensed after clinical trials that solicited adverse reactions for only four days after vaccination.<sup>56</sup>

71. As described above, the AHRQ issued a report on vaccine safety in 2014 which HHS explained represents “the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States.”<sup>57</sup> This “comprehensive review” apparently also searched for studies that would support the claim that the Hepatitis B

---

<sup>56</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>; <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>

<sup>57</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

vaccine does not cause autism, but did not identify for inclusion in the review a single study to support this claim.<sup>58</sup>

72. To the contrary, it identified a study from the Stony Brook University Medical Center in New York, which found a 300% increased rate of autism among newborns receiving the Hepatitis B vaccine at birth, compared to those who did not get this vaccine at birth.<sup>59</sup> The 2014 review summarizes the results of this study as follows:

Result was significant for the risk of autism in children who received their first dose of Hepatitis B vaccine during the first month of life (OR 3.00, 95% CI 1.11, 8.13), compared with those who received the vaccination after the first month of life or not at all.<sup>60</sup>

Even though it found one study that showed an association and no studies to disprove this association, the AHRQ's review did not reach any conclusion regarding whether the Hepatitis B vaccine can cause autism.<sup>61</sup> Rather, it concluded it does not know whether the Hepatitis B vaccine causes autism.<sup>62</sup>

73. Nonetheless, given the CDC's assertion that "Vaccines Do Not Cause Autism" and that the CDC's childhood vaccine schedule provides that the Hepatitis B vaccine be injected three times by six months of age, the Autism Groups searched for studies conducted after 2014 to support the claim that Hepatitis B vaccine does not cause autism. The Autism Groups were unable to identify any such studies. The CDC has also not produced any studies responsive to the Hep B-Autism FOIA Request nor confirmed that it does not have any responsive studies.

---

<sup>58</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>59</sup> [http://hisunim.org.il/images/documents/scientific\\_literature/Gallagher\\_Goodman\\_HepB\\_2010.pdf](http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf)

<sup>60</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>61</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>62</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

**IV. FOIA Request for Studies Supporting that Prevnar 13 Does Not Cause Autism**

74. On July 18, 2019, the Autism Groups submitted a FOIA request to CDC requesting “All studies relied upon by CDC to claim that Prevnar 13 does not cause autism.” (the “**Prevnar-Autism FOIA Request**”.)

75. Prevnar 13 is manufactured by Pfizer and the CDC’s childhood vaccine schedule provides that every baby receive Prevnar 13, a vaccine for pneumococcal, at two months, four months and six months of life.

76. Prior to licensure, Prevnar 13 was not assessed for whether it can cause autism. Instead, Prevnar 13 was licensed in 2010 based on a clinical trial in which Pfizer used Prevnar (an earlier version of the vaccine) as the control.<sup>63</sup> In turn, Prevnar was licensed based on a clinical trial in which the control was “an investigational meningococcal group C conjugate vaccine [MnCC].”<sup>64</sup> MnCC, is an unlicensed product and hence was obviously never licensed based on a placebo-controlled trial.<sup>65</sup>

77. The clinical trial for Prevnar 13 found that “Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13 recipients and 7.2% among Prevnar recipients.”<sup>66</sup> The FDA defines a “serious adverse event” is follows:

An adverse event or suspected adverse reaction is considered “serious” if, in the view of either the investigator or sponsor [meaning, the pharmaceutical company seeking licensure or the investigator hired by that pharmaceutical company], it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the

---

<sup>63</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>; <http://labeling.pfizer.com/showlabeling.aspx?id=134>

<sup>64</sup> <http://labeling.pfizer.com/showlabeling.aspx?id=134>

<sup>65</sup> See tables above.

<sup>66</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>

ability to conduct normal life functions, or a congenital anomaly/birth defect.

Despite the serious adverse reaction rate seen in children receiving Prevnar 13 and those receiving Prevnar, licensure for Prevnar 13 to be injected into babies was still granted because it had a similar serious adverse reaction rate as the control group did when receiving Prevnar.<sup>67</sup>

78. The Autism Groups are also not aware of a study after licensure to support that Prevnar 13 does not cause autism. On the other hand, there are many parents who have reported that their children began exhibiting the behavioral features of autism shortly after receiving this vaccine. Therefore, these concerns are very real concerns for the members of the Autism Groups, which is why the groups are so interested in posting the studies if they exist, or advocating for additional research if the studies do not exist. For example, a set of triplets all received Prevnar on the same day. Within twenty-four hours, all three of them suffered rapid declines in their behavioral and cognitive functions. An abridged three minute version of the interview with the parents of these triplets is available at <https://www.youtube.com/watch?v=KN0qxO3G7eo> and the following is a transcription of portion of this three minute video:

*Mother of the Triplets:* We have triplets. Two boys and a girl: Richie, Robbie, and Claire. ... Every single day they were smiling and laughing and looking at each other and engaging in each other. On June 25th, 2007, we brought them in for the pneumococcal shot [Prevnar]. My daughter still has the mark on her leg from the shot. She was the first one to get it and she screamed and never really stopped screaming after that, but we continued, we didn't know. We did the boys, as well.

By noon, Claire shut completely off. It was as if she was blind and deaf, and all she did at that moment was stare at the ceiling. So that was at noon. We had the shot at 10 a.m.

At two o'clock, we watched Ritchie shut off. They lost all their reflexes. I'm an educational audiologist. I actually did the test for

---

<sup>67</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>

the stapedial reflex, which is a little muscle in the middle ear, just to see if a muscle they can't control was still working, and it didn't. The stapedial reflex dampens sounds, so your ears don't hurt from a really loud sound. And both of them had no stapedial reflex. They stopped blinking, stopped yawning, stopped coughing, stopped sneezing.

The worst was when we saw the final one shut down. Robbie, from that moment on, had a stunned look on his face. If you asked, or said his name, he still acted deaf, or acted like he couldn't hear. Although they did have normal hearing. I had it all tested. But he lost his happiness.

Three months after the shot, they were no longer engaged in anything or anyone. We were told it was genetic. And then we were told by geneticists that there is no possible way three children would shut off on the same day.

We had severe autism spectrum disorder for all three kids entering kindergarten. We have spent hundreds of thousands of dollars trying to recover them. The only person we got back was Robbie. The one that was last to shut off. Ritchie can only say single, maybe two, words together. Claire is still completely nonverbal, not potty trained. And Robbie is approaching grade level, but severe OCD.

*Father of the Triplets:* So, you've got, say a six-or seven-year-old child, who is not potty trained. And at two or three, four o'clock in the morning they fill their diaper. Well you can assume that pretty uncomfortable, so they take it off. Pretty soon it's all of them, it's all over the bed. In short order, it's all over me, it's all over her. I'm snapping at her, she's snapping at me. We are both snapping at the kid who is the only innocent party in the whole scenario. And the one thing that is conspicuously absent from that scenario is anybody who told you that shot was safe. They are all asleep in their bed. They haven't got a problem in the world.

79. Given the CDC's assertion that "Vaccines Do Not Cause Autism" and that the CDC's childhood vaccine schedule provides that Prevnar 13 be injected three times by six months of age, the Autism Groups searched for studies which support that Prevnar 13 does not cause autism. The Autism Groups could not identify any such study. The CDC has also not produced

any studies responsive to the Prevnar-Autism FOIA Request, nor has it asserted it does not have any responsive studies.

**V. FOIA Request for Studies Supporting that Hib Vaccine Does Not Cause Autism**

80. On July 18, 2019, the Autism Groups submitted a FOIA request to CDC requesting “All studies relied upon by CDC to claim that Hib vaccines does not cause autism.” (the “**Hib-Autism FOIA Request**”.)

81. There are three Hib vaccines used in the United States -- ActHIB (manufactured by Sanofi), Hiberix (manufactured by GSK), and PedvaxHIB (manufactured by Merck) – and the CDC’s childhood vaccine schedule provides that every baby receive a Hib vaccine at two months, four months and six months of life.

82. Like Hep B and Prevnar 13, none of these Hib vaccines were assessed, prior to licensure, for whether they can cause autism. Likewise, none of the clinical trials relied upon to license these vaccines included a placebo control group or had a safety review duration longer than thirty-one days after injection.

83. Nevertheless, given the CDC’s assertions that “Vaccines Do Not Cause Autism” and that the CDC’s childhood vaccine schedule provides the Hib vaccine be injected intramuscularly three times by six months of age, the Autism Groups searched for studies which support that Hib vaccines do not cause autism. The Autism Groups were unable to identify any such study. The CDC has also not produced any such studies in response to the Hib-Autism FOIA Request, nor has it asserted that it does not have any responsive studies.

**VI. FOIA Request for Studies Supporting that IPV Vaccine Does Not Cause Autism**

84. On July 18, 2019, the Autism Groups submitted a FOIA request to CDC requesting “All studies relied upon by CDC to claim that inactivated polio vaccine (‘IPV’) does not cause autism.” (the “**IPV-Autism FOIA Request**”.)

85. The only vaccine currently used in the United States for polio is the inactivated polio vaccine (“IPV”), tradename Ipol, licensed in 1990, and manufactured by Sanofi. The oral polio vaccine (“OPV”) was used in the United States until 2000 when it was discontinued and replaced with the IPV because the OPV was found to cause paralysis.

86. Like the previously listed vaccines, prior to licensure, IPV was never assessed for whether it can cause autism. The clinical trial relied upon to license IPV had no control group and a safety review period of three days.

87. Given the CDC’s assertion that “Vaccines Do Not Cause Autism” and that the CDC’s childhood vaccine schedule provides that IPV be injected intramuscularly three times by six months of age, the Autism Groups searched for studies to support that IPV does not cause autism. The Autism Groups were unable to find any such study. The CDC has also not produced any studies responsive to the IPV-Autism FOIA Request, nor has it asserted that it does not have any responsive studies.

**VII. Cumulative Exposure to Vaccines Given During the First Six Months of Life and Autism**

88. On July 25, 2019, the Autism Groups submitted a FOIA request to CDC requesting “Copies of the studies the CDC relies upon to claim that the cumulative exposure of vaccines it recommends that babies be administered during the first six months of life do not cause autism.”

89. Given the CDC’s assertion that “Vaccines Do Not Cause Autism,” the Autism Groups searched for studies to support that the cumulative exposure to all vaccines given during

the first six months of life do not cause autism. The Autism Groups were unable to find any such studies. The CDC has also not produced any studies responsive to this request, nor has it asserted that it does not have any responsive studies.

**VIII. The Truth Matters**

90. The CDC is seen as one of the most trusted authorities in the world with regard to vaccinations. Its pronouncements regarding vaccines impact policy, research, and funding priorities across all HHS agencies as well as research institutions in the United States and around the world. The CDC should be able to support, with credible robust studies, the claims it makes regarding vaccine safety -- especially for the vaccine safety issue it has claimed to have studied more thoroughly than any other claimed vaccine injury.

91. The most recent data from CDC reveals that 1 in 36 children born this year in the United States will have an autism diagnosis. This is a true epidemic. The CDC and health authorities have conducted a decades-long media campaign seeking to assure parents that vaccines do not cause autism. But, making such statements without supporting studies is irresponsible. Perhaps this is why a majority of parents of children with autism still assert, based on their lived experience, that it was one or more vaccines that caused their child's autism. If the CDC and health authorities had spent resources on conducting the proper studies, rather than media relations, maybe they could produce the studies today which actually support this claim.

92. Administrative appeals were filed in regard to each of the FOIA requests discussed above; however, the statutory time to respond to same has elapsed. As such, all administrative remedies have been exhausted.

**REQUESTED RELIEF**

WHEREFORE, Plaintiff prays that this Court:

- a. Provide for expeditious proceedings in this action;

b. Enter an Order directing the CDC to (i) assert it does not have studies to support that DTaP vaccines do not cause autism or (ii) forthwith provide copies of the studies which support that DTaP vaccines do not cause autism;

c. Enter an Order directing the CDC to (i) assert it does not have studies to support that Hepatitis B vaccines do not cause autism or (ii) forthwith provide copies of the studies which support that Hepatitis B vaccines do not cause autism;

d. Enter an Order directing the CDC to (i) assert it does not have studies to support that Prevnar 13 does not cause autism or (ii) forthwith provide copies of the studies which support that Prevnar 13 does not cause autism;

e. Enter an Order directing the CDC to (i) assert it does not have studies to support that Hib vaccines do not cause autism or (ii) forthwith provide copies of the studies which support that Hib vaccines do not cause autism;

f. Enter an Order directing the CDC to (i) assert it does not have studies to support that IPV does not cause autism or (ii) forthwith provide copies of the studies which support that IPV does not cause autism;

g. Enter an Order directing the CDC to (i) assert it does not have studies to support that the cumulative exposure to the vaccines it recommends babies receive during the first six months of life does not cause autism or (ii) forthwith provide copies of the studies which support that the cumulative exposure to the vaccines it recommends babies receive during the first six months of life does not cause autism;

h. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

i. Grant such other and further relief as the Court may deem just and proper.

December 31, 2019

SIRI & GLIMSTAD LLP

A handwritten signature in blue ink, appearing to read 'ASiri', is written over a horizontal line.

Aaron Siri  
200 Park Avenue, 17th Floor  
New York, New York 10166  
Tel: (212) 532-1091

*Attorneys for Plaintiffs*

# Exhibit A

# Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger

UNITED STATES  
2019

## Vaccines in the Child and Adolescent Immunization Schedule\*

Vaccines	Abbreviations	Trade names
Diphtheria, tetanus, and acellular pertussis vaccine	<b>DTaP</b>	Daptacel Infanrix
Diphtheria, tetanus vaccine	<b>DT</b>	No Trade Name
<i>Haemophilus influenzae</i> type b vaccine	<b>Hib (PRP-T)</b> <b>Hib (PRP-OMP)</b>	ActHIB Hiberix PedvaxHIB
Hepatitis A vaccine	<b>HepA</b>	Havrix Vaqta
Hepatitis B vaccine	<b>HepB</b>	Engerix-B Recombivax HB
Human papillomavirus vaccine	<b>HPV</b>	Gardasil 9
Influenza vaccine (inactivated)	<b>IIV</b>	Multiple
Influenza vaccine (live, attenuated)	<b>LAIV</b>	FluMist
Measles, mumps, and rubella vaccine	<b>MMR</b>	M-M-R II
Meningococcal serogroups A, C, W, Y vaccine	<b>MenACWY-D</b> <b>MenACWY-CRM</b>	Menactra Menveo
Meningococcal serogroup B vaccine	<b>MenB-4C</b> <b>MenB-FHbp</b>	Bexsero Trumenba
Pneumococcal 13-valent conjugate vaccine	<b>PCV13</b>	Prenvar 13
Pneumococcal 23-valent polysaccharide vaccine	<b>PPSV23</b>	Pneumovax
Poliovirus vaccine (inactivated)	<b>IPV</b>	IPOL
Rotavirus vaccine	<b>RV1</b> <b>RV5</b>	Rotarix RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	<b>Tdap</b>	Adacel Boostrix
Tetanus and diphtheria vaccine	<b>Td</b>	Tenivac Td vaccine
Varicella vaccine	<b>VAR</b>	Varivax
<b>Combination Vaccines</b> (Use combination vaccines instead of separate injections when appropriate)		
DTaP, hepatitis B, and inactivated poliovirus vaccine	<b>DTaP-HepB-IPV</b>	Pediarix
DTaP, inactivated poliovirus, and <i>Haemophilus influenzae</i> type b vaccine	<b>DTaP-IPV/Hib</b>	Pentacel
DTaP and inactivated poliovirus vaccine	<b>DTaP-IPV</b>	Kinrix Quadacel
Measles, mumps, rubella, and varicella vaccines	<b>MMRV</b>	ProQuad

\*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

## How to use the child/adolescent immunization schedule

- 1** Determine recommended vaccine by age (**Table 1**)
- 2** Determine recommended interval for catch-up vaccination (**Table 2**)
- 3** Assess need for additional recommended vaccines by medical condition and other indications (**Table 3**)
- 4** Review vaccine types, frequencies, intervals, and considerations for special situations (**Notes**)

Recommended by the Advisory Committee on Immunization Practices ([www.cdc.gov/vaccines/acip](http://www.cdc.gov/vaccines/acip)) and approved by the Centers for Disease Control and Prevention ([www.cdc.gov](http://www.cdc.gov)), American Academy of Pediatrics ([www.aap.org](http://www.aap.org)), American Academy of Family Physicians ([www.aafp.org](http://www.aafp.org)), and American College of Obstetricians and Gynecologists ([www.acog.org](http://www.acog.org)).

### Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or (800-822-7967)



Download the CDC Vaccine Schedules App for providers at [www.cdc.gov/vaccines/schedules/hcp/schedule-app.html](http://www.cdc.gov/vaccines/schedules/hcp/schedule-app.html).

### Helpful information

- Complete ACIP recommendations: [www.cdc.gov/vaccines/hcp/acip-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/index.html)
- General Best Practice Guidelines for Immunization: [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html)
- Outbreak information (including case identification and outbreak response), see Manual for the Surveillance of Vaccine-Preventable Diseases: [www.cdc.gov/vaccines/pubs/surv-manual](http://www.cdc.gov/vaccines/pubs/surv-manual)



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

**Table 1**

**Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger United States, 2019**

These recommendations must be read with the Notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Table 1. To determine minimum intervals between doses, see the catch-up schedule (Table 2). School entry and adolescent vaccine age groups are shaded in gray.

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs
Hepatitis B (HepB)	1 <sup>st</sup> dose	2 <sup>nd</sup> dose			←----- 3 <sup>rd</sup> dose -----→												
Rotavirus (RV) RV1 (2-dose series); RV5 (3-dose series)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	See Notes												
Diphtheria, tetanus, & acellular pertussis (DTaP: <7 yrs)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose			←----- 4 <sup>th</sup> dose -----→				5 <sup>th</sup> dose					
Haemophilus influenzae type b (Hib)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	See Notes		←----- 3 <sup>rd</sup> or 4 <sup>th</sup> dose, See Notes -----→										
Pneumococcal conjugate (PCV13)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose		←----- 4 <sup>th</sup> dose -----→										
Inactivated poliovirus (IPV: <18 yrs)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	←----- 3 <sup>rd</sup> dose -----→							4 <sup>th</sup> dose					
Influenza (IIV)					Annual vaccination 1 or 2 doses										Annual vaccination 1 dose only		
Influenza (LAIV)												Annual vaccination 1 or 2 doses		Annual vaccination 1 dose only			
Measles, mumps, rubella (MMR)					See Notes	←----- 1 <sup>st</sup> dose -----→						2 <sup>nd</sup> dose					
Varicella (VAR)						←----- 1 <sup>st</sup> dose -----→						2 <sup>nd</sup> dose					
Hepatitis A (HepA)					See Notes	2-dose series, See Notes											
Meningococcal (MenACWY-D ≥9 mos; MenACWY-CRM ≥2 mos)			See Notes										1 <sup>st</sup> dose		2 <sup>nd</sup> dose		
Tetanus, diphtheria, & acellular pertussis (Tdap: ≥7 yrs)																	Tdap
Human papillomavirus (HPV)																	See Notes
Meningococcal B																	See Notes
Pneumococcal polysaccharide (PPSV23)												See Notes					

Range of recommended ages for all children
  Range of recommended ages for catch-up immunization
  Range of recommended ages for certain high-risk groups
  Range of recommended ages for non-high-risk groups that may receive vaccine, subject to individual clinical decision-making
  No recommendation

**Table 2****Catch-up immunization schedule for persons aged 4 months–18 years who start late or who are more than 1 month behind, United States, 2019**

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Table 1 and the notes that follow.

<b>Children age 4 months through 6 years</b>					
<b>Vaccine</b>	<b>Minimum Age for Dose 1</b>	<b>Minimum Interval Between Doses</b>			
		<b>Dose 1 to Dose 2</b>	<b>Dose 2 to Dose 3</b>	<b>Dose 3 to Dose 4</b>	<b>Dose 4 to Dose 5</b>
Hepatitis B	Birth	<b>4 weeks</b>	<b>8 weeks and at least 16 weeks after first dose.</b> Minimum age for the final dose is 24 weeks.		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days	<b>4 weeks</b>	<b>4 weeks</b> Maximum age for final dose is 8 months, 0 days.		
Diphtheria, tetanus, and acellular pertussis	6 weeks	<b>4 weeks</b>	<b>4 weeks</b>	<b>6 months</b>	<b>6 months</b>
<i>Haemophilus influenzae</i> type b	6 weeks	<b>No further doses needed</b> if first dose was administered at age 15 months or older. <b>4 weeks</b> if first dose was administered before the 1 <sup>st</sup> birthday. <b>8 weeks (as final dose)</b> if first dose was administered at age 12 through 14 months.	<b>No further doses needed</b> if previous dose was administered at age 15 months or older. <b>4 weeks</b> if current age is younger than 12 months <b>and</b> first dose was administered at younger than age 7 months, <b>and</b> at least 1 previous dose was PRP-T (ActHib, Pentacel, Hiberix) or unknown. <b>8 weeks and age 12 through 59 months (as final dose)</b> if current age is younger than 12 months <b>and</b> first dose was administered at age 7 through 11 months; OR if current age is 12 through 59 months <b>and</b> first dose was administered before the 1 <sup>st</sup> birthday, <b>and</b> second dose administered at younger than 15 months; OR if both doses were PRP-OMP (PedvaxHIB; Comvax) <b>and</b> were administered before the 1 <sup>st</sup> birthday.	<b>8 weeks (as final dose)</b> This dose only necessary for children age 12 through 59 months who received 3 doses before the 1 <sup>st</sup> birthday.	
Pneumococcal conjugate	6 weeks	<b>No further doses needed</b> for healthy children if first dose was administered at age 24 months or older. <b>4 weeks</b> if first dose administered before the 1 <sup>st</sup> birthday. <b>8 weeks (as final dose for healthy children)</b> if first dose was administered at the 1 <sup>st</sup> birthday or after.	<b>No further doses needed</b> for healthy children if previous dose administered at age 24 months or older. <b>4 weeks</b> if current age is younger than 12 months and previous dose given at <7 months old. <b>8 weeks (as final dose for healthy children)</b> if previous dose given between 7-11 months (wait until at least 12 months old); OR if current age is 12 months or older and at least 1 dose was given before age 12 months.	<b>8 weeks (as final dose)</b> This dose only necessary for children age 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age.	
Inactivated poliovirus	6 weeks	<b>4 weeks</b>	4 weeks if current age is < 4 years. 6 months (as final dose) if current age is 4 years or older.	<b>6 months</b> (minimum age 4 years for final dose).	
Measles, mumps, rubella	12 months	<b>4 weeks</b>			
Varicella	12 months	<b>3 months</b>			
Hepatitis A	12 months	<b>6 months</b>			
Meningococcal	2 months MenACWY-CRM 9 months MenACWY-D	<b>8 weeks</b>	See Notes	See Notes	
<b>Children and adolescents age 7 through 18 years</b>					
Meningococcal	Not Applicable (N/A)	<b>8 weeks</b>			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	<b>4 weeks</b>	<b>4 weeks</b> if first dose of DTaP/DT was administered before the 1 <sup>st</sup> birthday. <b>6 months (as final dose)</b> if first dose of DTaP/DT or Tdap/Td was administered at or after the 1 <sup>st</sup> birthday.	<b>6 months</b> if first dose of DTaP/DT was administered before the 1 <sup>st</sup> birthday.	
Human papillomavirus	9 years	<b>Routine dosing intervals are recommended.</b>			
Hepatitis A	N/A	<b>6 months</b>			
Hepatitis B	N/A	<b>4 weeks</b>	<b>8 weeks and</b> at least 16 weeks after first dose.		
Inactivated poliovirus	N/A	<b>4 weeks</b>	<b>6 months</b> A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years or if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	<b>4 weeks</b>			
Varicella	N/A	<b>3 months</b> if younger than age 13 years. <b>4 weeks</b> if age 13 years or older.			

**Table 3**

**Recommended Child and Adolescent Immunization Schedule by Medical Indication United States, 2019**

VACCINE	INDICATION									
	Pregnancy	Immunocompromised status (excluding HIV infection)	HIV infection CD4+ count <sup>1</sup>		Kidney failure, end-stage renal disease, on hemodialysis	Heart disease, chronic lung disease	CSF leaks/cochlear implants	Asplenia and persistent complement deficiencies	Chronic liver disease	Diabetes
			<15% and total CD4 cell count of <200/mm <sup>3</sup>	≥15% and total CD4 cell count of ≥200/mm <sup>3</sup>						
Hepatitis B	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Rotavirus	Yellow	Orange	Orange	Orange	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Diphtheria, tetanus, & acellular pertussis (DTaP)	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
<i>Haemophilus influenzae</i> type b	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Pneumococcal conjugate	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Inactivated poliovirus	Orange	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Influenza (IIV)	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
<b>or</b> Influenza (LAIV)	Red	Red	Red	Red	Red	Orange	Red	Red	Orange	Orange
Measles, mumps, rubella	Red	Red	Red	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Varicella	Red	Red	Red	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Hepatitis A	Purple	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Meningococcal ACWY	Purple	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Tetanus, diphtheria, & acellular pertussis (Tdap)	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Human papillomavirus	Pink	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Meningococcal B	Orange	Purple	Purple	Purple	Purple	Purple	Purple	Yellow	Purple	Purple
Pneumococcal polysaccharide	Purple	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow

Yellow Vaccination according to the routine schedule recommended  
Purple Recommended for persons with an additional risk factor for which the vaccine would be indicated  
Yellow with dots Vaccination is recommended, and additional doses may be necessary based on medical condition. See Notes.  
Red Contraindicated or use not recommended—vaccine should not be administered because of risk for serious adverse reaction  
Orange Precaution—vaccine might be indicated if benefit of protection outweighs risk of adverse reaction  
Pink Delay vaccination until after pregnancy if vaccine indicated  
Light Gray No recommendation

1 For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization “Altered Immunocompetence” at [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html), and Table 4-1 (footnote D) at: [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html).

2 Severe Combined Immunodeficiency

3 LAIV contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months.

## Notes

## Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2019

For vaccine recommendations for persons 19 years of age and older, see the Recommended Adult Immunization Schedule.

### Additional information

- Consult relevant ACIP statements for detailed recommendations at [www.cdc.gov/vaccines/hcp/acip-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/index.html).
- For information on contraindications and precautions for the use of a vaccine, consult the General Best Practice Guidelines for Immunization and relevant ACIP statements at [www.cdc.gov/vaccines/hcp/acip-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/index.html).
- For calculating intervals between doses, 4 weeks = 28 days. Intervals of  $\geq 4$  months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as “through.”
- Vaccine doses administered  $\leq 4$  days before the minimum age or interval are considered valid. Doses of any vaccine administered  $\geq 5$  days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age-appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval. For further details, see Table 3-1, Recommended and minimum ages and intervals between vaccine doses, in General Best Practice Guidelines for Immunization at [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html).
- Information on travel vaccine requirements and recommendations is available at [wwwnc.cdc.gov/travel/](http://wwwnc.cdc.gov/travel/).
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in General Best Practice Guidelines for Immunization at [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html), and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*. 31<sup>st</sup> ed. Itasca, IL: American Academy of Pediatrics; 2018:67–111).
- For information regarding vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All routine child and adolescent vaccines are covered by VICP except for pneumococcal polysaccharide vaccine (PPSV23). For more information, see [www.hrsa.gov/vaccinecompensation/index.html](http://www.hrsa.gov/vaccinecompensation/index.html).

### Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

#### Routine vaccination

- 5-dose series at 2, 4, 6, 15–18 months, 4–6 years
  - **Prospectively:** Dose 4 may be given as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4<sup>th</sup> dose that was inadvertently given as early as 12 months may be counted if at least 4 months have elapsed since dose 3.

#### Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older.
- For other catch-up guidance, see Table 2.

### Haemophilus influenzae type b vaccination (minimum age: 6 weeks)

#### Routine vaccination

- **ActHIB, Hiberix, or Pentacel:** 4-dose series at 2, 4, 6, 12–15 months
- **PedvaxHIB:** 3-dose series at 2, 4, 12–15 months

#### Catch-up vaccination

- **Dose 1 at 7–11 months:** Administer dose 2 at least 4 weeks later and dose 3 (final dose) at 12–15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- **Dose 1 before 12 months and dose 2 before 15 months:** Administer dose 3 (final dose) 8 weeks after dose 2.
- **2 doses of PedvaxHIB before 12 months:** Administer dose 3 (final dose) at 12–59 months and at least 8 weeks after dose 2.
- **Unvaccinated at 15–59 months:** 1 dose
- For other catch-up guidance, see Table 2.

#### Special situations

- **Chemotherapy or radiation treatment:**
  - 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

*Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.*
- **Hematopoietic stem cell transplant (HSCT):**
  - 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant regardless of Hib vaccination history

- **Anatomic or functional asplenia (including sickle cell disease):**

#### 12–59 months

- Unvaccinated or only 1 dose before 12 months: 2 doses, 8 weeks apart
- 2 or more doses before 12 months: 1 dose at least 8 weeks after previous dose

#### Unvaccinated\* persons age 5 years or older

- 1 dose

- **Elective splenectomy:**

#### Unvaccinated\* persons age 15 months or older

- 1 dose (preferably at least 14 days before procedure)

- **HIV infection:**

#### 12–59 months

- Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

#### Unvaccinated\* persons age 5–18 years

- 1 dose

- **Immunoglobulin deficiency, early component complement deficiency:**

#### 12–59 months

- Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
- 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

\*Unvaccinated = Less than routine series (through 14 months) OR no doses (14 months or older)

# Notes

## Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2019

### Hepatitis A vaccination

(minimum age: 12 months for routine vaccination)

#### Routine vaccination

- 2-dose series (**Havrix** 6–12 months apart or **Vaqta** 6–18 months apart, minimum interval 6 months); a series begun before the 2<sup>nd</sup> birthday should be completed even if the child turns 2 before the second dose is administered.

#### Catch-up vaccination

- Anyone 2 years of age or older may receive HepA vaccine if desired. Minimum interval between doses: 6 months
- Adolescents 18 years and older may receive the combined HepA and HepB vaccine, **Twinrix**, as a 3-dose series (0, 1, and 6 months) or 4-dose series (0, 7, and 21–30 days, followed by a dose at 12 months).

#### International travel

- Persons traveling to or working in countries with high or intermediate endemic hepatitis A ([wwwnc.cdc.gov/travel/](http://wwwnc.cdc.gov/travel/)):
  - **Infants age 6–11 months:** 1 dose before departure; revaccinate with 2 doses, separated by 6–18 months, between 12 to 23 months of age.
  - **Unvaccinated age 12 months and older:** 1<sup>st</sup> dose as soon as travel considered

#### Special situations

At risk for hepatitis A infection: 2-dose series as above

- **Chronic liver disease**
- **Clotting factor disorders**
- **Men who have sex with men**
- **Injection or non-injection drug use**
- **Homelessness**
- **Work with hepatitis A virus** in research laboratory or nonhuman primates with hepatitis A infection
- **Travel** in countries with high or intermediate endemic hepatitis A
- **Close, personal contact with international adoptee** (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A (administer dose 1 as soon as adoption is planned, at least 2 weeks before adoptee's arrival)

### Hepatitis B vaccination

(minimum age: birth)

#### Birth dose (monovalent HepB vaccine only)

- **Mother is HBsAg-negative:** 1 dose within 24 hours of birth for **all** medically stable infants  $\geq 2,000$  grams. Infants  $< 2,000$  grams: administer 1 dose at chronological age 1 month or hospital discharge.

- **Mother is HBsAg-positive:**

- Administer **HepB vaccine** and **0.5 mL of hepatitis B immune globulin (HBIG)** (at separate anatomic sites) within 12 hours of birth, regardless of birth weight. For infants  $< 2,000$  grams, administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.

- Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose.

- **Mother's HBsAg status is unknown:**

- Administer **HepB vaccine** within 12 hours of birth, regardless of birth weight.

- For infants  $< 2,000$  grams, administer **0.5 mL of HBIG** in addition to HepB vaccine within 12 hours of birth. Administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.

- Determine mother's HBsAg status as soon as possible. If mother is HBsAg-positive, administer **0.5 mL of HBIG** to infants  $\geq 2,000$  grams as soon as possible, but no later than 7 days of age.

#### Routine series

- 3-dose series at 0, 1–2, 6–18 months (use monovalent HepB vaccine for doses administered before age 6 weeks)
- Infants who did not receive a birth dose should begin the series as soon as feasible (see Table 2).
- Administration of **4 doses** is permitted when a combination vaccine containing HepB is used after the birth dose.
- **Minimum age** for the final (3<sup>rd</sup> or 4<sup>th</sup>) dose: 24 weeks
- **Minimum intervals:** dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks (when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations)

#### Catch-up vaccination

- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months.
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation **Recombivax HB** only).
- Adolescents 18 years and older may receive a 2-dose series of HepB (**Heplisav-B**) at least 4 weeks apart.
- Adolescents 18 years and older may receive the combined HepA and HepB vaccine, **Twinrix**, as a 3-dose series (0, 1, and 6 months) or 4-dose series (0, 7, and 21–30 days, followed by a dose at 12 months).
- For other catch-up guidance, see Table 2.

### Human papillomavirus vaccination

(minimum age: 9 years)

#### Routine and catch-up vaccination

- HPV vaccination routinely recommended for all adolescents **age 11–12 years (can start at age 9 years)** and through age 18 years if not previously adequately vaccinated
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9 through 14 years at initial vaccination:** 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
- If completed valid vaccination series with any HPV vaccine, no additional doses needed

#### Special situations

- **Immunocompromising conditions, including HIV infection:** 3-dose series as above
- **History of sexual abuse or assault:** Start at age 9 years
- **Pregnancy:** HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant; pregnancy testing not needed before vaccination

### Inactivated poliovirus vaccination

(minimum age: 6 weeks)

#### Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after the 4<sup>th</sup> birthday and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before the 4<sup>th</sup> birthday when a combination vaccine containing IPV is used. However, a dose is still recommended after the 4<sup>th</sup> birthday and at least 6 months after the previous dose.

#### Catch-up vaccination

- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- IPV is not routinely recommended for U.S. residents 18 years and older.

**Series containing oral polio vaccine (OPV)**, either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See [www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s\\_cid=mm6601a6\\_w](http://www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s_cid=mm6601a6_w).

## Notes

## Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2019

- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements. For guidance to assess doses documented as “OPV,” see [www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s\\_cid=mm6606a7\\_w](http://www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w).
- For other catch-up guidance, see Table 2.

**Influenza vaccination**

(minimum age: 6 months [IIV], 2 years [LAIV], 18 years [RIV])

**Routine vaccination**

- 1 dose any influenza vaccine appropriate for age and health status annually (2 doses separated by at least 4 weeks for **children 6 months–8 years** who did not receive at least 2 doses of influenza vaccine before July 1, 2018)

**Special situations**

- **Egg allergy, hives only:** Any influenza vaccine appropriate for age and health status annually
- **Egg allergy more severe than hives** (e.g., angioedema, respiratory distress): Any influenza vaccine appropriate for age and health status annually in medical setting under supervision of health care provider who can recognize and manage severe allergic conditions
- **LAIV should not be used for** those with a history of severe allergic reaction to any component of the vaccine (excluding egg) or to a previous dose of any influenza vaccine, children and adolescents receiving concomitant aspirin or salicylate-containing medications, children age 2 through 4 years with a history of asthma or wheezing, those who are immunocompromised due to any cause (including immunosuppression caused by medications and HIV infection), anatomic and functional asplenia, cochlear implants, cerebrospinal fluid-orpharyngeal communication, close contacts and caregivers of severely immunosuppressed persons who require a protected environment, pregnancy, and persons who have received influenza antiviral medications within the previous 48 hours.

**Measles, mumps, and rubella vaccination**  
(minimum age: 12 months for routine vaccination)**Routine vaccination**

- 2-dose series at 12–15 months, 4–6 years
- Dose 2 may be administered as early as 4 weeks after dose 1.

**Catch-up vaccination**

- Unvaccinated children and adolescents: 2 doses at least 4 weeks apart
- The maximum age for use of *MMRV* is 12 years.

**Special situations****International travel**

- **Infants age 6–11 months:** 1 dose before departure; revaccinate with 2 doses at 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.
- **Unvaccinated children age 12 months and older:** 2-dose series at least 4 weeks apart before departure

**Meningococcal serogroup A,C,W,Y vaccination**  
(minimum age: 2 months [MenACWY-CRM, Menveo], 9 months [MenACWY-D, Menactra])**Routine vaccination**

- 2-dose series: 11–12 years, 16 years

**Catch-up vaccination**

- Age 13–15 years: 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- Age 16–18 years: 1 dose

**Special situations****Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, eculizumab use:**

- **Menveo**
  - Dose 1 at age 8 weeks: 4-dose series at 2, 4, 6, 12 months
  - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after the 1<sup>st</sup> birthday)
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- **Menactra**
  - **Persistent complement component deficiency:**
    - Age 9–23 months: 2 doses at least 12 weeks apart
    - Age 24 months or older: 2 doses at least 8 weeks apart
  - **Anatomic or functional asplenia, sickle cell disease, or HIV infection:**
    - **Age 9–23 months:** Not recommended
    - **24 months or older:** 2 doses at least 8 weeks apart
    - **Menactra** must be administered at least 4 weeks after completion of PCV13 series.

**Travel in countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj** ([wwwnc.cdc.gov/travel/](http://wwwnc.cdc.gov/travel/)):

- Children age less than 24 months:
  - **Menveo (age 2–23 months):**
    - Dose 1 at 8 weeks: 4-dose series at 2, 4, 6, 12 months
    - Dose 1 at 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after the 1<sup>st</sup> birthday)
  - **Menactra (age 9–23 months):**
    - 2-dose series (dose 2 at least 12 weeks after dose 1; dose 2 may be administered as early as 8 weeks after dose 1 in travelers)
- Children age 2 years or older: 1 dose **Menveo** or **Menactra**

**First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:**

- 1 dose **Menveo** or **Menactra**

**Note:** **Menactra** should be administered either before or at the same time as DTaP. For MenACWY booster dose recommendations for groups listed under “Special situations” above and additional meningococcal vaccination information, see meningococcal *MMWR* publications at [www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html](http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html).

**Meningococcal serogroup B vaccination**  
(minimum age: 10 years [MenB-4C, Bexsero; MenB-FHbp, Trumenba])**Clinical discretion**

- MenB vaccine may be administered based on individual clinical decision to **adolescents not at increased risk** age 16–23 years (preferred age 16–18 years):
- **Bexsero:** 2-dose series at least 1 month apart
- **Trumenba:** 2-dose series at least 6 months apart; if dose 2 is administered earlier than 6 months, administer a 3<sup>rd</sup> dose at least 4 months after dose 2.

**Special situations****Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, eculizumab use:**

- **Bexsero:** 2-dose series at least 1 month apart
  - **Trumenba:** 3-dose series at 0, 1–2, 6 months
- Bexsero** and **Trumenba** are not interchangeable; the same product should be used for all doses in a series. For additional meningococcal vaccination information, see meningococcal *MMWR* publications at [www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html](http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html).

**Pneumococcal vaccination**

(minimum age: 6 weeks [PCV13], 2 years [PPSV23])

**Routine vaccination with PCV13**

- 4-dose series at 2, 4, 6, 12–15 months

**Catch-up vaccination with PCV13**

- 1 dose for healthy children age 24–59 months with any incomplete\* PCV13 series
- For other catch-up guidance, see Table 2.

**Special situations**

**High-risk conditions below: When both PCV13 and PPSV23 are indicated, administer PCV13 first. PCV13 and PPSV23 should not be administered during same visit.**

**Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:**

Age 2–5 years

- Any incomplete\* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

Age 6–18 years

- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

**Cerebrospinal fluid leak, cochlear implant:**Age 2–5 years

- Any incomplete\* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13, 8 weeks after the most recent dose and administered 8 weeks apart
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

Age 6–18 years

- No history of either PCV13 or PPSV23: 1 dose PCV13, 1 dose PPSV23 at least 8 weeks later
- Any PCV13 but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV13
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent dose of PPSV23

**Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases**

**associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:**

Age 2–5 years

- Any incomplete\* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose) and a 2<sup>nd</sup> dose of PPSV23 5 years later

Age 6–18 years

- No history of either PCV13 or PPSV23: 1 dose PCV13, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- Any PCV13 but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent PPSV23 dose and a 2<sup>nd</sup> dose of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV13

**Chronic liver disease, alcoholism:**Age 6–18 years

- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

\*An incomplete series is defined as not having received all doses in either the recommended series or an age-appropriate catch-up series. See Tables 8, 9, and 11 in the ACIP pneumococcal vaccine recommendations ([www.cdc.gov/mmwr/pdf/rr/rr5911.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf)) for complete schedule details.

**Rotavirus vaccination**

(minimum age: 6 weeks)

**Routine vaccination**

- **Rotarix:** 2-dose series at 2 and 4 months.
- **RotaTeq:** 3-dose series at 2, 4, and 6 months.

If any dose in the series is either **RotaTeq** or unknown, default to 3-dose series.

**Catch-up vaccination**

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Figure 2.

**Tetanus, diphtheria, and pertussis (Tdap) vaccination**

(minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

**Routine vaccination**

- **Adolescents age 11–12 years:** 1 dose Tdap
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

**Catch-up vaccination**

- **Adolescents age 13–18 years who have not received Tdap:** 1 dose Tdap, then Td booster every 10 years
- **Persons age 7–18 years not fully immunized with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td.
- **Children age 7–10 years** who receive Tdap inadvertently or as part of the catch-up series should receive the routine Tdap dose at 11–12 years.
- **DTaP inadvertently given after the 7<sup>th</sup> birthday:**
  - **Child age 7–10 years:** DTaP may count as part of catch-up series. Routine Tdap dose at 11–12 should be administered.
  - **Adolescent age 11–18 years:** Count dose of DTaP as the adolescent Tdap booster.
- For other catch-up guidance, see Table 2.
- For information on use of Tdap or Td as tetanus prophylaxis in wound management, see [www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm](http://www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm).

**Varicella vaccination**

(minimum age: 12 months)

**Routine vaccination**

- 2-dose series: 12–15 months, 4–6 years
- Dose 2 may be administered as early as 3 months after dose 1 (a dose administered after a 4-week interval may be counted).

**Catch-up vaccination**

- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at [www.cdc.gov/mmwr/pdf/rr/rr5604.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf)) have 2-dose series:
  - **Ages 7–12 years:** routine interval: 3 months (minimum interval: 4 weeks)
  - **Ages 13 years and older:** routine interval: 4–8 weeks (minimum interval: 4 weeks).
  - The maximum age for use of *MMRV* is 12 years.

# Exhibit B

**TABLE 1. Recommended schedule for active immunization of normal infants and children (See individual ACIP recommendations for details.)**

Recommended age*	Vaccine(s) <sup>†</sup>	Comments
2 mo.	DTP-1, <sup>§</sup> OPV-1 <sup>¶</sup>	Can be given earlier in areas of high endemicity
4 mo.	DTP-2, OPV-2	6-wks-2-mo. interval desired between OPV doses to avoid interference
6 mo.	DTP-3	An additional dose of OPV at this time is optional for use in areas with a high risk of polio exposure
15 mo.**	MMR <sup>††</sup>	
18 mo.**	DTP-4, OPV-3	Completion of primary series
4-6 yr. <sup>§§</sup>	DTP-5, OPV-4	Preferably at or before school entry
14-16. yr	Td <sup>¶¶</sup>	Repeat every 10 years throughout life

\*These recommended ages should not be construed as absolute, i.e. 2 mos. can be 6-10 weeks, etc.

<sup>†</sup>For all products used, consult manufacturer's package enclosure for instructions for storage, handling, and administration. Immunobiologics prepared by different manufacturers may vary, and those of the same manufacturer may change from time to time. The package insert should be followed for a specific product.

<sup>§</sup>DTP—Diphtheria and tetanus toxoids and pertussis vaccine.

<sup>¶</sup>OPV—Oral, attenuated poliovirus vaccine contains poliovirus types 1, 2, and 3.

\*\*Simultaneous administration of MMR, DTP, and OPV is appropriate for patients whose compliance with medical care recommendations cannot be assured.

<sup>††</sup>MMR—Live measles, mumps, and rubella viruses in a combined vaccine (see text for discussion of single vaccines versus combination).

<sup>§§</sup>Up to the seventh birthday.

<sup>¶¶</sup>Td—Adult tetanus toxoid and diphtheria toxoid in combination, which contains the same dose of tetanus toxoid as DTP or DT and a reduced dose of diphtheria toxoid.

**1983 childhood immunization schedule**

# Exhibit C



**VIA FEDEX**

October 12, 2017

U.S. Department of Health & Human Services  
HHS Office of the Secretary  
Eric D. Hargan  
Acting Secretary of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: *HHS Vaccine Safety Responsibilities and Notice Pursuant to 42 U.S.C. § 300aa-31*

Dear Secretary Hargan:

Informed Consent Action Network hereby provides notice per 42 U.S.C. § 300aa-31(b).

Americans, including the over 55 organizations listed below, whose members exceed 5 million Americans, are concerned about vaccine safety. The National Childhood Vaccine Injury Act of 1986 (the **1986 Act**) made nearly every aspect of vaccine safety the exclusive responsibility of the Department of Health & Human Services (**HHS**). As the Secretary of HHS (the **Secretary**), this means you shoulder virtually all responsibility for assuring the safety of vaccines administered to America's 78 million children.

This notice respectfully requests confirmation that certain obligations regarding vaccine safety required under the 1986 Act have been fulfilled or will forthwith be fulfilled. These specific requests are numbered sequentially in this notice. We would welcome the opportunity to meet and discuss reasonable means for complying with these requests. If that is not possible, the 1986 Act authorizes "a civil action ... against the Secretary where there is alleged a failure of the Secretary to perform any act or duty" under the 1986 Act.

**I. Background**

The 1986 Act granted economic immunity to pharmaceutical companies for injuries caused by their vaccines. (42 U.S.C. § 300aa-11.) The 1986 Act thereby eliminated the market force which drives safety for all other products – actual and potential product liability. Recognizing the unprecedented elimination of this market force, the 1986 Act makes HHS directly responsible for virtually every aspect of vaccine safety. (42 U.S.C. §§ 300aa-2, 300aa-27.)

When the CDC recommends a pediatric vaccine for universal use, it creates for that vaccine's maker a liability free market of 78 million children typically required by law to receive the vaccine. The number of required vaccines has grown rapidly since 1986. In 1983, the CDC recommended that babies under one receive two vaccines: DTP and Polio.<sup>1</sup> As of 2017, the CDC recommends that babies under one receive multiple doses of ten vaccines: DTaP, Polio, Hep B, Rotavirus, Hib, Pneumococcal, Influenza, MMR, Varicella, and Hep A.<sup>2</sup> In total, the current CDC childhood vaccine schedule includes 56 injections of 73 doses of 30 different vaccines.

## II. Deficiencies in the Pre-Licensure Safety Review of Pediatric Vaccines

All drugs licensed by the FDA undergo long-term double-blind pre-licensure clinical trials during which the rate of adverse reactions in the group receiving the drug under review is compared to the rate of adverse reactions in a group receiving an inert placebo, such as a sugar pill or saline injection. For example: Enbrel's pre-licensure trials followed subjects up to 80 months and controls received a saline injection.<sup>3</sup> Lipitor's pre-licensure trials lasted a median of 4.8 years and controls received a sugar pill.<sup>4</sup> Botox's pre-licensure trials lasted a median of 51 weeks and controls received a saline injection.<sup>5</sup> And even with these long-term studies, drugs are still often recalled.

In contrast, vaccines are *not* required to undergo long-term double-blind inert-placebo controlled trials to assess safety. In fact, not a single one of the clinical trials for vaccines given to babies and toddlers had a control group receiving an inert placebo. Further, most pediatric vaccines currently on the market have been approved based on studies with inadequate follow-up periods of only a few days or weeks.

For example, of the two Hepatitis B vaccines licensed by the FDA for injection into one-day-old babies, Merck's was licensed after trials that solicited adverse reactions for *only five days* after vaccination and GlaxoSmithKline's was licensed after trials that solicited adverse reactions for *only four days* after vaccination.<sup>6</sup> Similarly, the HiB vaccines sold by these same companies were licensed based on trials which solicited adverse reactions for three and four days, respectively, after vaccination.<sup>7</sup> The only stand-alone polio vaccine was licensed after a mere 48-hour follow-up period.<sup>8</sup>

---

<sup>1</sup> <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg>

<sup>2</sup> <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

<sup>3</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/103795s5503lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf)

<sup>4</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020702s056lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf)

<sup>5</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/103000s5302lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf)

<sup>6</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>;

<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>

<sup>7</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf>;

<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf>

<sup>8</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf>

Moreover, these trials either had no control group or a control group which received other vaccines as a “placebo.”<sup>9</sup> This means each new vaccine need only be roughly as safe as one (or in some cases numerous) previously licensed vaccines. Such flawed and unscientific study designs cannot establish the actual safety profile of any vaccine. The real adverse event rate for a vaccine can only be determined by comparing subjects receiving the vaccine with those receiving an inert placebo. Yet, this basic study design, required for every drug, is not required before or after licensing a vaccine.

The 1986 Act expressly requires that you, as the Secretary, “shall make or assure improvements in ... the licensing ... and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.” (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

- (1) Please explain how HHS justifies licensing any pediatric vaccine without first conducting a long-term clinical trial in which the rate of adverse reactions is compared between the subject group and a control group receiving an inert placebo?**
- (2) Please list and provide the safety data relied upon when recommending babies receive the Hepatitis B vaccine on the first day of life?**

### **III. Post-Licensure Surveillance of Vaccine Adverse Events**

The lack of pre-licensure safety data leaves the assessment of vaccine safety to the post-licensing period when they are being administered to children in the “real world.” To capture vaccine adverse events in the real world, the 1986 Act established the Vaccine Adverse Events Reporting System (VAERS) operated by HHS. (42 U.S.C. § 300aa-25.)

In 2016, VAERS received 59,117 reports of adverse vaccine events, including 432 deaths, 1,091 permanent disabilities, 4,132 hospitalizations, and 10,284 emergency room visits.<sup>10</sup>

However, only a tiny fraction of adverse vaccine events are reported to VAERS. An HHS-funded study by Harvard Medical School tracked reporting to VAERS over a three-year period at Harvard Pilgrim Health Care involving 715,000 patients and found that “fewer than 1% of vaccine adverse events are reported.”<sup>11</sup> A U.S. House Report similarly stated: “Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events.”<sup>12</sup>

---

<sup>9</sup> Ibid.

<sup>10</sup> <https://wonder.cdc.gov/vaers.html>

<sup>11</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>12</sup> <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>

Assuming VAERS captures a full 1 percent of adverse events – which is more than is estimated – the VAERS data above from 2016 may reflect that in that year alone there were 5,911,700 adverse vaccine events, including 43,200 deaths, 109,100 permanent disabilities, 413,200 hospitalizations, and 1,028,400 emergency room visits.

Of course, these figures are merely estimates. It would be far better if adverse events reports were automatically created and submitted to VAERS to avoid the issue of underreporting. Automated reporting would provide invaluable information that could clarify which vaccines might cause which harms and to whom, potentially avoiding these injuries and deaths.

The idea of automating adverse reaction reporting to VAERS is not new or even difficult to achieve.<sup>13</sup> An agency within HHS, the Agency for Healthcare Research and Quality, sought to do exactly that in 2007 when it provided an approximately \$1 million grant to automate VAERS reporting at Harvard Pilgrim Health Care.<sup>14</sup> The result was the successful automation of adverse event reports at Harvard Pilgrim:

*Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions ... were identified.*<sup>15</sup>

These results should have been concerning to HHS since they show that over only a three-year period, there were 35,570 reportable reactions in just 376,452 vaccine recipients.

After automating adverse events reports at Harvard Pilgrim, the developers of this system asked the CDC to take the final step of linking VAERS with the Harvard Pilgrim system so that these reports could be automatically transmitted into VAERS. Instead, the CDC refused to cooperate. As the Harvard grant recipients explained:

*Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.*<sup>16</sup>

After three years and spending \$1 million of taxpayers' money, the CDC refused to even communicate with the HHS' Harvard Medical School grant recipients. Given HHS's statutory mandate to assure safer vaccines, it should have rushed forward with automating VAERS reporting -- not ignored the requests by the HHS's Harvard grant recipients.

---

<sup>13</sup> <https://healthit.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system>

<sup>14</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>15</sup> Ibid.

<sup>16</sup> Ibid.

While HHS strongly supports automating public health surveillance systems, when it comes to vaccine safety, the CDC has only supported projects that would limit VAERS to passive surveillance.<sup>17</sup> Automation would improve safety and address many of the long-standing issues and limitations raised by CDC regarding VAERS.<sup>18</sup> Capturing “fewer than 1% of vaccine adverse events” thirty years after the passage of the 1986 Act is unacceptable -- and potentially deadly.

The 1986 Act expressly provides that you, as the Secretary, “shall make or assure improvements in ... adverse reaction reporting ... in order to reduce the risks of adverse reactions to vaccines.” (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

**(3) Please explain why HHS failed to cooperate with Harvard to automate VAERS reporting? And detail any steps that HHS has taken since toward automating VAERS reporting?**

**(4) Please explain any specific steps taken by HHS to improve adverse reaction reporting to VAERS?**

#### **IV. Identifying What Injuries Are Caused by Vaccines**

The first step in assuring safer vaccines is to identify what harms they cause. This would normally be accomplished pre-licensure by long-term, inert-placebo controlled trials – but these are never performed for vaccines. As for post-licensure monitoring, HHS has refused to improve VAERS as discussed above. Hence, assessing which vaccines cause which injuries is mainly left to post-licensure studies. HHS, unfortunately, has neglected to perform these studies.

In 1991, the Institute of Medicine (IOM) examined 22 commonly reported serious injuries following the DTP vaccine.<sup>19</sup> The IOM concluded the scientific literature supported a causal relationship between the DTP vaccine and 6 of these injuries: acute encephalopathy, chronic arthritis, acute arthritis, shock and unusual shock-like state, anaphylaxis, and protracted inconsolable crying.<sup>20</sup> The IOM, however, found the scientific literature was insufficient to conclude whether or not the DTP vaccine can cause 12 other serious injuries:

*Aseptic meningitis; Chronic neurologic damage; Learning disabilities and attention-deficit disorder; Hemolytic anemia; Juvenile diabetes; Guillain-Barre syndrome; Erythema multiforme; Autism; Peripheral mononeuropathy; Radiculoneuritis and other neuropathies; Thrombocytopenia; Thrombocytopenic purpura*<sup>21</sup>

---

<sup>17</sup> [http://www.ajpmonline.org/article/S0749-3797\(12\)00249-8/pdf](http://www.ajpmonline.org/article/S0749-3797(12)00249-8/pdf); <https://www.ncbi.nlm.nih.gov/pubmed/26209838>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/>

<sup>18</sup> Ibid.

<sup>19</sup> <https://www.nap.edu/read/1815/chapter/2#7>

<sup>20</sup> Ibid.

<sup>21</sup> Ibid.

The IOM lamented that it “encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines” and on the poor design of the few existing studies.<sup>22</sup> It therefore cautioned that: “If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.”<sup>23</sup>

In 1994, the IOM issued another report which examined the scientific literature for evidence that could either prove or disprove a causal link between 54 commonly reported serious injuries and vaccination for diphtheria, tetanus, measles, mumps, polio, hepatitis B, and Hib.<sup>24</sup> The IOM located sufficient science to support a causal connection between these vaccines and 12 injuries, including death, anaphylaxis, thrombocytopenia, and Guillain-Barre syndrome.<sup>25</sup> The IOM, however, found the scientific literature was insufficient to conclude whether or not these vaccines caused 38 other commonly reported serious injuries, including:

*Demyelinating diseases of the central nervous system, Sterility, Arthritis, Neuropathy, Residual seizure disorder, Transverse myelitis, Sensorineural deafness, Optic neuritis, Aseptic meningitis, Insulin-dependent diabetes mellitus, SIDS*<sup>26</sup>

As in 1991, this IOM Report again stated, “The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern.”<sup>27</sup>

In 2011, more than fifteen years after the IOM Reports in 1991 and 1994, HHS paid the IOM to conduct another assessment regarding vaccine safety.<sup>28</sup> This third IOM Report reviewed the available science with regard to the 158 most common vaccine injuries claimed to have occurred from vaccination for varicella, hepatitis B, tetanus, measles, mumps, and rubella.<sup>29</sup> The IOM located science which “convincingly supports a causal relationship” with 14 of these injuries, including pneumonia, meningitis, hepatitis, MIBE, febrile seizures, and anaphylaxis.<sup>30</sup> The review found sufficient evidence to support “acceptance of a causal relationship” with 4 additional serious injuries.<sup>31</sup>

The IOM, however, found the scientific literature was insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

---

<sup>22</sup> <https://www.nap.edu/read/1815/chapter/2#8>

<sup>23</sup> <https://www.nap.edu/read/1815/chapter/9>

<sup>24</sup> <https://www.nap.edu/read/2138/chapter/2#12>

<sup>25</sup> <https://www.nap.edu/read/2138/chapter/2#12>

<sup>26</sup> Ibid.

<sup>27</sup> <https://www.nap.edu/read/2138/chapter/12>

<sup>28</sup> <https://www.nap.edu/read/13164/chapter/2#2>

<sup>29</sup> Ibid.

<sup>30</sup> <https://www.nap.edu/read/13164/chapter/2#3>

<sup>31</sup> Ibid.

*Encephalitis, Encephalopathy, Infantile Spasms, Afebrile Seizures, Seizures, Cerebellar Ataxia, Acute Disseminated Encephalomyelitis, Transverse Myelitis, Optic Neuritis, Neuromyelitis Optica, Multiple Sclerosis, Guillain-Barre Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy, Brachial Neuritis, Amyotrophic Lateral Sclerosis, Small Fiber Neuropathy, Chronic Urticaria, Erythema Nodosum, Systemic Lupus Erythematosus, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Arthralgia, Autoimmune Hepatitis, Stroke, Chronic Headache, Fibromyalgia, Sudden Infant Death Syndrome, Hearing Loss, Thrombocytopenia, Immune Thrombocytopenic Purpura*<sup>32</sup>

Thus, out of the 158 most common serious injuries reported to have been caused by the vaccines under review, the evidence supported a causal relationship for 18 of them, rejected a causal relationship for 5 of them, but for the remaining 135 vaccine-injury pairs, over 86 percent of those reviewed, the IOM found that the science simply had not been performed.<sup>33</sup>

The 1986 Act expressly provides that you, as the Secretary, “shall promote the development of childhood vaccines that result in fewer and less adverse reactions” and “shall make or assure improvements in ... the ... labeling, warning, ... and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.” (42 U.S.C. § 300aa-27(a)(2).) The first step in reducing adverse reactions is identifying what adverse reactions are caused by vaccine. Given this statutory obligation:

- (5) For each of the 38 vaccine-injury pairs reviewed in the 1994 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?**
  
- (6) For each of the 135 vaccine-injury pairs reviewed in the 2011 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?**

Further to your duties to identify what injuries are caused by vaccines, the 1986 Act also expressly requires you to “make or assure improvements in ... the ... recall of reactogenic lots or batches, of vaccines ... in order to reduce the risks of adverse reactions to vaccines” and thus each “health care provider who administers a vaccine ... shall record ... in such person’s permanent

---

<sup>32</sup> Ibid.

<sup>33</sup> Ibid.

medical record ... the vaccine manufacturer and lot number.” (42 U.S.C. §§ 300aa-25(a), 300aa-27(a)(2).) Since health care providers often fail to record this information:

**(7) Please explain what HHS has done to assure that health care providers record the manufacturer and lot number for each vaccine they administer?**

**V. Identifying Which Children are Susceptible to Vaccine Injury**

The IOM has consistently acknowledged there is individual susceptibility to serious vaccine injuries. The IOM has also acknowledged that research on such susceptibility must be done on an individual basis, considering a child’s personal genome, behaviors, microbiome, intercurrent illness, and present and past environmental exposure. HHS, unfortunately, has not conducted this research.

In 1994, the IOM, building on concerns raised in its 1991 report, stated: “The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not.”<sup>34</sup> The IOM urged that “research should be encouraged to elucidate the factors that put certain people at risk.”<sup>35</sup>

Yet, seventeen years later, in 2011, the IOM acknowledged this research had still not been done:

*Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact...*

*Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine... much work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients.*<sup>36</sup>

In 2013, HHS commissioned the IOM to review the safety of the entire vaccine schedule.<sup>37</sup> The IOM again explained that while “most children who experience an adverse reaction to immunization have preexisting susceptibility,” the IOM:

---

<sup>34</sup> <https://www.nap.edu/read/2138/chapter/12#307>. See also <https://www.nap.edu/read/1815/chapter/9>

<sup>35</sup> Ibid.

<sup>36</sup> <https://www.nap.edu/read/13164/chapter/5#82>

<sup>37</sup> <https://www.nap.edu/read/13563/chapter/1>

*found that evidence assessing outcomes in sub populations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes.*<sup>38</sup>

HHS had failed to even define the terminology for the study of susceptible subpopulations and hence IOM admonished HHS to “develop a framework that clarifies and standardizes definitions of ... populations that are potentially susceptible to adverse events.”<sup>39</sup>

The IOM correctly points out in 2011 that given the “widespread use of vaccines” and “state mandates requiring vaccination of children ... it is essential that safety concerns receive assiduous attention.”<sup>40</sup> This is the same call for diligent attention that the IOM made in 1991 and 1994. Unfortunately, all of these calls for action have gone unheeded. The critical scientific inquiry to identify individuals susceptible to serious vaccine injury has never been conducted.

The 1986 Act expressly provides that you, as the Secretary, “shall promote the development of childhood vaccines that result in fewer and less adverse reactions” and “shall make or assure improvements in ... the ... labeling, warning, ... and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.” (42 U.S.C. § 300aa-27(a)(2).) Given this statutory obligation:

**(8) Please advise when HHS intends to begin conducting research to identify which children are susceptible to serious vaccine injury? If HHS believes it has commenced this research, please detail its activities regarding same?**

## **VI. Removing Claim “Vaccines Do Not Cause Autism” from the CDC Website**

HHS, unfortunately, has treated vaccine safety as a public relations issue rather than a public health imperative. For example, the CDC claims on its website that “Vaccines Do Not Cause Autism” even though this broad claim is plainly not supported by the scientific literature.<sup>41</sup>

Indeed, as part of the IOM’s 2011 review of vaccine safety, it was asked by HHS whether there is a causal relationship between autism and the DTaP vaccine administered to children at two, four, six, and fifteen months of age.<sup>42</sup> The IOM could not locate a single study supporting

<sup>38</sup> <https://www.nap.edu/read/13563/chapter/9#130>

<sup>39</sup> Ibid.

<sup>40</sup> <https://www.nap.edu/read/13164/chapter/3#28>

<sup>41</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>42</sup> <https://www.nap.edu/read/13164/chapter/2#2>

that DTaP does not cause autism.<sup>43</sup> The IOM therefore concluded: “The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.”<sup>44</sup> The IOM’s full explanation in its 2011 Report for this finding is attached as Appendix B. In fact, the only study the IOM could locate regarding whether DTaP causes autism, (Geier and Geier, 2004), concluded there *was* an association between DTaP and autism.<sup>45</sup> No research has been published since 2011 that could change the IOM’s conclusion. Based on the foregoing, the CDC cannot validly make the blanket assertion that there is no causal relationship between vaccines and autism. The CDC nonetheless claims on its website that “Vaccines Do Not Cause Autism.”

As with DTaP, there are also no published studies showing that autism is not caused by Hepatitis B, Rotavirus, Hib, Pneumococcal, Inactivated Poliovirus, Influenza, Varicella, or Hepatitis A vaccines – all of which HHS recommends babies receive, typically multiple times, by one year of age.<sup>46</sup>

Instead, HHS’s claim that “Vaccines Do Not Cause Autism” relies almost entirely upon studies exclusively studying only one vaccine, MMR (which is administered no earlier than one year of age), or only one vaccine ingredient, thimerosal, with regard to autism.<sup>47</sup> Putting aside the controversy surrounding these studies, studies which focus on only one vaccine and one ingredient while ignoring the entire balance of the CDC’s pediatric vaccine schedule cannot support the CDC’s overarching declaration that “Vaccines Do Not Cause Autism.”

As for the MMR vaccine, the CDC’s own Senior Scientist, Dr. William Thompson<sup>48</sup>, recently provided a statement through his attorney that the CDC “omitted statistically significant information” showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by the CDC with American children.<sup>49</sup> Dr. Thompson, in a recorded phone call, stated the following regarding concealing this association: “Oh my God, I can’t believe we did what we did. But we did. It’s all there. It’s all there. I have handwritten notes.”<sup>50</sup> Dr. Thompson further stated on that call:

*I have great shame now when I meet families with kids with autism because I have been part of the problem ... the CDC is so paralyzed right now by anything related to autism. They’re not doing what they should be doing because they’re afraid to look for things that might be associated. So anyway*

<sup>43</sup> <https://www.nap.edu/read/13164/chapter/12#545>

<sup>44</sup> Ibid.

<sup>45</sup> Ibid. Ironically, this study was disregarded “because it provided data from a passive surveillance system [VAERS] and lacked an unvaccinated comparison population,” which would be true of any study using VAERS data.

<sup>46</sup> <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

<sup>47</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>48</sup> Dr. Thompson has been a scientist at CDC for nearly two generations and a senior scientist on over a dozen CDC publications at the core of many of CDC’s vaccine safety claims. <https://www.ncbi.nlm.nih.gov/pubmed>

<sup>49</sup> <http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf>

<sup>50</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

*there's still a lot of shame with that. ... I am completely ashamed of what I did.*<sup>51</sup>

Hence, as for the only vaccine, MMR, actually studied by the CDC with regard to autism, it appears the CDC may have concealed an association between that vaccine and autism.<sup>52</sup>

When the former Director of the National Institute of Health, Dr. Bernadine Healy, was asked about whether public health authorities are correct to claim that vaccines do not cause autism, she answered: "You *can't* say that."<sup>53</sup> When asked again, Dr. Healy explained: "The more you delve into it – if you look at the basic science – if you look at the research that's been done, in animals – if you also look at some of these individual cases – *and*, if you look at the evidence that there *is* no link - what I come away with is: *The question has not been answered.*"<sup>54</sup>

Former NIH Director Dr. Healy goes on to explain:

*This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine... I haven't seen major studies that focus on - three hundred kids, who got autistic symptoms within a period of a few weeks of a vaccine. I think that the public health officials have been too quick to dismiss the hypothesis as irrational, without sufficient studies of causation. ...*

*The reason why they didn't want to look for those susceptibility groups was because they're afraid if they found them—however big or small they were—that that would scare the public away. First of all, I think the public's smarter than that; the public values vaccines. But, more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show!*<sup>55</sup>

The CDC has also failed to address the science supporting a link between vaccines and autism.<sup>56</sup> For example, the CDC has not addressed a study which found a 300% increased rate of autism among newborns receiving the hepatitis B vaccine at birth compared to those that did not.<sup>57</sup> Nor a recent and first ever vaccinated vs. unvaccinated pilot study which found vaccinated

---

<sup>51</sup> Ibid.

<sup>52</sup> Studies of MMR and autism are also erroneous because of healthy user bias, which has been emphasized as a serious source of error in epidemiological vaccine safety studies by CDC scientists. <https://doi.org/10.1093/oxfordjournals.aje.a116479>

<sup>53</sup> <http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/>

<sup>54</sup> Ibid.

<sup>55</sup> Ibid.

<sup>56</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>57</sup> [http://hisunim.org.il/images/documents/scientific\\_literature/Gallagher\\_Goodman\\_HepB\\_2010.pdf](http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf)

children had a 420% increased rate of autism and that vaccinated preterm babies had an even higher rate of autism.<sup>58</sup> There is also a persuasive body of science supporting a clear connection between aluminum adjuvants in vaccines and autism which the CDC, despite numerous requests, has failed to directly or substantively address.<sup>59</sup> Letters from three aluminum adjuvant experts on this point are attached as Appendix C.

The critical need for HHS to properly engage in vaccine safety science regarding autism is made even more vital by the fact that vaccine makers are immune from liability for vaccine injury and vaccines are not safety-tested prior to licensure to assess whether they cause autism. Without proper long-term trials comparing those receiving the vaccine to an inert-placebo group, it is impossible to know prior to licensure whether these products cause autism. There are also no follow-up studies which compare vaccinated with unvaccinated individuals and hence no supportable basis to claim that vaccines do not cause any cases of autism. For the CDC to make this claim, it must demonstrate that a child receiving the entire vaccine schedule is at no greater risk of becoming autistic than a child that is unvaccinated. No such study has ever been done. The IOM Report referenced above has confirmed that the CDC cannot make this claim even for children receiving only the DTaP vaccine, let alone the entire vaccine schedule.

The 1986 Act expressly provides that you, as the Secretary, are to “develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table.” (42 U.S.C. § 300aa-26(a).) This section further provides that:

The information in such materials shall be based on available data and information ... and shall include ... (1) a concise description of the benefits of the vaccine, (2) a concise description of the risks associated with the vaccine, (3) a statement of the availability of the National Vaccine Injury Compensation Program, and (4) such other relevant information as may be determined by the Secretary.

(42 U.S.C. § 300aa-26(c).) The VIS produced for every vaccine, including for DTaP, provides that other relevant information regarding the vaccine is available at the CDC website, [www.cdc.gov](http://www.cdc.gov).<sup>60</sup> The CDC website in turn claims that “Vaccines Do Not Cause Autism.”<sup>61</sup> Since HHS has chosen to incorporate the CDC’s website into the VIS as a resource, the information on that website regarding the relevant vaccine must be “based on available data and information.” *Id.* But, based on available data and information, as highlighted by the IOM, HHS cannot validly claim that “Vaccines Do Not Cause Autism.” Hence:

---

<sup>58</sup> <http://www.oatext.com/pdf/ITS-3-186.pdf>; <http://www.oatext.com/pdf/ITS-3-187.pdf>

<sup>59</sup> <http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf>

<sup>60</sup> <https://www.cdc.gov/vaccines/hcp/vis/current-vis.html>

<sup>61</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

- (9) Please confirm that HHS shall forthwith remove the claim that “Vaccines Do Not Cause Autism” from the CDC website, or alternatively, please identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism?

## VII. Refusal to Conduct Vaccinated Versus Unvaccinated Study

The only scientifically valid way to answer a large portion of the questions raised regarding vaccine safety would be a long-term, properly powered and controlled study comparing the rate of all adverse events between vaccinated children and completely unvaccinated children. This is the same type of study required by HHS for every drug pre-licensure. HHS has nonetheless refused to conduct any such study, even retrospectively.

The need for this study is highlighted by the results of a few recent limited vaccinated vs. unvaccinated studies.

Dr. Peter Aaby is renowned for studying and promoting vaccines in Africa with over 300 published studies.<sup>62</sup> In 2017, he published a study finding children vaccinated with DTP were 10 times more likely to die in the first 6 months of life than the unvaccinated.<sup>63</sup> Dr. Aaby’s study therefore concluded that: “All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis.”<sup>64</sup> More disturbing is that children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.<sup>65</sup> This indicated that while DTP reduced the incidence of diphtheria, tetanus, and pertussis, it increased susceptibility to other infections.<sup>66</sup>

It is equally troubling that Dr. Aaby’s study was based on data that had been collecting dust for over 30 years<sup>67</sup> This begs the question: what other serious vaccine injuries are we missing because of neglect to conduct proper vaccine safety science.

A pilot study comparing 650 vaccinated and unvaccinated homeschooled children in the United States provides a glimpse of the potential scope of vaccine harm.<sup>68</sup> The study found that, compared to completely-unvaccinated children, fully-vaccinated children had an increased risk

<sup>62</sup> <https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D>

<sup>63</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/> Dr. Aaby’s study was more reliable than other vaccine safety studies because the subjects were accurately matched. An increasingly recognized problem in vaccine safety studies is that subjects are typically not well-matched. People with pre-existing health problems are reluctant to receive a vaccine, and are therefore unwittingly used as controls. When this happens, the control group is sicker than the vaccine-exposed group at the outset of the study. Studies with this problem give wrong results, and make the vaccine look much safer than it really is. Dr. Aaby’s study was one of the few specifically designed to avoid this error.

<sup>64</sup> Ibid.

<sup>65</sup> Ibid.

<sup>66</sup> Ibid.

<sup>67</sup> Ibid.

<sup>68</sup> <http://www.oatext.com/pdf/IJS-3-186.pdf>

of 390% for allergies, 420% for ADHD, 420% for autism, 290% for eczema, 520% for learning disabilities, and 370% for any neuro-developmental delay.<sup>69</sup> Fully-vaccinated pre-term infants had an increased risk of 1,450% for a neurodevelopmental disorder, which includes a learning disability, ADHD or autism, compared to completely unvaccinated preterm infants.<sup>70</sup>

Another recent study compared children receiving the flu shot with those receiving a saline injection in a prospective randomized double-blind study.<sup>71</sup> Both groups had the same rate of influenza but the group receiving the flu shot had a 440% increased rate of non-influenza infection.<sup>72</sup> Like the DTP study, the flu vaccine increased susceptibility to other infections.

A properly sized vaccinated versus unvaccinated study is necessary and possible. As stated by the IOM in 2013: “It is possible to make this comparison through analyses of patient information contained in large databases such as VSD.”<sup>73</sup> Senior CDC Scientist, Dr. Thompson similarly stated this type of study can and “needs to be done” but that the CDC is “not doing what they should be doing because they’re afraid to look for things that might be associated.”<sup>74</sup> When vaccine makers are generating over \$33 billion in vaccine revenue annually and the CDC is spending over \$5 billion annually to promote and purchase vaccines, there is no justification for not performing this study.<sup>75</sup>

The 1986 Act expressly provides that you, as the Secretary, “shall promote the development of childhood vaccines that result in fewer and less adverse reactions” and “shall make or assure improvements in ... the ... labeling, warning, ... and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.” (42 U.S.C. § 300aa-27(a)(2).) Since comparing children receiving the vaccines recommended by the CDC with those that have not received any vaccines is the only scientifically valid way to assess the safety of the CDC’s vaccine schedule:

**(10) Please advise whether HHS intends to forthwith conduct adequately powered and controlled prospective as well as retrospective studies comparing total health outcomes of**

<sup>69</sup> Ibid.

<sup>70</sup> <http://www.oatext.com/pdf/ITS-3-187.pdf>

<sup>71</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>72</sup> Ibid. See also [http://vaccine-safety.s3.amazonaws.com/CDC\\_FOIA\\_Response\\_UnpublishedStudy.pdf](http://vaccine-safety.s3.amazonaws.com/CDC_FOIA_Response_UnpublishedStudy.pdf) (The CDC in 2001 apparently conducted a narrow vaccinated versus unvaccinated study comparing children receiving the Hepatitis B vaccine during the first month of life versus those who did not. The results of this study were never released by the CDC, and an abstract of the study was only recently obtained under a FOIA request. Children vaccinated with Hepatitis B vaccine in the first month of life, compared to children receiving no vaccines in the first month of life, had an increased risk of 829% for ADHD, 762% for autism, 638% for ADD, 565% for tics, 498% for sleep disorders, and 206% for speech delays. Note that while the abstract discusses comparing thimerosal exposure, since the only vaccine recommended by one month of age was Hepatitis B, and since only thimerosal containing Hepatitis B vaccine was available at the time of this study, this study appears to have primarily compared children receiving Hepatitis B with children that did not receive this vaccine.)

<sup>73</sup> <https://www.nap.edu/read/13563/chapter/2#13>

<sup>74</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

<sup>75</sup> <https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf>; <https://www.bccresearch.com/market-research/pharmaceuticals/vaccine-technologies-markets-report-phm014f.html>

**fully/partially vaccinated children with completely unvaccinated children?**

### **VIII. Reducing Conflicts of Interest at HHS**

The 1986 Act created a system in which vaccines are licensed, recommended, encouraged, subsidized, and defended by HHS. The 1986 Act's scheme thus places HHS in charge of two competing duties. On one hand, HHS is responsible for vaccine safety. On the other hand, HHS is required to promote vaccine uptake and defend against any claim they cause any harm.

Regrettably, it appears that HHS has chosen to focus almost entirely on its vaccine promotion and defense function to such a degree that it has essentially abandoned its vaccine safety function. To restore balance, HHS must take serious steps to create an "ethics firewall" between these competing functions. HHS also must take action with regard to its vaccine committee members and employees that have conflicts with vaccine makers.

**HHS Licenses & Recommends Vaccines.** With regard to the FDA's Vaccines and Related Biological Products Advisory Committee (**VRBPAC**), which effectively decides whether to license a vaccine, in 2000 the U.S. House Committee on Government Reform (the **Committee**) "determined that conflict of interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings."<sup>76</sup> The Committee concluded of the VRBPAC: "The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."<sup>77</sup>

With regard to the CDC's Advisory Committee on Immunization Practices (**ACIP**), which effectively decides whether to universally recommend a pediatric vaccine, the Committee found that ACIP members routinely fail to disclose conflicts with vaccine makers and when conflicts are disclosed "[t]he CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of their conflicts."<sup>78</sup> The Committee drew focus on the vaccine most recently approved by the ACIP and found extensive and troubling conflicts of interest for most the ACIP members voting to recommend its universal use for children.<sup>79</sup> The Committee was further concerned that "ACIP liaison representatives have numerous ties to

---

<sup>76</sup> <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf> (For instance, "3 out of 5 FDA advisory committee [VRBPAC] members who voted to approve the rotavirus vaccine in December 1997 [then the most recently approved vaccine by the VRBPAC] had significant financial ties to pharmaceutical companies that were developing different versions of the vaccine.")

<sup>77</sup> Ibid.

<sup>78</sup> Ibid.

<sup>79</sup> Ibid. (The Committee's findings were that: (1) The chairman served on Merck's Immunization Advisory Board; (2) another member, who shared the patent on a rotavirus vaccine, had a \$350,000 grant from Merck to develop the vaccine, and was a consultant for Merck; (3) another member was under contract with the Merck Vaccine Division, a principal investigator for SmithKline and received funds from various vaccine makers; (4) another member received a salary and other payments from Merck; (5) another member participated in vaccine studies with Merck, Wyeth, and SmithKline; and (6) another member received grants from Merck and SmithKline.)

vaccine manufacturers” but act like voting members of ACIP.<sup>80</sup> The Committee further took issue with the extensive conflicts of interests of members of ACIP’s working groups which convene behind closed doors and whose recommendations are typically rubber stamped by the ACIP.<sup>81</sup> The Committee concluded that ACIP reflected “a system where government officials make crucial decisions affecting American children without the advice and consent of the governed.”<sup>82</sup>

Despite the concerns the Committee expressed in its 2000 report, not much changed. A December 2009 report by the HHS Office of Inspector General found that the “CDC had a systemic lack of oversight of the ethics program for SGEs [a.k.a. **committee members**]”.<sup>83</sup> For example, “Most of the experts who served on advisory panels in 2007 to evaluate vaccines for flu and cervical cancer had potential conflicts that were never resolved.”<sup>84</sup>

In fact, the Inspector General found that the “CDC certified [conflict disclosure forms] with at least one omission in 2007 for 97 percent ... of SGEs,” “58 percent ... of SGEs had at least one potential conflict of interest that CDC did not identify,” and when the CDC identified a conflict, it improperly granted broad waivers despite being castigated for this improper practice in 2000.<sup>85</sup> Even worse, “32 percent ... of SGEs ... had at least one potential conflict of interest that CDC identified but did not resolve” and 13 percent of SGEs were allowed to participate in committee meetings without even having a conflict disclosure form on file.<sup>86</sup>

As the system is set up, an ACIP vote to recommend a vaccine, grants a vaccine manufacturer a liability-free market of 78 million American children, who are legally compelled to receive the vaccine, and billions of taxpayer dollars guaranteeing payment. In such a system, an ACIP vote must be completely insulated from any influence by the vaccine manufacturer. Instead, the opposite appears to be the norm.

**HHS Promotes Vaccines.** Moreover, while the CDC states on its website -- not less than 130 times -- that “CDC does not accept commercial support,” this is simply not true.<sup>87</sup> For example, the British Medical Journal reported in 2015 that: “Despite the agency’s disclaimer, the CDC does receive millions of dollars in industry gifts and funding, both directly and indirectly, and several recent CDC actions and recommendations have raised questions about the science it cites, the clinical guidelines it promotes, and the money it is taking.”<sup>88</sup> As another example, pharmaceutical companies and other private entities, through the “CDC Foundation,” can create and fund programs at the CDC (over half a billion dollars’ worth to-date), endow positions at the

---

<sup>80</sup> Ibid.

<sup>81</sup> Ibid.

<sup>82</sup> Ibid.

<sup>83</sup> <https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf>

<sup>84</sup> <http://www.nytimes.com/2009/12/18/health/policy/18cdc.html>

<sup>85</sup> <https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf> (Splicing down this 58% of unidentified conflicts, 40% involved employment or grants, 13% involved equity ownership, and 5% involved consulting.)

<sup>86</sup> Ibid.

<sup>87</sup> <https://search.cdc.gov/search?query=%22cdc+does+not+accept+commercial+support%22&utf8=%E2%9C%93&affiliate=cdc-main>

<sup>88</sup> <http://www.bmj.com/content/350/bmj.h2362>

CDC, and even place individuals to work at the CDC, paid through “private funding.” (42 U.S.C.A. § 280e-11(h)(1), (2).)

Worse, the promotion track for CDC management extends into vaccine makers. The most prominent example is former CDC Director Dr. Julie Gerberding, who headed the agency from 2002 through 2009. Dr. Gerberding oversaw several controversial studies regarding vaccines produced by Merck, which sought to silence those calling for an increase in the safety profile of those vaccines. When she left the CDC she was rewarded with the position of President of Merck Vaccines in 2010 with a reported \$2.5 million annual salary and lucrative stock options.<sup>89</sup>

**HHS Defends Vaccines.** After HHS licenses, effectively mandates, and promotes a vaccine to 78 million American children with very limited safety data, this very same government agency is mandated to defend against any claim that the vaccine caused harm.

There is no other for-profit product where the very department responsible for regulating that product is statutorily required to promote its uptake and simultaneously defend against any claim it causes harm.

The Vaccine Injury Compensation Program (**VICP**) is effectively the only legal recourse in America to obtain compensation for a pediatric vaccine injury. (42 U.S.C. § 300aa-10 *et seq.*)<sup>90</sup> The injured must litigate against HHS and the DOJ in a quasi-judicial process filed under seal where the injured child effectively cannot obtain documents from or depose vaccine makers to prove how the vaccine caused injury. (§ 300aa-12.) DOJ and HHS have the government’s vast resources, while the injured child must secure a private attorney. (§ 300aa-15.) Moreover, the injured child’s damages are limited to \$250,000 for death and pain and suffering. (*Id.*)

Worst of all, the injured child must almost always prove “causation” – the biological mechanism by which the vaccine injured the child.<sup>91</sup> Requiring an injured child to prove causation adds insult to injury because had HHS conducted the vaccine safety science it demands as proof in the VICP before licensing a vaccine, the child’s injury may have been avoided altogether.

This truly is the epitome of injustice: requiring a child receiving a compulsory pharmaceutical product to medically prove to HHS how the vaccine caused his or her injury, where the science to understand vaccine injuries is not being done by the government department, HHS, tasked with this job.<sup>92</sup> As confirmed by the IOM, HHS has not conducted the basic science needed to even determine whether commonly claimed vaccine injuries are caused by vaccines.<sup>93</sup> It has failed to conduct even one properly sized study comparing vaccinated to

---

<sup>89</sup> <https://www.sec.gov/cgi-bin/own-disp?action=getowner&CIK=0001628884>

<sup>90</sup> See also *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011)

<sup>91</sup> <http://www.gao.gov/assets/670/667136.pdf>

<sup>92</sup> See Sections II, III, IV, V, VI, and VII above.

<sup>93</sup> See Section IV above.

unvaccinated children, despite all the resources at its disposal.<sup>94</sup> It is no wonder a single injured child's claim faces a high likelihood of failure in the VICP.

Many parents, doctors and scientists, as well as politicians, are legitimately concerned about the process whereby vaccines are licensed, recommended, promoted and defended by the same department. This is not because of any conspiracy, or belief an insidious intent. Rather, this system eliminates the incentive, and in fact creates a disincentive for HHS and vaccine makers, to conduct research to uncover long term chronic conditions, including the immune and neurological system disorders, which can result from the current vaccine schedule.

The 1986 Act expressly provides that you, as the Secretary, have at least equal and arguably greater responsibility for vaccine safety than for vaccine promotion. (42 U.S.C. §§ 300aa-2, 300aa-27.) In accordance with this statutory responsibility:

**(11) Please advise if you will:**

- a. **prohibit conflict waivers for members of HHS's vaccine committees (ACIP, VRBPAC, NVAC & ACCV)?**
- b. **prohibit HHS vaccine committee members or HHS employees with duties involving vaccines from accepting any compensation from a vaccine maker for five years?**
- c. **require that vaccine safety advocates comprise half of HHS's vaccine committees?**
- d. **allocate toward vaccine safety an amount at least equal to 50% of HHS's budget for promoting/purchasing vaccines?**
- e. **support the creation of a vaccine safety department independent of HHS?**
- f. **support the repeal of the 1986 Act to the extent it grants immunity to pharmaceutical companies for injuries caused by their vaccine products?**

**IX. Conclusion**

HHS can do better. With hundreds of vaccines in the pipeline it must do better. Children susceptible to vaccine injury are as deserving of protection as any other child. Avoiding injury to these children is not only a moral and ethical duty, but will in fact strengthen the vaccine program. Every parent that does not witness their child suffer a serious reaction after vaccination, such as a seizure or paralysis, is another parent that will not add their voice to the growing chorus of parents opposed to HHS's vaccine program due to safety concerns.

---

<sup>94</sup> See Section VII above.

Unless HHS performs its vital statutory obligations regarding vaccine safety, and until a frank conversation is possible regarding vaccine safety, children susceptible to vaccine injury will not be protected from such injuries. Nor will children injured by vaccines be able to access the services they need. We can do far better in protecting and serving children who are susceptible or succumb to serious injuries from vaccination. The first step in avoiding these harms and helping children already harmed is admitting there are deficiencies and working diligently to improve vaccine safety.

We respectfully request your attention to the important concerns outlined above and hope you agree that addressing these concerns is in everyone's best interest. These, in fact, reflect nothing more than what Congress already explicitly recognized when passing the 1986 Act: vaccines can and do cause serious injury and HHS needs to work diligently to identify and reduce these harms. If you would like to meet and discuss the foregoing, we would welcome that opportunity and hope to work cooperatively to address these issues.

If that is not possible, Congress, as a final resort to assure vaccine safety, authorized a "civil action ... against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under" the 1986 Act. (42 U.S.C. § 300aa-31(a).) We are prepared to authorize such an action and this letter constitutes the notice required by 42 U.S.C. § 300aa-31(b). It is, however, our hope that the vaccine safety issues identified herein can be resolved cooperatively, with all interested parties working together toward the common goal of vaccine safety entrusted to HHS under the 1986 Act.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Del Bigtree', written in a cursive style.

Del Bigtree

cc: See Appendix A.

Enclosures: Appendices A to C.

# Appendix A

A Voice For Choice  
A Voice For Choice Advocacy  
Christina Hildebrand, President  
530 Showers Drive, Suite 7404  
Mountain View, CA 94040

Alliance For Natural Health  
Gretchen DuBeau, President  
3525 Piedmont Road NE B6-310  
Atlanta, GA 30305

Arizona Coalition Against Mandated  
Vaccines  
Kelsey Davis, President  
Gilbert, AZ 85212

Autism Action Network  
John Gilmore, President  
550 East Chester Street  
Long Beach, NY 11561

Autism Giving Tree  
Christina Stafford, M.Ed., BCBA, LBS,  
President  
660 'W' Street  
King of Prussia, PA 19406

AutismOne  
Ed Arranga, President  
1816 West Houston Avenue  
Fullerton, CA 92833

The Canary Party  
Jennifer Larson, President  
6533 Flying Cloud Drive, Suite 1200  
Eden Prairie, MN 55344

Colorado Coalition for Vaccine Choice  
Fran Sincere, President  
125 S. Zephyr  
Lakewood, CO 80226

DAIR Foundation  
Dawn Loughborough, President  
10200 US HWY 290 West  
Austin, TX 78736

Elizabeth Birt Center for Autism Law and  
Advocacy  
Kim Mack Rosenberg, President  
200 Cabrini Boulevard, Suite 66  
New York, NY 10033

Enriched Parenting  
Rebecca Fleischman, President  
1208 Avenue M, Suite 2323  
Brooklyn, NY 11230

Focus for Health Foundation  
Shannon Mulvihill, R.N., Executive Director  
776 Mountain Boulevard, Suite 202  
Watchung, NJ 07069

Georgia Coalition for Vaccine Choice  
Sandi Marcus, Founder/CEO  
P.O. Box 45  
Silver Creek, GA 30173

Health Choice  
Mark Blaxil, President  
6533 Flying Cloud Drive, Suite 1200  
Eden Prairie, MN 55344

Health Choice Massachusetts  
Candice Edwards, President  
P.O. Box 175  
Manchaug, MA 01526

Indiana for Medical Freedom  
Melissa Sura, President  
5424 Grapevine Drive  
Indianapolis, IN 46235

Health Choice Maryland  
Emily Tarsell, President  
1501 Sulgrave Avenue, Suite 208  
Baltimore, MD 21209

Informed Choice Washington  
Jena Dalpez, President  
14106 93rd Avenue NE  
Kirkland, WA 98034

Health Choice Connecticut  
Dr. Elissa Diamond Fields, President  
P.O. Box 29  
Roxbury, CT 06783

Kentucky Vaccine Rights Coalition  
Jennifer Benge & Ashley Kennedy, Co-  
Presidents  
899 Corinth Road  
Corbin, KY 40701

Health Freedom Florida  
Dr. Ryan Fenn & MacKenzie Fraser, Co-  
Presidents  
153 Ivernia Loop  
Tallahassee, FL 32312

Know The Vax  
Angela Gallagher, President  
4553 Aldrich Avenue North  
Minneapolis, MN 55412

Health Freedom Idaho  
Miste Gardner Karlfeldt, President  
1045 S Ancona Ave Ste 140  
Eagle, ID 83616

Learn the Risk  
Brandy Vaughan, President  
3463 State Street, Suite 182  
Santa Barbara, CA 93105

Healthcare Freedom Hawaii  
Jessica McCormick &  
Natasha Sky, Co-Directors  
Mililani, HI 96789

Louisiana Parents for Vaccine Rights  
Melisha Dooley &  
Sunny Dixon, Co-Directors  
413 Toby Lane  
Metairie, LA 70003

Illinois Coalition for Informed Consent  
Jen Suter &  
Danielle Olson, Co-Directors  
Jacksonville, IL 62650

Maine Coalition for Vaccine Choice  
Ginger Taylor, Director  
11 High Street  
Brunswick, ME 04011

March Against Monsanto  
Tami Canal, President  
7878 South 1960 East  
South Weber, UT 84405

Moms Across America  
Zen Honeycutt, President  
24000 Alicia Parkway, Suite 17-236  
Mission Viejo, CA 92691

Michigan for Vaccine Choice  
Suzanne M. Waltman, President  
22615 Francis Street  
St. Clair Shores, MI 48082

Montanans For Medical Freedom  
Edna Kent, Director  
PO Box 1443  
Florence, MT 59833

Minnesota Natural Health Coalition  
Lee Beaty, President  
1043 Grand Ave, Suite 317  
St. Paul MN 55105

My Kids, My Choice  
Rita Palma, President  
2 Purdy Avenue  
Baypoint, NY 11705

Minnesota Natural Health Legal Reform  
Project  
Leo Cashman, President  
1043 Grand Ave, Suite 317  
St. Paul, MN 55105

National Health Freedom Action  
Jerri Johnson, President  
PMB 218, 2136 Ford Parkway  
St. Paul, MN 55116

Minnesota Vaccine Freedom Coalition  
Angela Gallagher, President  
4553 Aldrich Avenue North  
Minneapolis, MN 55412

National Health Freedom Coalition  
Roseanne Lindsay, President  
PMB 218, 2136 Ford Parkway  
St. Paul, MN 55116

Mississippi Parents for Vaccine Rights  
MaryJo Perry, President  
P.O. Box 141  
Pelahatchie, MS 39145

New York Alliance for Vaccine Rights  
Aimee Villella McBride & Maria Gavriel,  
Co-Presidents  
550 East Chester Street  
Long Beach, NY 11561

Missouri Parents Against Vaccines  
Janessa Baake & Kendal Bourne, Co-  
Presidents  
323 N. Fox Ridge Drive, Suite 204  
Raymore, MO 64083

Ohio Advocates for Medical Freedom  
Robert M. Wise, President  
P.O. Box 1236  
Hartville, OH 44632

Oklahomans for Vaccine and Health Choice  
Liza Greve, President  
P.O. Box 721356  
Norman, OK 73070

Spectrum Revolution  
Catharine Layton, President  
357 S. Earlham Street  
Orange, CA 92869

Organic Consumers Association  
Ronnie Cummins, CEO  
6771 South Silver Hill Dr.  
Finland, MN 55603

Tennessee Coalition for Vaccine Choice  
Kristen Odom-Holland, President  
P.O. Box 4508  
Chattanooga, TN 37405

Parents United 4 Kids  
Stefanie Fetzer & Shawna Lambert, Co-  
Presidents  
2925 Bonanza  
San Clemente, CA 92673

Vaccine Injury Awareness League  
Michelle Ford, President  
10866 Washington Blvd, Suite 65  
Culver City, CA 90232

People Advocating Vaccine Education, Inc.  
Lisa Jillani, CEO  
P.O. Box 690712  
Charlotte, NC 28227

Vaccine Safety Council Minnesota  
Patti Carroll, President  
6533 Flying Cloud Drive, Suite 1200  
Eden Prairie, MN 55344

Physicians for Informed Consent  
Dr. Shira Miller, Executive Director  
13749 Riverside Drive  
Sherman Oaks, CA 91423

Vermont Coalition for Vaccine Choice  
Jennifer Stella, President  
P.O. Box 74  
Waitsfield, VT 05673

Rogue Recovery  
Tyler Dahm, President  
3221 West 96th Avenue  
Westminster, CO 80031

Virginians for Health Freedom  
Deborah Hommer, President  
P.O. Box 2015  
Spotsylvania, VA 22553

South Carolina Health Coalition  
Jennifer Black & Rebekah Watson, Co-  
Presidents  
1754 Woodruff Road, Suite 112  
Greenville, SC 29607

West Virginians for Health Freedom  
Dr. Chanda Adkins, Director  
108 Yorktown Court  
Beckley, WV 25801

Weston A. Price Foundation  
Sally Fallon Morell, President  
PMB 106-380, 4200 Wisconsin Avenue NW  
Washington, D.C., 20016

World Mercury Project  
Robert F. Kennedy, Jr., Chairman  
1227 North Peachtree Parkway, Suite 202  
Peachtree City, GA 3026

# Appendix B

# Adverse Effects of Vaccines

## Evidence and Causality

Committee to Review Adverse Effects of Vaccines  
Board on Population Health and Public Health Practice  
Kathleen Stratton, Andrew Ford, Erin Rusch, and Ellen Wright Clayton,  
*Editors*

INSTITUTE OF MEDICINE  
*OF THE NATIONAL ACADEMIES*

THE NATIONAL ACADEMIES PRESS  
Washington, D.C.  
[www.nap.edu](http://www.nap.edu)

*Weight of Epidemiologic Evidence*

*The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and ataxia.*

**Mechanistic Evidence**

The committee identified one publication reporting the development of ataxia after the administration of DTaP vaccine. Kubota and Takahashi (2008) did not provide evidence of causality beyond a temporal relationship of 2 days between vaccine administration and development of cerebellar symptoms leading to a diagnosis of acute cerebellar ataxia. The publication did not contribute to the weight of mechanistic evidence.

*Weight of Mechanistic Evidence*

*The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and ataxia as lacking.*

**Causality Conclusion**

**Conclusion 10.5:** The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and ataxia.

**AUTISM****Epidemiologic Evidence**

The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

*Weight of Epidemiologic Evidence*

*The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.*

### Mechanistic Evidence

The committee did not identify literature reporting clinical, diagnostic, or experimental evidence of autism after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis antigens alone or in combination.

#### *Weight of Mechanistic Evidence*

*The committee assesses the mechanistic evidence regarding an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism as lacking.*

### Causality Conclusion

**Conclusion 10.6:** The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.

## ACUTE DISSEMINATED ENCEPHALOMYELITIS

### Epidemiologic Evidence

No studies were identified in the literature for the committee to evaluate the risk of acute disseminated encephalomyelitis (ADEM) after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, or acellular pertussis antigens alone or in combination.

#### *Weight of Epidemiologic Evidence*

*The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccines and ADEM.*

### Mechanistic Evidence

The committee identified five publications of ADEM developing after the administration of vaccines containing diphtheria toxoid and tetanus toxoid antigens alone or in combination. Four publications did not provide evidence beyond temporality, one of which was deemed too short based on the possible mechanisms involved (Abdul-Ghaffar and Achar, 1994; Bolukbasi and Ozmenoglu, 1999; Hamidon and Raymond, 2003; Rogalewski et al., 2007). In addition, Rogalewski et al. (2007) reported the administration of vaccines against hepatitis B, hepatitis A, and poliovirus in

# Appendix C



a place of mind  
THE UNIVERSITY OF BRITISH COLUMBIA

Faculty of Medicine  
Department of Ophthalmology  
& Visual Sciences  
Shaw Laboratory  
828 West 10th Avenue, Room 386  
Vancouver, BC Canada V5Z 1L8

June 24, 2017

United States Department of Health & Human Services  
National Institutes of Health  
Food & Drug Administration  
Centers for Disease Control & Prevention  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Phone 604 875 4111 Local 68375  
Fax 604 875 4376  
www.neuraldynamicsubc.ca

Re: *Aluminum Adjuvants*

Dear Directors:

I am writing to you in regard to aluminum adjuvants in vaccines. This subject is one my laboratory works on intensively and therefore one where I feel that I have some expertise. In particular, we have studied the impact of aluminum adjuvants in animal models of neurological disease, including autism spectrum disorder (ASD). Our relevant studies on the general topic of aluminum neurotoxicity in general and specifically in regard to adjuvants are cited below.

These studies and the broader existing literature regarding aluminum toxicity, lead almost invariably to the conclusion that aluminum in any chemical form is always neurotoxic when administered to humans. Further, I am convinced that aluminum adjuvants in vaccines may contribute to neurological disorders across the lifespan. In adults, such adjuvant may induce macrophagic myofasciitis, a disease with neuropathological aspects. In children, there is growing evidence that aluminum adjuvants may disrupt developmental processes in the central nervous system and therefore contribute to ASD in susceptible children.

Despite the foregoing, the safety of aluminum adjuvants in vaccines has not been properly studied in humans even though, pursuant to the recommended vaccine schedule published by the Centers for Disease Control (CDC), a baby may be injected with up to 3,675 micrograms of aluminum adjuvant by six months of age.

In regard to the above, it is my belief that the CDC's claim on its website that "Vaccines Do Not Cause Autism" is wholly unsupported. Given this, I remain convinced that much more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is warranted and should be a research priority for the NIH and other funding bodies.

Yours sincerely,

Christopher A. Shaw, Ph.D  
Professor  
Dept. of Ophthalmology and Visual Sciences  
University of British Columbia  
828 W. 10<sup>th</sup> Ave.  
Vancouver, British Columbia  
Canada, V5Z1M9  
Tel: 604-875-4111 (ext. 68373)  
Email: [cashawlab@gmail.com](mailto:cashawlab@gmail.com)



## Relevant Publications (Shaw Laboratory)

1. Crepeaux G, Eidi H, David MO, Baba-Amer Y, Tzavara E, giros B, authier FJ, Exley C, Shaw CA, Cadusseau J, Gherardi RK. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective dose neurotoxicity. *Toxicology*. 375:48-57. (2016).
2. Crepeaux G, Eidi H, David M-O, Tzavara E, Giros B, Exley C, Curmi PA, Shaw CA, Gherardi RK, Cadusseau J. Highly delayed systemic translocation of aluminium-based adjuvant in CD1 mice following intramuscular injections. *J. Inorg. Biochem.* 152:199-205. (2015).
3. Shaw CA, Li D, Tomljenovic L. Are there negative CNS impacts of aluminum adjuvants in vaccines and immunotherapy? *Immunotherapy*. 6 (10):1055-1071. (2014).
4. Shaw CA, Seneff S, Kette SD, Tomljenovic L, Oller Jr JW, Davidson RM. Aluminum-induced entropy in biological systems: Implications for neurological disease. *J Toxicology*. Volume 2014, Article ID 491316. (2014).
5. Shaw CA, Kette SD, Davidson RM, Seneff S. Aluminum's role in CNS-immune system interactions leading to neurological disorders. *Immunome Res*. 9:1.
6. Shaw CA, Marler TE. Aluminum and the human diet revisited. In: *Communicative & Integrative Biology; Landes Bioscience*. 6:e26369. (2013).
7. Shaw CA, Tomljenovic L. Aluminum in the central nervous system (CNS): toxicity in humans and animals, vaccine adjuvants, and autoimmunity. *Immunol Res*. (2013).
8. Shaw CA, Li Y, Tomljenovic L. Administration of aluminum to neonatal mice in vaccine in vaccine-relevant amounts is associated with adverse long term neurological outcomes. *J Inorg Chem*. (2013).
9. Tomljenovic L, Shaw CA. Mechanisms of aluminum adjuvant toxicity and autoimmunity in pediatric populations. *Lupus*. 21:223-230. (2012).
10. Tomljenovic L and Shaw CA. Editorial, Special Issue: The Biochemistry/Toxicity of Aluminum. *Current Inorganic Chemistry*. 2(1): 1-2. (2012).
11. Tomljenovic L and Shaw CA. Do aluminum vaccine adjuvants contribute to the rising prevalence of autism? *J Inorg Biochem*. 105(11):1489-99. (2011).
12. Tomljenovic L and Shaw CA. Aluminum vaccine adjuvants: Are they safe? *Current Medicinal Chemistry*. 18:2630 – 2637. (2011).
13. Shaw CA and Petrik MS. Aluminum hydroxide injections lead to motor deficits and motor neuron degeneration. *J Inorganic Biochem*. 103 (11): 1555-62. (2009).
14. Petrik MS, Wong MC, Tabata RC, Garry RF, and Shaw CA. Aluminum adjuvant linked to Gulf War illness induces motor neuron death in mice. *J Neuromolecular Medicine*. 9: 83-100. (2007).

June 15, 2017

United States Department of Health & Human Services  
National Institutes of Health  
Food & Drug Administration  
Centers for Disease Control & Prevention  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: *Aluminum Adjuvants*

Dear Directors:

I am an expert in the field of aluminum adjuvants toxicity in humans and animal models. I have been working in this field since the initial description of the Al vaccine-induced macrophagic myofasciitis in 1998. Since that time I have written 40 peer-reviewed scientific publications and one book on this subject.

I strongly support the contention that aluminum adjuvants in vaccines may have a role in the etiology of autism spectrum disorder (ASD). My view is founded on a significant and burgeoning body of peer-reviewed scientific evidence which makes the link between ASD and exposure to aluminum through vaccinations and other sources. Examples of this literature from my own group are detailed below and I urge the HHS to take them into consideration in forming any future opinion on the safety of aluminum adjuvants in vaccines.

The Center for Disease Control's claim on its website that "Vaccines Do Not Cause Autism" is unsupported with respect to aluminum adjuvants and this claim stifles the important research to determine the safety of aluminum adjuvants used in vaccines. As an expert in the field of aluminum adjuvants and aluminum toxicity I solemnly declare that more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is essential and urgently required.

Yours very sincerely



Romain K. Gherardi  
Professor, Neuromuscular Pathology Expert Centre  
University Paris-Est, INSERM U955-E10,  
Henri Mondor hospital, Créteil France  
Contact at the hospital  
Tel 00 (33) 1 49812746  
[romain.gherardi@hmn.aphp.fr](mailto:romain.gherardi@hmn.aphp.fr)

UMR U955 INSERM / UPEC

Team 10

« Biology of the neuromuscular system »

Fred Relaix, director

FrançoisJérôme Authier, co-director

Romain Gherardi, former director

Tél. +33 (0)1 49 81 27 42

Fax. +33 (0)1 49 81 27 33

[romain.gherardi@inserm.fr](mailto:romain.gherardi@inserm.fr)

**Selection of significant publications from our group in the field**

Gherardi R. Toxic Story: deux ou trois vérités embarrassantes sur les adjuvants des vaccins. **Actes Sud** (publisher), Paris, 2016, 250 pages

Crépeaux G, Eidi H, David MO, Baba-Amer Y, Tzavara E, Giros B, Authier FJ, Exley C, Shaw CA, Cadusseau J, Gherardi RK. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective low dose neurotoxicity. **Toxicology**. 2017 Jan 15;375:48-57.

Masson JD, Crépeaux G, Authier FJ, Exley C, Gherardi RK. [Critical analysis of reference studies on aluminium-based adjuvants toxicokinetics]. **Ann Pharm Fr**. 2017 May 30. pii: S0003-4509(17)30033-0.

Van Der Gucht A, Aoun Sebaiti M, Guedj E, Aouizerate J, Yara S, Gherardi RK, Evangelista E, Chalaye J, Cottureau AS, Verger A, Bachoud-Levi AC, Abulizi M, Itti E, Authier FJ. Brain (18)F-FDG PET Metabolic Abnormalities in Patients with Long-Lasting Macrophagic Myofasciitis. **J Nucl Med**. 2017 Mar;58(3):492-498.

Crépeaux G, Eidi H, David MO, Tzavara E, Giros B, Exley C, Curmi PA, Shaw CA, Gherardi RK, Cadusseau J. Highly delayed systemic translocation of aluminum-based adjuvant in CD1 mice following intramuscular injections. **J Inorg Biochem**. 2015 Nov;152:199-205.

Eidi H, David MO, Crépeaux G, Henry L, Joshi V, Berger MH, Sennour M, Cadusseau J, Gherardi RK, Curmi PA. Fluorescent nanodiamonds as a relevant tag for the assessment of alum adjuvant particle biodisposition. **BMC Med**. 2015 Jun 17;13:144.

Van Der Gucht A, Aoun Sebaiti M, Itti E, Aouizerate J, Evangelista E, Chalaye J, Gherardi RK, Ragunathan-Thangarajah N, Bachoud-Levi AC, Authier FJ. Neuropsychological Correlates of Brain Perfusion SPECT in Patients with Macrophagic Myofasciitis. **PLoS One**. 2015 Jun 1;10(6):e0128353.

Khan Z, Combadière C, Authier FJ, Itier V, Lux F, Exley C, Mahrouf-Yorgov M, Decroux X, Moretto P, Tillement O, Gherardi RK, Cadusseau J. Slow CCL2-dependent translocation of biopersistent particles from muscle to brain. **BMC Med**. 2013 Apr 4;11:99.

Couette M, Boisse MF, Maison P, Brugieres P, Cesaro P, Chevalier X, Gherardi RK, Bachoud-Levi AC, Authier FJ. Long-term persistence of vaccine-derived aluminum hydroxide is associated with chronic cognitive dysfunction. **J Inorg Biochem**. 2009 Nov;103(11):1571-8.

Authier FJ, Sauvat S, Christov C, Chariot P, Raisbeck G, Poron MF, Yiou F, Gherardi R. Al(OH)<sub>3</sub>-adjuvanted vaccine-induced macrophagic myofasciitis in rats is influenced by the genetic background. **Neuromuscul Disord**. 2006 May;16(5):347-52.

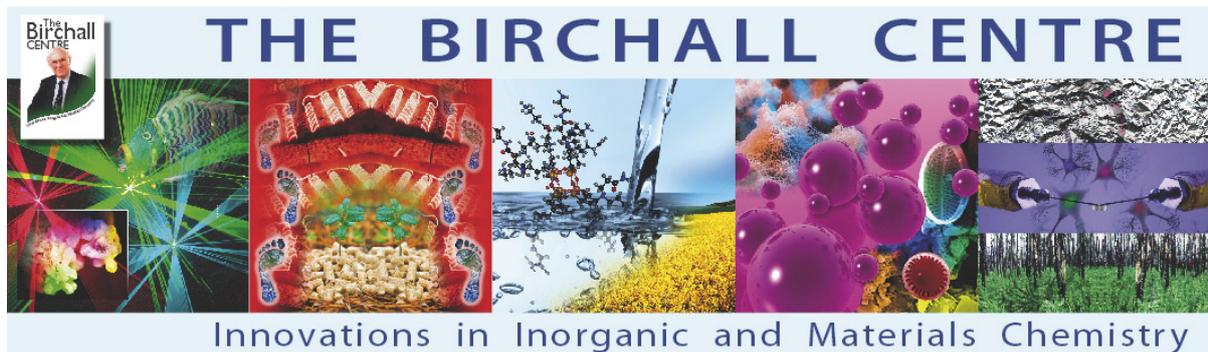
Authier FJ, Sauvat S, Champey J, Drogou I, Coquet M, Gherardi RK. Chronic fatigue syndrome in patients with macrophagic myofasciitis. **Arthritis Rheum**. 2003 Feb;48(2):569-70.

Gherardi RK. [Lessons from macrophagic myofasciitis: towards definition of a vaccine adjuvant-related syndrome]. **Rev Neurol (Paris)**. 2003 Feb;159(2):162-4. Review. French.

Authier FJ, Cherin P, Creange A, Bonnotte B, Ferrer X, Abdelmoumni A, Ranoux D, Pelletier J, Figarella-Branger D, Granel B, Maisonobe T, Coquet M, Degos JD, Gherardi RK. Central nervous system disease in patients with macrophagic myofasciitis. **Brain**. 2001 May;124(Pt 5):974-83.

Gherardi RK, Coquet M, Cherin P, Belec L, Moretto P, Dreyfus PA, Pellissier JF, Chariot P, Authier FJ. Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminium hydroxide in muscle. **Brain**. 2001 Sep;124(Pt 9):1821-31.

Gherardi RK, Coquet M, Chérin P, Authier FJ, Laforêt P, Bélec L, Figarella-Branger D, Mussini JM, Pellissier JF, Fardeau M. Macrophagic myofasciitis: an emerging entity. **Lancet**. 1998 Aug 1;352(9125):347-52.



**Tel: 01782 734080**

**Fax: 01782 712378**

**e-mail: [c.exley@keele.ac.uk](mailto:c.exley@keele.ac.uk)**

**<http://www.keele.ac.uk/aluminium>**

June 15, 2017

United States Department of Health & Human Services  
National Institutes of Health  
Food & Drug Administration  
Centers for Disease Control & Prevention  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

*Re: Aluminum Adjuvants*

Dear Directors:

I am an expert in the field of aluminum adjuvants and aluminum toxicity. I have been working in this field for more than 30 years during which time I have written in excess of 150 peer-reviewed scientific publications on this subject.

I strongly support the contention that aluminum adjuvants in vaccines may have a role in the etiology of autism spectrum disorder (ASD). My view is founded on a significant and burgeoning body of peer-reviewed scientific evidence which makes the link between ASD and exposure to aluminum through vaccinations and other sources. Examples of this literature from my own group are detailed below and I urge the HHS to take them into consideration in forming any future opinion on the safety of aluminum adjuvants in vaccines.

The Center for Disease Control's claim on its website that "Vaccines Do Not Cause Autism" is unsupported with respect to aluminum adjuvants and this claim stifles the important research to determine the safety of aluminum adjuvants used in vaccines. As an expert in the field of aluminum adjuvants and aluminum toxicity I solemnly declare that more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is essential and urgently required.

Telephone number +44 (01782) 584211

Fax +44 (01782) 712378

Yours faithfully



Christopher Exley PhD  
Professor in Bioinorganic Chemistry

Honorary Professor, University of the Highlands and Islands

**List of Recent, Relevant and Significant Publications From Our Group**

Exley C, Siesjö P & Eriksson H (2010) The immunobiology of aluminium adjuvants: how do they really work? *Trends in Immunology* 31, 103-109.

Exley C and House E (2011) Aluminium in the human brain. *Monatshefte für Chemie - Chemical Monthly* 142, 357-363.

House E, Esiri M, Forster G, Ince PG and Exley C (2012) Aluminium, iron and copper in human brain tissues donated to the medical research council's cognitive function and ageing study. *Metallomics* 4, 56-65.

Exley C (2011) Aluminium-based adjuvants should not be used as placebos in clinical trials. *Vaccine* 29, 9289.

Exley C (2012) When an aluminium adjuvant is not an aluminium adjuvant used in human vaccination programmes. *Vaccine* 30, 2042.

Exley C (2012) The coordination chemistry of aluminium in neurodegenerative disease. *Coordination Chemistry Reviews* 256, 2142-2146.

Exley C, House E, Polwart A and Esiri MM (2012) Brain burdens of aluminium, iron and copper and their relationships with amyloid beta pathology in 60 human brains. *Journal of Alzheimer's Disease* 31, 725-730.

Davenward S, Bentham P, Wright J, Crome P, Job, D, Polwart A and Exley C (2013) Silicon-rich mineral water as a non-invasive test of the 'aluminium hypothesis' in Alzheimer's disease. *Journal of Alzheimer's Disease* 33, 423-430.

Khan Z, Combadière C, Authier FJ, Itier V, Lux F, Exley C, Mahrouf-Yorgov M, Decrouy X, Moretto P, Tillement O, Gherardi RK, and Cadusseau J (2013) Slow CCL2-dependent translocation of biopersistent particles from muscle to brain. *BMC Medicine* 11:99.

Exley C (2013) Human exposure to aluminium. *Environmental Science:Processes and Impacts* 15, 1807-1816.

Ohlsson L, Exley C, Darabi A, Sandén E, Siesjö P and Eriksson H (2013) Aluminium based adjuvants and their effects on mitochondria and lysosomes of phagocytosing cells. *Journal of Inorganic Biochemistry* 128, 229-236.

Exley C (2014) Aluminium adjuvants and adverse events in sub-cutaneous allergy immunotherapy. *Allergy, Asthma and Clinical Immunology* 10, 4.

Exley C and Vickers T (2014) Elevated brain aluminium and early onset Alzheimer's disease in an individual occupationally exposed to aluminium: a case report. *Journal of Medical Case Reports* 8,41.

Exley C (2014) What is the risk of aluminium as a neurotoxin? *Expert Review of Neurotherapeutics* 14, 589-591.

Mold M, Eriksson H, Siesjö P, Darabi A, Shardlow E and Exley C (2014) Unequivocal identification of intracellular aluminium adjuvant in a monocytic THP-1 cell line. *Scientific Reports* 4, 6287.

Telephone number +44 (01782) 584211  
Fax +44 (01782) 712378

Exley C (2014) Why industry propaganda and political interference cannot disguise the inevitable role played by human exposure to aluminium in neurodegenerative diseases, including Alzheimer's disease. *Frontiers in Neurology* 5:212. doi: 10.3389/fneur.2014.00212.

Crépeaux G, Eidi H, David M-O, Tzavara E, Giros B, Exley C, Curmi PA, Shaw CA, Gherardi RK and Cadusseau J (2015) Highly delayed systemic translocation of aluminium-based adjuvant in CD1 mice following intramuscular injections. *Journal of Inorganic Biochemistry* 152, 199-205.

Exley C (2016) The toxicity of aluminium in humans. *Morphologie* 100, 51-55.

Mirza A, King A, Troakes C and Exley C (2016) The identification of aluminium in human brain tissue using lumogallion and fluorescence microscopy. *Journal of Alzheimer's Disease* 54, 1333-1338.

Mold M, Shardlow E and Exley C (2016) Insight into the cellular fate and toxicity of aluminium adjuvants used in clinically-approved human vaccinations. *Scientific Reports* 6:31578.

Mirza A, King A, Troakes C and Exley C (2017) Aluminium in brain tissue in familial Alzheimer's disease. *Journal of Trace Elements in Medicine and Biology* 40, 30-36.

Shardlow E, Mold M and Exley C (2017) From stock bottle to vaccine: Elucidating the particle size distributions of aluminium adjuvants using dynamic light scattering. *Frontiers in Chemistry* 4, 48.

Exley C (2017) Aluminium should now be considered a primary aetiological factor in Alzheimer's disease. *Journal of Alzheimer's Disease Reports* 1, 23-25.

Telephone number +44 (01782) 584211  
Fax +44 (01782) 712378

# Exhibit D



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health  
Office of Public Health and Science  
Washington D.C. 20201

JAN 18 2018

Mr. Del Bigtree  
Informed Consent Action Network  
10200 US HWY 290 W, Suite 301  
Austin, Texas 78736

Dear Mr. Bigtree:

Acting Secretary Hargan has asked me to thank you for your letter expressing interest in vaccine safety and in and the federal policies guiding the licensing, recommendation, and safety monitoring of immunizations, and to respond to you directly.

The Department of Health and Human Services has a far-reaching mission to enhance and protect the health of all Americans. Vaccines are held to the highest standard of safety to both protect people from adverse reactions and enhance their health by preventing a number of serious diseases. I am proud to report that data show the United States currently has the safest supply in history.

I have provided responses to your specific questions in the enclosure to this letter. Thank you for the opportunity to address your concerns.

Sincerely yours,

A handwritten signature in blue ink that reads "Melinda Wharton".

Melinda Wharton, MD, MPH  
Acting Director, National Vaccine Program Office

Enclosure

### HHS Responses to Questions and Comments from Mr. Bigtree

I would like to address a comment made in section II of your letter about pre-licensure safety review of pediatric vaccines. Contrary to statements made on page two of your letter, many pediatric vaccines have been investigated in clinical trials that included a placebo. In addition, there appears to be a misunderstanding regarding the term “solicited” adverse events. Typically, in vaccine trials, the incidence of certain specific clinical findings that might be expected after vaccination is monitored for a short period of time after vaccination. Because these events are pre-specified, they are considered to be “solicited” events. In addition, other unexpected or severe adverse events, which may occur over a longer period of time following vaccination, are also analyzed and evaluated by FDA, but because these events are not predicted prior to initiation of the study, these are not called “solicited” adverse events. Please be assured that vaccine safety is carefully examined regardless of whether there is a placebo included in the clinical trials. Once vaccines are approved, the safety is also carefully monitored, in some cases by manufacturer-conducted post-marketing studies by Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), or the Post-licensure Rapid Immunization Safety Monitoring System (PRISM), as well as other mechanisms.

- (1) Please explain how HHS justifies licensing any pediatric vaccine without first conducting a long-term clinical trial in which the rate of adverse reactions is compared between the subject group and a control group receiving an inert placebo?**

Inert placebo controls are not required to understand the safety profile of a new vaccine, and are thus not required. In some cases, inclusion of placebo control groups is considered unethical. Even in the absence of a placebo, control groups can be useful in evaluating whether the incidence of a specific observed adverse event exceeds that which would be expected without administration of the new vaccine. Serious adverse events are always carefully evaluated by FDA to determine potential association with vaccination regardless of their rate of incidence in the control group. In cases where an active control is used, the adverse event profile of that control group is usually known and the findings of the study are reviewed in the context of that knowledge.

- (2) Please list and provide the safety data relied upon when recommending babies receive the Hepatitis B vaccine on the first day of life?**

Data relied upon in licensing infant use of hepatitis B vaccines is summarized in the respective package inserts. Furthermore, pediatric data from other countries and in the literature, support the safety of these vaccines in infants. The recommendation for all children to receive these vaccines was made by the Advisory Committee for

Immunization Practices. Their reasoning is summarized in a *Morbidity and Mortality Weekly Report* at <https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>. Follow-up studies support the safety of infant vaccination with hepatitis B vaccines.

**(3) Please explain why HHS failed to cooperate with Harvard to automate VAERS reporting? And detail any steps that HHS has taken since toward automating VAERS reporting?**

On June 30, 2017, the Centers for Disease Control and Prevention (CDC) and FDA implemented a revised reporting form and a new process for submitting reports to the VAERS for non-manufacturer reports. Persons reporting adverse events are now able to use the VAERS 2.0 online reporting tool to submit reports directly online; alternatively, they may download and complete the writable and savable VAERS 2.0 form and submit it using an electronic document upload feature. Vaccine manufacturers submit VAERS reports electronically through the FDA Electronic Submissions Gateway (ESG). With VAERS 2.0 and the FDA ESG, multiple electronic options exist for VAERS reporting.

In addition, CDC is developing the next generation of spontaneous reporting mechanisms for the VAERS. Following its initial work with Harvard, CDC completed a successful proof of concept study with Harvard and other partners that takes advantage of electronic health records (EHR) and computer algorithms to facilitate direct reporting from EHR systems. You can read about that study at <https://academic.oup.com/cid/article/61/6/864/451758>. CDC continues to explore options to further develop this capability.

**(4) Please explain any specific steps taken by HHS to improve adverse reaction reporting to VAERS?**

Please see my response to question #3.

**(5) For each of the 38 vaccine-injury pairs reviewed in the 1994 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?**

Please refer to the latest review of the “Safety of Vaccines Used for Routine Immunization in the United States” published in 2014 at <https://www.ahrq.gov/research/findings/evidence-based-reports/vaccinestp.html>. This report reviewed and accepted the findings of the 2011 Institute of Medicine report and provides an independent, systematic review of the literature published after that report on the safety of vaccines recommended for routine immunization of children, adolescents,

and adults in the United States. The report, highlighted in the July 2014 issue of *Pediatrics*, provides the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States. The report concludes that the risk of rare adverse events must be weighed against the protective benefits that vaccines provide. Furthermore, the Centers for Disease Control and Prevention (CDC) has been working to address several of the vaccine-injury pairs that have been identified in the reports mentioned above. A list of CDC vaccine safety publications can be found at:

<https://www.cdc.gov/vaccinesafety/research/publications/index.html>.

- (6) For each of the 135 vaccine-injury pairs reviewed in the 2011 IOM Report which the IOM found lacked studies to determine causation, please identify the studies undertaken by the HHS to determine whether each injury is caused by vaccination?**

Please see response to question #5.

- (7) Please explain what HHS has done to assure that health care providers record the manufacturer and lot number for each vaccine they administer?**

Health care providers who administer vaccines covered by the National Vaccine Injury Compensation Program (VICP) are required under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), as amended, to ensure that the permanent medical record of the recipient (or a permanent office log or file) indicates the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine. This provision of the Vaccine Act applies to any vaccine for which there is a routine recommendation for childhood vaccination, even if many or most doses of the vaccine are administered to adults (e.g., influenza vaccine). In addition, the provider is required to record the edition date of the Vaccine Information Statement (VIS) distributed and the date those materials were provided.

The Advisory Committee on Immunization Practices (ACIP) also issued “General Best Practice Guidelines for Immunization” at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/records.html>. This report provides information for clinicians and other health care providers about concerns that commonly arise when vaccinating persons of various ages, and includes a chapter on vaccination records that reinforces the Vaccine Act’s requirement to record in the recipient’s medical record (or a permanent office log or file) the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine.

- (8) Please advise when HHS intends to begin conducting research to identify which children are susceptible to serious vaccine injury? If HHS believes it has commenced this research, please detail its activities regarding same?**

HHS is currently supporting several initiatives that focus on advancing research on the fields of precision vaccinology (vaccine formulations tailored on the individual immune reactivity status) and adversomics (the study of vaccine adverse reactions using immunogenomics and systems biology approaches). Two examples are listed below:

- <https://www.immuneprofilng.org/hipc/page/showPage?pg=about>
- <https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html>

- (9) Please confirm that HHS shall forthwith remove the claim that "Vaccines Do Not Cause Autism" from the CDC website, or alternatively, please identify the specific studies on which HHS bases its blanket claim that no vaccines cause autism?**

Vaccines are held to strict standards of safety. Many studies have looked at whether there is a relationship between vaccines and autism spectrum disorder (ASD). These studies continue to show that vaccines do **not** cause ASD. For more information, please refer to the literature below:

- <https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf>
- <http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx>
- [http://www.jpeds.com/article/S0022-3476\(13\)00144-3/pdf?ext=.pdf](http://www.jpeds.com/article/S0022-3476(13)00144-3/pdf?ext=.pdf)  
<http://nationalacademies.org/HMD/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>

While there is still a lot to learn about ASD, research from public and private organizations indicate that environmental and genetic factors may increase the risk of autism, not vaccines or vaccine ingredients. HHS continues to research this issue to search for answers to better understand the risk factors and causes of this disease. Recent efforts to coordinate autism research are reflected in the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee at <https://iacc.hhs.gov/publications/strategic-plan/2017/>.

- (10) Please advise whether HHS intends to forthwith conduct adequately powered and controlled prospective as well as retrospective studies comparing total health outcomes of fully/partially vaccinated with completely unvaccinated children?**

HHS tasked the Institute of Medicine (IOM) to identify research approaches, methodologies, and study designs that could address questions about the safety of the current schedule. This report is the most comprehensive examination of the immunization schedule to date and can be found at

<http://nationalacademies.org/HMD/Reports/2013/The-Childhood-Immunization-Schedule-and-Safety.aspx>. The IOM committee uncovered no evidence of major safety concerns associated with adherence to the childhood immunization schedule. The committee also cited ethical concerns about conducting a new study to compare the health outcomes of vaccinated children with their fully unvaccinated counterparts, as this would intentionally leave unvaccinated people and the communities they live in subject to increased risk of death and illness.

Should signals arise that there may be need for investigation, however, the report offers a framework for conducting safety research using existing or new data collection systems. One of the systems that the IOM report considered best suited to conduct these types of studies is CDC's Vaccine Safety Datalink (VSD). In response to the IOM report, CDC commissioned a white paper on the feasibility of conducting studies of the safety of the vaccine schedule in VSD. This report states, "Additionally, CDC has started conducting some of the studies mentioned in the white paper." Additional information on the white paper can be found at: [https://www.cdc.gov/vaccinesafety/pdf/whitepapersafety\\_web.pdf](https://www.cdc.gov/vaccinesafety/pdf/whitepapersafety_web.pdf).

**(11) Please advise if you will:**

**a. prohibit conflict waivers for members of HHS's vaccine committees (ACIP, VRBPAC, NVAC & ACCV)?**

HHS employs a thorough process for soliciting and vetting candidates for advisory committees to minimize any potential for financial conflicts of interest and works to identify all potential financial conflicts related to the particular matter before a committee. In accordance with 18 U.S.C. § 208(b)(1) and (b)(3), a member of an HHS vaccine advisory committee may be granted a waiver to allow individuals with potentially conflicting financial interests to participate in meetings where it concludes, after close scrutiny, that certain criteria are met. See 18 U.S.C. § 208 for more information.

**b. prohibit HHS vaccine committee members or HHS employees with duties involving vaccines from accepting any compensation from a vaccine maker for five years?**

The current federal ethics laws and regulations do not provide HHS or any other federal agency the authority to restrict the future employment of a career federal employee or an advisory committee member after they leave federal service. However, there are some restrictions on communication by former employees back to their federal agency, such as

a lifetime ban on communicating or appearing before the government on behalf of their new employer or anyone else regarding specific policy matters in which they participated personally and substantially during their entire government service. See 18 U.S.C. § 207(a)(1) for more information. There are a number of other exceptions that may apply as well including restrictions on representations to the government for matters under the former employee's official responsibility and restrictions that apply to senior-level government officials.

Federal advisory committee members and career federal employees are prohibited from participating personally and substantially in a particular government matter that will affect their financial interests, as well as the financial interests of their spouse or minor child, general partner, or groups or people covered by 18 U.S.C. § 208. Many federal employees, depending on their duties, must file financial disclosure reports to help identify and mitigate potential conflicts of interest with the employees' duties. See 5 CFR Part 2634. Additionally, special government employees serving on advisory committees must report certain financial interests before attending committee meetings. See 5 CFR § 2634.904(a)(2). A 208(b)(3) waiver may be granted to such committee members, based on a determination that the need for the service outweighs the potential for a conflict of interest.

**c. require that vaccine safety advocates comprise half of HHS's vaccine committees?**

The Vaccine Act defines memberships for the NVAC and ACCV. See 42 U.S.C. §§ 300aa-5 and 300aa-19. The VRBPAC charter states that "Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology; bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry."

You can learn more about the VRBAC charter at:

<https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm129571.htm>. The ACIP charter provides that "the committee shall consist of 15 members, including the Chair. Members and the Chair shall be selected by the Secretary, HHS, from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety. The committee shall include a person or persons knowledgeable about consumer perspectives and/or social and community aspects of immunization programs." You can find out more about the ACIP by reading the charter at

<https://www.cdc.gov/vaccines/acip/committee/charter.html>. New members are selected based on the candidate's qualifications and their ability to contribute to the specific objectives or needs of the committee, with an overall goal of ensuring a diverse committee that reflects the charge.

**d. allocate toward vaccine safety an amount at least equal to 50% of HHS's budget for promoting/purchasing vaccines?**

The United States has a robust vaccine safety system that closely and constantly monitors the safety of vaccines. Several agencies within HHS dedicate a significant portion of their budgets and expertise to collaboratively ensure that vaccination efforts are as safe as possible. Due to the significant progress made in the last few years to monitor side effects and conduct relevant vaccine safety research, HHS does not foresee drastically changing current budget allocations in this area. However, this could change pending a vaccine safety signal. Likewise, advances in the development of new vaccines or ways of administering immunizations may require additional vaccine safety funding.

To address comments you made in your letter about vaccine monitoring, I want to clarify a few things. The Vaccine Adverse Event Reporting System (VAERS) is a national system to collect reports of adverse events that happen after vaccination. The adverse events reported to this system are not necessarily caused by vaccination and may or may not be a condition that occurred by chance alone, so they must be further investigated. For more information, please visit: <https://vaers.hhs.gov/>.

HHS places a priority on vaccine safety. To fulfill public health and regulatory functions, the Centers for Disease Control and Prevention (CDC) and FDA use the Vaccine Safety Datalink (VSD) and Post-licensure Rapid Immunization Safety Monitoring System (PRISM) to evaluate if adverse events are related to vaccination. You can find more details about VSD and PRISM at:

<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html> and <http://onlinelibrary.wiley.com/doi/10.1002/pds.2323/abstract>.

**e. support the creation of a vaccine safety department independent of HHS?**

HHS works in close partnership with other federal, state and local agencies, as well as private entities to monitor and communicate about the safety of U.S. vaccines. To adequately address safety-related issues, strengthen the system that monitors the safety of vaccines throughout production and use, and advance the safety profile of vaccines, the expertise of several groups within HHS is required. For example, FDA regulates vaccine clinical trials, licenses vaccines, and monitors vaccine safety after vaccine use and the Health Resources and Services Administration runs the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program. As HHS plays a significant and cross-cutting role in vaccine safety, the diverse federal

vaccine safety portfolio is coordinated at HHS to leverage collaboration among the many groups, inside and outside of HHS, involved in vaccine and immunization activities.

To address your point about conducting research to uncover long-term adverse events, HHS both conducts research in this area and funds outside research in this area. For example, after a safety signal in Europe indicated an increased risk of narcolepsy, a chronic neurological disorder caused by the brain's inability to normally regulate sleep-wake cycles, after vaccination with a monovalent 2009 H1N1 influenza vaccine, CDC began research to determine if there was a safety issue not only in the United States but globally as well. To respond to this signal, an international team of researchers conducted a dynamic retrospective cohort study to estimate incidence rates of narcolepsy diagnoses using a common protocol on electronic data in seven countries during 2003–2013. For the case control study, conducted according to a common protocol in six countries, cases were identified from sleep center records. Overall, the results of this study did not support an association between receipt of the 2009 H1N1 vaccine and narcolepsy. The successful completion of this study proves that the United States has the infrastructure to not only investigate vaccine safety signals at a local level, but to also collaborate with international partners when such signal is of global concern.

**f. support the repeal of the 1986 Act to the extent it grants immunity to pharmaceutical companies for injuries caused by their vaccine products?**

The National Vaccine Injury Compensation Program (VICP) does vital work to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines. According to the VICP website, over 5000 petitions were compensated, supply shortages of vaccines have been reduced, and pricing of vaccines stabilized since the program was enacted. Likewise, this program provides an alternative to civil litigation that includes attorney fees and costs. Although the Vaccine Act provides liability protections to manufacturers of covered vaccines in many circumstances, these protections are not absolute. The Vaccine Act provides that there are instances when a manufacturer of a covered vaccine is not protected from liability by the Act, such as when an individual files a petition and is requesting damages of \$1,000 or less. In such a case, a civil suit against an administrator may be permitted to be filed in state or Federal court without first filing a petition in the VICP.

Further, a repeal of the National Childhood Vaccine Injury Act of 1986 is unlikely. Congress recently passed the 21st Century Cures Act (Public Law 114-255), which made several amendments to the Vaccine Act. The amendments expand the VICP's coverage to include new vaccines that previously were not covered by the VICP (vaccines recommended by the CDC for routine administration in pregnant women) and make clear

that vaccine-injury claims may be filed both with respect to injuries alleged to have been sustained by women receiving covered vaccines during pregnancy and with respect to injuries alleged to have been sustained by live-born children who were in utero at the time those women were administered such vaccines.

# Exhibit E



December 31, 2018

U.S. Department of Health & Human Services  
HHS Office of the Secretary  
Alex M. Azar II, Secretary of Health & Human Services  
Tammy R. Beckham, Acting Director, National Vaccine Program Office  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: *HHS Vaccine Safety Responsibilities and Notice Pursuant to 42 U.S.C. § 300aa-31*

Dear Secretary Azar and Acting Director Beckham:

In our letter of October 12, 2017, we notified HHS of a number of serious concerns regarding how the Department of Health & Human Services (**HHS**) fulfills its obligations to ensure vaccine safety under the National Childhood Vaccine Injury Act of 1986 (the **1986 Act**).<sup>1</sup> We voiced these concerns along with 55 other organizations who were copied on our letter and who represent over 5 million Americans.<sup>2</sup>

We thank HHS for the time and resources it dedicated to respond to our concerns in its letter of January 18, 2018, including having its response reviewed and cleared by the following agencies within HHS: the Centers for Disease Control and Prevention (**CDC**), Food & Drug Administration (**FDA**), National Institutes of Health (**NIH**), Office of the General Counsel (**OGC**), Human Resources & Services Administration (**HRSA**), and Agency for Healthcare Research and Quality (**AHRQ**).<sup>3</sup>

We write again because, after careful review, the substance of HHS's responses heightens the serious concerns we previously raised regarding the safety of HHS's childhood vaccine schedule.

As HHS is aware, the 1986 Act gave pharmaceutical companies immunity from liability for injuries caused by most of their vaccines and instead made vaccine safety the responsibility of HHS.<sup>4</sup> As the Secretary of HHS (the **Secretary**), you have the ultimate authority and responsibility to assure implementation of the vaccine safety obligations in

---

<sup>1</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

<sup>2</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

<sup>3</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>4</sup> [42 U.S.C. § 300aa-10](#); [42 U.S.C. § 300aa-11](#); [42 U.S.C. § 300aa-27](#); [Bruesewitz v. Wyeth LLC](#), 562 U.S. 223 (2011)

the 1986 Act.<sup>5</sup> The importance of assuring the safety of the 71 vaccine doses injected into children pre-and-postnatally pursuant to HHS's vaccine schedule cannot be overstated.<sup>6</sup>

Given the gravity of HHS's responsibility, it is deeply troubling that the majority of HHS's letter contains little more than broad unsupported conclusory assertions. Most of these conclusory assertions do not withstand basic scrutiny. HHS's responses even often contradict its own source materials.

HHS's letter begins with the incorrect claim that the safety of many pediatric vaccines was investigated in clinical trials that included a placebo, and falsely implies these trials are typically longer than mere days or weeks. (Section I below). It then fails to support the safety of injecting babies with the Hepatitis B vaccine (Section II) and reaffirms HHS's refusal to: automate VAERS reporting (Section III); research the most commonly claimed vaccine-injury pairs (Section IV); identify which children will suffer a serious vaccine injury (Section V); pause claiming "Vaccines Do Not Cause Autism" until it has the studies to support this claim (Section VI); conduct vaccinated versus unvaccinated studies (Section VII); purge itself of conflicts of interest (Section VIII); or use the Vaccine Safety Datalink and PRISM to actually improve vaccine safety (Section IX).

History is replete with products that caused harm for years or decades longer than necessary because of gridlock at HHS.<sup>7</sup> The gridlock at HHS over vaccines makes that history look trivial.

A large and growing proportion of Americans have concerns regarding vaccines.<sup>8</sup> In order to persuade this population, including the over five million Americans represented by the groups listed on our opening letter, HHS must either substantiate that its vaccine schedule and representations regarding vaccine safety are based on rigorous and robust science, or acknowledge areas of failure to fulfill its vaccine safety duties. Unsupported and incorrect assertions will not suffice and will only deepen concerns regarding vaccine safety.

Only by providing the science to support vaccine safety or acknowledging shortcomings in this science can HHS begin to restore Americans' confidence in its ability to objectively assess and improve vaccine safety. Since parents and children are the most important stakeholders when it comes to vaccine safety, in addition to distributing these letters to the organizations listed in our opening letter, we intend to widely distribute these letters to the news media and the public at large.

---

<sup>5</sup> [42 U.S.C. § 300aa-27](#)

<sup>6</sup> <https://www.vaccines.gov/>

<sup>7</sup> [https://prescriptiondrugs.procon.org/view\\_resource.php?resourceID=005528](https://prescriptiondrugs.procon.org/view_resource.php?resourceID=005528)

<sup>8</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf) ("an increasing number of parents have been expressing concerns about vaccine safety over the last two decades" and, in particular, "parents have been voicing concerns about the safety of the recommended immunization schedule as a whole"); <https://www.hhs.gov/nvpo/featured-priorities/vaccine-confidence/index.html>

## I. INVALID PRE-LICENSURE SAFETY REVIEW OF PEDIATRIC VACCINES

In our opening letter, we asked that HHS identify the clinical trial data showing that the safety of pediatric vaccines was carefully studied *prior* to licensing and injecting them into millions of American children.<sup>9</sup> In response, HHS did not cite any such data. Instead, HHS merely made conclusory assertions regarding pediatric vaccine clinical trials that contradict HHS's published documents. We take each point in HHS's letter regarding vaccine clinical trials in turn below.

### A. Placebo Controls Were Not Used in Pediatric Clinical Trials

Our opening letter expressed serious concern that the clinical trials relied upon to license pediatric vaccines did not include a control group receiving a placebo. Reflecting its importance, HHS's response letter addresses this concern in its first two sentences:

I would like to address a comment made in Section II of your letter about pre-licensure safety review of pediatric vaccines. Contrary to statements made on page two of your letter, many pediatric vaccines have been investigated in clinical trials that included a placebo.<sup>10</sup>

Unfortunately, HHS's assertion that prior to licensure for children "many pediatric vaccines have been investigated in clinical trials that included a placebo" is untrue.

#### (i) *HHS's False Claim Regarding Use of Placebos*

As defined by the CDC, a "placebo" is: "A substance or treatment that has no effect on human beings."<sup>11</sup> As HHS is aware, common examples of a placebo are a saline injection or sugar pill.<sup>12</sup> The reason that drugs are first evaluated in a clinical trial against a placebo control group, prior to being released to the public, is to assess the drug's safety and effectiveness. As explained by HHS:

In undertaking a clinical trial, researchers don't want to leave anything to chance. They want to be as certain as possible that the results of the testing show whether or not a treatment is safe and effective. The "gold standard" for testing interventions in people is the "randomized, placebo-controlled" clinical trial. ...

---

<sup>9</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

<sup>10</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>11</sup> <https://www.cdc.gov/vaccines/terms/glossary.html>

<sup>12</sup> <https://www.ncbi.nlm.nih.gov/pubmed/1330942> ("a placebo is a pharmacologically inactive substance")

A placebo is an inactive substance that looks like the drug or treatment being tested.<sup>13</sup>

However, for each pediatric vaccine – except one – that HHS promotes for routine injection into children, **the clinical trials relied upon to assess its safety prior to licensing its use in children did *not* use a placebo-control group.**

The following three tables, compiled from HHS’s own publications, list each pediatric vaccine that HHS’s vaccine schedule provides be routinely injected into American children.<sup>14</sup> Each table addresses a different age range and answers whether the trials relied upon to license each vaccine for use in children included at least one clinical trial that assessed its safety against a placebo control group.

According to HHS’s childhood vaccine schedule, babies receive three injections of each of the following vaccines between day one and 6 months of life:

HHS’S CHILDHOOD SCHEDULE: ONE DAY TO 6 MONTHS OF LIFE			
VACCINE TYPE	TEST GROUP RECEIVED	CONTROL GROUP RECEIVED <sup>15</sup>	PLACEBO CONTROL?
DTaP	Infanrix (GSK) <sup>16</sup>	DTP	NO
	Daptacel (Sanofi) <sup>17</sup>	DT or DTP	NO
Hib	ActHIB (Sanofi) <sup>18</sup>	Hepatitis B Vaccine	NO
	Hiberix (GSK) <sup>19</sup>	ActHIB	NO
	PedvaxHIB (Merck) <sup>20</sup>	Lyophilized PedvaxHIB <sup>21</sup>	NO
Hepatitis B	Engerix-B (GSK) <sup>22</sup>	No control group	NO
	Recombivax HB (Merck) <sup>23</sup>	No control group	NO
Pneumococcal	Prevnar 13 (Pfizer) <sup>24</sup>	Prevnar <sup>25</sup>	NO
Polio	Ipol (Sanofi) <sup>26</sup>	No control group	NO

<sup>13</sup> <https://www.nia.nih.gov/health/why-are-placebos-important>

<sup>14</sup> Pursuant to 21 C.F.R. 201.57 and other relevant regulations, the package insert for each vaccine is required to describe its “clinical trial experience,” including identifying the “drug and comparators (e.g., placebo),” as well as accurately describe the clinical trials for each vaccine in its summary basis of approval and clinical trial review, and this letter assumes these documents, available on the FDA website, comply with these regulations. <https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>

<sup>15</sup> Most vaccines had multiple trials; and where some trials used a control and others did not, only the control is listed.

<sup>16</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf>

<sup>17</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm103037.pdf> (lists DT vaccine in one of its efficacy trials as a “placebo”)

<sup>18</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf>

<sup>19</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf>

<sup>20</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM253652.pdf>

<sup>21</sup> In Lyophilized PedvaxHIB’s pre-licensure trials, the test group received Lyophilized PedvaxHIB, OPV and DTP, and the control group received a placebo, OPV and DTP. *Ibid.* Concomitantly injecting OPV and DTP negate the benefit of having a placebo as it prevents assessing the actual safety profile between Lyophilized PedvaxHIB and a placebo.

<sup>22</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>

<sup>23</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>

<sup>24</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM574852.pdf> (While a placebo was used in trials for adults over 65 years old, no placebo was used in trials to license this vaccine for children.)

<sup>25</sup> “Prevnar” was also licensed without a placebo-controlled trial. <http://labeling.pfizer.com/showlabeling.aspx?id=134>

<sup>26</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf>

HHS'S CHILDHOOD SCHEDULE: ONE DAY TO 6 MONTHS OF LIFE			
VACCINE TYPE	TEST GROUP RECEIVED	CONTROL GROUP RECEIVED <sup>15</sup>	PLACEBO CONTROL?
Combination Vaccines	Pediarix (GSK) <sup>27</sup>	ActHIB, Engerix-B, Infanrix, IPV, and OPV	NO
	Pentacel (Sanofi) <sup>28</sup>	HCPDT, PolioVAX, ActHIB, Daptacel, and IPOL	NO

As the above table and HHS's own documentation show, there is not a single vaccine brand routinely injected into American children between day one and 6 months of life that was licensed based on a clinical trial which included a placebo-control group.

According to HHS's childhood vaccine schedule, babies receive a fourth injection of most vaccines in the table above as well as one or two injections of each of the following additional vaccines between 6 months and 18 months of life:

HHS'S CHILDHOOD SCHEDULE: 6 TO 18 MONTHS OF LIFE			
VACCINE TYPE	TEST GROUP RECEIVED	CONTROL GROUP RECEIVED	PLACEBO CONTROL?
Hepatitis A	Havrix (GSK) <sup>29</sup>	Engerix-B	NO
	Vaqta (Merck) <sup>30</sup>	AAHS and Thimerosal	NO
MMR	M-M-R II (Merck) <sup>31</sup>	No control group	NO
Chicken Pox	Varicella (Merck) <sup>32</sup>	Stabilizer and 45mg of Neomycin	NO
Combo Vaccine	ProQuad (Merck) <sup>33</sup>	M-M-R II and Varivax	NO
Flu <sup>34</sup>	Fluarix (IIV4) (GSK) <sup>35</sup>	Prevnar13, Havrix and/or Varivax or unlicensed vaccine	NO
	FluLaval (IIV4) (ID Bio) <sup>36</sup>	Fluzone (IIV4), Fluarix (IIV3) or Havrix	NO
	Fluzone (IIV4) (Sanofi) <sup>37</sup>	Fluzone (IIV3)	NO

<sup>27</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241874.pdf>

<sup>28</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109810.pdf> (lists DT vaccine in one of its efficacy trials as a "placebo")

<sup>29</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224555.pdf>

<sup>30</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110049.pdf> ("Placebo (Alum Diluent)" contained 300µg AAHS and thimerosal, see <https://www.nejm.org/doi/full/10.1056/NEJM199208133270702>)

<sup>31</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123789.pdf> (The package insert for M-M-R-II cites a number of pre-licensure trials, typically with small sample sizes and often using children from orphanages, psychiatric institutions, or schools for the handicapped. In total, it cites: one trial for the M-M-R-II comparing it with other vaccines (ref. # 16), one for the measles vaccine in which the test and control group both received the measles vaccine (ref. # 7), three trials for the mumps vaccine in which controls were injected with various experimental vaccines (ref. # 8, 9, 11) and fifteen trials for the rubella vaccine comparing different types of rubella vaccine except for one trial with 23 apparently untreated controls and one trial with 19 controls receiving a saline nasal spray where rubella vaccine was also given intranasally (ref. # 1, 2, 19-26, 28, 29, 31, 56, 57).)

<sup>32</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf> (While this insert states 465 children received a "placebo," Merck's peer reviewed publication explains the "placebo consisted of lyophilized stabilizer containing approximately 45 mg of neomycin." <https://www.ncbi.nlm.nih.gov/pubmed/6325909>. Neomycin is an antibiotic with serious side effects when swallowed, let alone injected: [www.pdr.net/drug-summary/neomycin-sulfate?druglabelid=819&mode=preview](http://www.pdr.net/drug-summary/neomycin-sulfate?druglabelid=819&mode=preview))

<sup>33</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123793.pdf> (In one clinical trial, 799 children received ProQuad+Placebo, MMR II+Placebo, or MMR II+Varivax, but none received only a placebo; hence, this was not a placebo-controlled trial nor does it pretend to be in its Clinical Review: <http://wayback.archive-it.org/7993/20170723150913/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123800.pdf>)

<sup>34</sup> This and the next table include all flu shots the CDC lists for injection into children for the 2018-2019 flu season. <https://www.cdc.gov/flu/protect/vaccine/vaccines.htm>. One flu vaccine, FluMist (LAIV4), is given via nasal spray, not injection, and hence not discussed.

<sup>35</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619534.pdf> (placebo control only used in adult trials but unfortunately never in trials to license this vaccine for children)

<sup>36</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619548.pdf>

<sup>37</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM356094.pdf>

As the above table and HHS's own documentation show, there is not a single vaccine brand routinely injected into American babies between 6 months and 18 months of life that was licensed based on a clinical trial which included a placebo-control group.

Finally, according to HHS's childhood vaccine schedule, children receive yet another injection of a majority of the vaccines in the above two tables as well as one to three injections of each of the following additional vaccines, along with an annual influenza vaccine, between 18 months and 18 years of life:

HHS'S CHILDHOOD SCHEDULE: 18 MONTHS TO 18 YEARS OF LIFE			
VACCINE TYPE	TEST GROUP RECEIVED	CONTROL GROUP RECEIVED	PLACEBO CONTROL?
Tdap	<b>Boostrix</b> (GSK) <sup>38</sup>	DECAVAC or Adacel	NO
	<b>Adacel</b> (Sanofi) <sup>39</sup>	Td (for adult use)	NO
HPV	<b>Gardasil</b> (Merck) <sup>40</sup>	AAHS or Gardasil carrier solution (Sodium Chloride, L-histidine, Polysorbate 80, Sodium Chloride, and Yeast Protein) (594 subjects)	NO
	<b>Gardasil-9</b> (Merck) <sup>41</sup>	Gardasil or Placebo (306 subjects that recently received 3 doses of Gardasil)	YES <sup>42</sup>
Meningococcal	<b>Menactra</b> (Sanofi) <sup>43</sup>	Menomune	NO
	<b>Menveo</b> (GSK) <sup>44</sup>	Menomune, Boostrix, Menactra, or Mencevax	NO
Combination Vaccines	<b>Kinrix</b> (GSK) <sup>45</sup>	Infanrix and Ipol	NO
	<b>Quadracel</b> (Sanofi) <sup>46</sup>	Daptacel and Ipol	NO
Flu <sup>47</sup>	<b>Afluria (IIV3)</b> (Seqirus) <sup>48</sup>	Fluzone (IIV3)	NO
	<b>Afluria (IIV4)</b> (Seqirus) <sup>49</sup>	Fluarix (IIV4)	NO
	<b>Flucelvax (IIV4)</b> (Seqirus) <sup>50</sup>	Flucelvax (IIV3) or a (Seqirus) investigational vaccine	NO

<sup>38</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152842.pdf>

<sup>39</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142764.pdf>

<sup>40</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf> (While this insert states 594 controls received a "saline placebo," Merck's peer reviewed publication explains the "placebo used in this study contained identical components to those in the vaccine, with the exception of HPV L1 VLPs and aluminum adjuvant," which means this "placebo" contained Sodium Chloride, L-histidine, Polysorbate 80, Sodium Chloride, and Yeast Protein. <https://www.ncbi.nlm.nih.gov/pubmed/17484215>)

<sup>41</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM429166.pdf>

<sup>42</sup> In only one clinical trial, 306 controls received a placebo, and Merck required the 618 subjects in this trial receiving Gardasil-9 to have recently received 3 doses of Gardasil and be in good health. <https://clinicaltrials.gov/ct2/show/NCT01047345>. Generalized safety conclusions therefore cannot be made from this small trial since it only included subjects with a proven record of receiving Gardasil without health complications. This trial does, however, prove that a saline placebo can be used in vaccine clinical trials.

<sup>43</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM131170.pdf> (In one clinical trial, 509 adolescents (between 11 and 18 years of age) received Td for Adult Use plus Menactra and 28 days later received a saline injection, and 512 adolescence received Td for Adult Use plus a saline injection and 28 days later received Menactra. Despite including a saline injection, this is not a placebo-controlled trial nor does it pretend to be in its Clinical Review: <http://wayback.archive-it.org/7993/20170722073019/https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm176044.htm>)

<sup>44</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201349.pdf>

<sup>45</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241453.pdf>

<sup>46</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM439903.pdf>

<sup>47</sup> This and the prior table list all injectable flu shots for children for the current flu season: <https://www.cdc.gov/flu/protect/vaccine/vaccines.htm>

<sup>48</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM263239.pdf> (placebo control only used in adult trials but unfortunately never in trials to license this vaccine for children)

<sup>49</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM518295.pdf>

<sup>50</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619588.pdf> (placebo control only used in adult trials but unfortunately never in trials to license this vaccine for children)

As the above three tables and HHS's own documentation establish, only one out of 30 vaccines brands routinely injected into American children was licensed based on a clinical trial which had a placebo-control group.<sup>51</sup>

The use of placebo control groups is essential to protect society from the harm that could result from widespread use of ineffective or unsafe medical treatments. The fact that HHS does not and apparently will not require pharmaceutical companies to use a placebo control in pediatric vaccine clinical trials evidences HHS's lack of confidence in the safety profile of these products. If HHS had confidence in their safety profiles, it would require that vaccine clinical trials – as is typical for drug clinical trials – include a placebo-control group. For example, drugs such as Botox,<sup>52</sup> Prozac,<sup>53</sup> and Lipitor,<sup>54</sup> typically given to adults rather than children, have placebo controls in their clinical trials. Like almost all drugs, pediatric vaccines should be licensed based on placebo-controlled clinical trials so that HHS can assess their safety profiles prior to approving them for injection into millions of children.

It is troubling that HHS chose to begin its response by misstating that prior to licensure for children “many pediatric vaccines have been investigated in clinical trials that included a placebo.”<sup>55</sup> At worst, HHS knowingly perpetuated this inaccurate claim, but at best, HHS was unaware this claim was incorrect. This leaves the public to wonder what other critical assumptions underpinning HHS's confidence in vaccine safety are incorrect.

***(ii) HHS Licenses New Vaccines Without Any Placebo-Controlled Trial Even When No Vaccine for the Same Disease Exists***

After making the false claim that many vaccines on HHS's childhood schedule were licensed based on a placebo-controlled trial, HHS then states:

Inert placebo controls are not required to understand the safety profile of a new vaccine, and are thus not required.

This claim is astonishing. For almost all new drugs, especially where no substantially similar product is already licensed, HHS's guidance expects a placebo control group to be part of the clinical trial so that the adverse event rate in the test group receiving the new drug can be assessed against the rate in the placebo group.

---

<sup>51</sup> Both Rotavirus vaccines are given via oral drop and hence not discussed. Nonetheless, RotaTeq (Merck)'s “placebo” contained Polysorbate 80, Sucrose, Citrate and Phosphate, and Rotarix (GSK)'s “placebo” contained Sucrose, Dextran, Sorbitol, Amino acids, Dulbecco's Modified Eagle Medium, Calcium Carbonate, and Xanthan. <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133539.pdf>; <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142288.pdf>

<sup>52</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/103000s5236lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103000s5236lbl.pdf)

<sup>53</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/018936s091lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/018936s091lbl.pdf)

<sup>54</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020702s056lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf)

<sup>55</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

HHS's industry guidance explains that using another drug as a so-called "active control" is only appropriate if it is for a similar indication and is a "drug whose effect is well-defined," which means "historical placebo-controlled trials are available to define the active control effect."<sup>56</sup> As the FDA explains:

The placebo-controlled trial measures the total pharmacologically mediated effect of treatment. In contrast, an active control trial ... measures the effect relative to another treatment. The placebo-controlled trial also allows a distinction between adverse events due to the drug and those due to the underlying disease or background noise.<sup>57</sup>

Hence, the reason researchers do not use a non-inert substance as a control is because, due to its pharmacological effects, it makes it impossible to isolate the effects of just the experimental product being studied. Nevertheless, a placebo control was only used in only one tiny clinical trial for one of the 30 vaccine brands listed in the tables above.

The critical difference between using an inert and non-inert substance as a control can be clearly seen from the trials relied upon to license Gardasil in 2006. The manufacturer's package insert for Gardasil states that it was licensed based on a clinical trial in which: (i) 10,706 women received Gardasil; (ii) 9,092 women received 225 mcg or 450 mcg of Amorphous Aluminum Hydroxyphosphate Sulfate (AAHS) – the so-called "AAHS Control" (aluminum adjuvant, such as AAHS, is a known cytotoxic and neurotoxic substance used to induce autoimmunity in lab animals, and which numerous peer-reviewed publications implicate in various autoimmune conditions<sup>58</sup>); and (iii) 320 women received a "Saline Placebo."<sup>59</sup> During the six month study follow-up, 2.3% of the women receiving Gardasil (the "test group") and 2.3% of the women receiving the AAHS Control or Saline Placebo (the "combined control group") reported developing a systemic autoimmune disorder.<sup>60</sup> Since the rate of systemic autoimmune disorders in the "test group" and the "combined control group" were similar, the vaccine was deemed safe and licensed by HHS.

---

<sup>56</sup> <https://www.fda.gov/downloads/Drugs/Guidances/UCM202140.pdf>

<sup>57</sup> <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073139.pdf>. Also see <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126501.htm> ("There are three principal difficulties in interpreting active-control trials. ... One problem is that there are numerous ways of conducting a study that can obscure differences between treatments, such as poor diagnostic criteria, poor methods of measurement, poor compliance, medication errors, or poor training of observers. As a general statement, carelessness of all kinds will tend to obscure differences between treatments. Where the objective of a study is to show a difference, investigators have powerful stimuli toward assuring study excellence. *Active-control studies, however, which are intended to show no significant difference between treatments, do not provide the same incentives toward study excellence, and it is difficult to detect or assess the kinds of poor study quality that can arise.* The other problem is that a finding of no difference between a test article and an effective treatment may not be meaningful.")

<sup>58</sup> <https://www.wiley.com/en-us/Vaccines+and+Autoimmunity-p-9781118663431>; <https://www.ncbi.nlm.nih.gov/pubmed/25923134>

<sup>59</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf>

<sup>60</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf>

What the manufacturer's package insert for Gardasil given to the public failed to disclose is that the Saline Placebo group had *zero* cases of systemic autoimmune disorder (when 7 cases – 2.3% of 320 subjects – would be expected if autoimmune disorders were equally distributed among the Saline Placebo and AAHS Control recipients).<sup>61</sup> This fact was obfuscated by combining the small Saline Placebo group with the large AAHS Control group into a single control group and reporting their combined systemic autoimmune disorder rate, even though all the cases of autoimmunity came from the AAHS Control group.<sup>62</sup> The following is an excerpt from Gardasil's package insert with the combined control group highlighted in yellow:

**Table 9: Summary of Girls and Women 9 Through 26 Years of Age Who Reported an Incident Condition Potentially Indicative of a Systemic Autoimmune Disorder After Enrollment in Clinical Trials of GARDASIL, Regardless of Causality**

Conditions	GARDASIL (N = 10,706)	AAHS Control* or Saline Placebo (N = 9412)
	n (%)	n (%)
Arthralgia/Arthritis/Arthropathy <sup>†</sup>	120 (1.1)	98 (1.0)
Autoimmune Thyroiditis	4 (0.0)	1 (0.0)
Celiac Disease	10 (0.1)	6 (0.1)
Diabetes Mellitus Insulin-dependent	2 (0.0)	2 (0.0)
Erythema Nodosum	2 (0.0)	4 (0.0)
Hyperthyroidism	27 (0.3)	21 (0.2)
Hypothyroidism	35 (0.3)	38 (0.4)
Inflammatory Bowel Disease	7 (0.1)	10 (0.1)
Multiple Sclerosis	2 (0.0)	4 (0.0)
Nephritis	2 (0.0)	5 (0.1)
Optic Neuritis	2 (0.0)	0 (0.0)
Pigmentation Disorder	4 (0.0)	3 (0.0)
Psoriasis	13 (0.1)	15 (0.2)
Raynaud's Phenomenon	3 (0.0)	4 (0.0)
Rheumatoid Arthritis	6 (0.1)	2 (0.0)
Scleroderma/Morphea	2 (0.0)	1 (0.0)
Stevens-Johnson Syndrome	1 (0.0)	0 (0.0)
Systemic Lupus Erythematosus	1 (0.0)	3 (0.0)
Uveitis	3 (0.0)	1 (0.0)
<b>All Conditions</b>	<b>245 (2.3)</b>	<b>218 (2.3)</b>

<sup>†</sup>AAHS Control = Amorphous Aluminum Hydroxyphosphate Sulfate

The fact that the Saline Placebo group had no cases of systemic autoimmune disorder is what would be expected.<sup>63</sup> It is not normal for 2.3% of previously healthy girls and women to develop a systemic autoimmune disorder within six months of the commencement of a clinical trial unless there was some environmental exposure that caused the harm, such as an injection of Gardasil or AAHS. This finding is nonetheless ignored because, to license this vaccine, HHS permitted AAHS to serve as the control.

It was also unethical to inject almost 10,000 girls and women with a known neurotoxin like AAHS, which has no therapeutic benefit.<sup>64</sup> The transparent purpose of this unethical study design was to create a "control group" that would yield a similar adverse event rate to the "test group" receiving Gardasil. In this manner the trial masked a serious

<sup>61</sup> <https://www.clinicaltrials.gov/ct2/show/results/NCT00092547?term=nct+00092547&rank=1&sect=X430156&view=results>

<sup>62</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf>

<sup>63</sup> <https://www.clinicaltrials.gov/ct2/show/results/NCT00092547?term=nct+00092547&rank=1&sect=X430156&view=results>

<sup>64</sup> <https://www.wiley.com/en-us/Vaccines+and+Autoimmunity-p-9781118663431>

safety issue with Gardasil that should have prevented its licensure.<sup>65</sup> Furthermore, there was no excuse for not requiring a placebo control (saline injection) in clinical trials for Gardasil because, at that time, no other vaccine was yet licensed for the four HPV strains Gardasil was intended to prevent.

As the Gardasil clinical trial shows, HHS does not require a placebo control group for clinical trials of even an entirely new vaccine for an infection for which no other vaccine exists. Another example is the Hepatitis A vaccine.

There are only two Hepatitis A vaccines on the market: Havrix (GSK), licensed in 1995, and Vaqta (Merck), licensed in 1996.<sup>66</sup> Because the clinical trials for both were conducted when there was no Hepatitis A vaccine on the market, these trials should certainly have used a placebo control to assess their safety. Yet, the safety profile for these products was never assessed using a placebo control. Instead, the trial for Havrix had no control group and the trial for Vaqta used AAHS and Thimerosal as a control.<sup>67</sup> The lack of a placebo control in the clinical trials relied upon to license Havrix was such a clear lapse in safety for an entirely new vaccine (for an infection that had no previously licensed vaccine) that its Clinical Review even made a point to disclaim: “There were no placebo controls.”<sup>68</sup>

A third example is Varivax (Merck), the very first vaccine licensed for varicella (chicken pox). Varivax was also licensed without any placebo-controlled clinical trial. Recognizing the importance of a placebo control, the package insert for Varivax claims that its safety was reviewed against a “placebo” control.<sup>69</sup> Putting aside that only 465 children received the purported “placebo,” Merck’s peer reviewed article regarding this trial makes clear this “placebo” was not a placebo, but rather an injection of “lyophilized stabilizer containing approximately 45 mg of neomycin per milliliter.”<sup>70</sup> Neomycin is an antibiotic which, in oral form, has a long list of serious adverse reactions, such as hearing loss, kidney problems and nerve problems.<sup>71</sup> An injection which includes neomycin is therefore plainly *not* a placebo. Using a control that can have serious adverse reactions when orally ingested, let alone injected, obfuscated Varivax’s actual safety profile.<sup>72</sup>

It is unethical and unacceptable that a placebo control, such as a saline injection, was not used for entirely new vaccines, such as for Hepatitis A and Varicella. Even worse, as

---

<sup>65</sup> This defective clinical trial design may have been influenced by the HHS agency and its employees that developed the patent used to develop Gardasil and receive royalties from its sale. <https://www.ott.nih.gov/news/nih-technology-licensed-merck-hpv-vaccine>

<sup>66</sup> <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/us-vaccines.pdf>

<sup>67</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110049.pdf> (The “Placebo (Alum Diluent)” contained 300µg AAHS and thimerosal, <https://www.nejm.org/doi/full/10.1056/NEJM199208133270702>)

<sup>68</sup> <http://wayback.archive-it.org/7993/20170723025039/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110035.pdf>

<sup>69</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142813.pdf>

<sup>70</sup> *Ibid.*; <https://www.ncbi.nlm.nih.gov/pubmed/6325909>

<sup>71</sup> [www.pdr.net/drug-summary/neomycin-sulfate?druglabelid=819&mode=preview](http://www.pdr.net/drug-summary/neomycin-sulfate?druglabelid=819&mode=preview)

<sup>72</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142812.pdf>

the next section shows, these same vaccines are then used as an “active control” for licensing other vaccines despite having never been safety tested for licensure themselves in a placebo-controlled trial. The use of medications and vaccines in the practice of medicine is ethically justified if the benefits substantially outweigh the harms.<sup>73</sup> When studies to approve vaccines are conducted in which the harms are not accurately assessed because there is no placebo control group, then the use of those vaccines is not justified.<sup>74</sup>

*(iii) HHS’s “Safety” Pyramid Scheme*

After licensing a vaccine without assessing its safety in a placebo-controlled clinical trial, HHS will then often license another vaccine as long as it has a similar adverse event rate to the licensed (but improperly safety tested) vaccine. This is a so-called “active control,” which HHS references in its letter. But this form of comparison only provides reliable safety data if the previously licensed “active control” itself had its safety profile previously assessed in a properly designed placebo-controlled trial.

HHS’s own industry guidance for drug testing explains that an active control is only appropriate if it is a “drug whose effect is well-defined,” which means “historical placebo-controlled trials are available to define the active control effect.”<sup>75</sup> Despite its own policy and guidance, HHS does not require this minimal assurance for vaccines. Instead, all vaccines on HHS’s pediatric schedule were licensed based on a clinical trial with no control whatsoever, or another vaccine/substance used as a control which itself was never licensed based on a placebo-controlled trial. As noted in our opening letter:

[Pediatric vaccines] either had no control group or a control group which received other vaccines as a “placebo.” This means each new vaccine need only be roughly as safe as one (or in some cases numerous) previously licensed vaccines. Such flawed and unscientific study designs cannot establish the actual safety profile of any vaccine. The real adverse event rate for a vaccine can only be determined by comparing subjects receiving the vaccine with those receiving an inert placebo. Yet, this basic study design, required for every drug, is not required before or after licensing a vaccine.<sup>76</sup>

Nonetheless, HHS claims in its letter that when an active control is used “the adverse event profile of that control group is usually known.”<sup>77</sup> But this claim is incorrect for all “active

---

<sup>73</sup> <https://global.oup.com/ushe/product/principles-of-biomedical-ethics-9780199924585?cc=us&lang=en&>

<sup>74</sup> <https://www.ncbi.nlm.nih.gov/pubmed/4907496>

<sup>75</sup> <https://www.fda.gov/downloads/Drugs/Guidances/UCM202140.pdf>

<sup>76</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

<sup>77</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

controls” used to license any vaccine on HHS’s childhood vaccine schedule because none of these “active controls” were licensed based on a placebo-controlled trial.

Pevnar 13 provides a good first example of how HHS’s claim is incorrect. HHS recommends that every child receive this vaccine at 2, 4, 6, and 12 months of age.<sup>78</sup> HHS licensed this vaccine in 2010 without a clinical trial assessing its safety in children against a placebo control.<sup>79</sup> Instead, it permitted a previously licensed vaccine, Pevnar, to act as the control.<sup>80</sup> However, like Pevnar 13, HHS licensed Pevnar without a clinical trial assessing its safety against a placebo control.<sup>81</sup> Rather, HHS licensed Pevnar based on a clinical trial in which the control was “an investigational meningococcal group C conjugate vaccine [MnCC].”<sup>82</sup> MnCC, in turn, an unlicensed product, was also never licensed based on any placebo-controlled trial.<sup>83</sup>

The clinical trial for Pevnar 13 found that “Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Pevnar 13 recipients and 7.2% among Pevnar recipients.”<sup>84</sup> Despite this finding, Pevnar 13 was deemed safe and therefore licensed for use in babies because it had a similar serious adverse reaction rate as the control group receiving Pevnar.<sup>85</sup> But a comparison with Pevnar was an invalid measure of safety because Pevnar was safety tested prior to licensure against another experimental vaccine. As a group of FDA and CDC scientists conceded after Pevnar was licensed:

Prior to licensure, ... the control group in [Pevnar’s] main study received another experimental vaccine, rather than a placebo. If both vaccines provoked similar adverse effects, little or no difference between the 2 groups might have been evident.<sup>86</sup>

Hence, the trial for Pevnar 13, in which both the Pevnar 13 and Pevnar groups have a 7% to 8% serious adverse event rate, could and should have caused serious concern regarding the safety of both vaccines. Instead, Pevnar 13 was deemed safe because it was as safe as Pevnar. But, as shown, Pevnar itself was only deemed safe because it was tested against an unlicensed experimental vaccine.

---

<sup>78</sup> <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

<sup>79</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>

<sup>80</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>; <http://labeling.pfizer.com/showlabeling.aspx?id=134>

<sup>81</sup> <http://labeling.pfizer.com/showlabeling.aspx?id=134>

<sup>82</sup> <http://labeling.pfizer.com/showlabeling.aspx?id=134>

<sup>83</sup> See tables above.

<sup>84</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>

<sup>85</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf>

<sup>86</sup> <https://www.ncbi.nlm.nih.gov/pubmed/15479935>

A second example is Heplisav-B, the most recent vaccine approved by HHS.<sup>87</sup> The trials for this new Hepatitis B vaccine, which contains a novel adjuvant, did not use a placebo control.<sup>88</sup> Instead, the control was Engerix-B.<sup>89</sup> The serious adverse event rate in the primary clinical trial for Heplisav-B was 6.2%, which the researchers deemed similar to the serious adverse event rate of 5.3% for Engerix-B.<sup>90</sup> Heplisav-B was therefore deemed safe only because it was as safe as Engerix-B, but Engerix-B was licensed based on a clinical trial without any control, let alone a placebo control.<sup>91</sup> As such, the serious adverse reaction rate for Engerix-B and Heplisav-B should have caused serious concern regarding the safety of both vaccines, not confidence that Heplisav-B is safe.

A third example are influenza vaccines (flu shots). In 1980, HHS licensed Fluzone (IIV3) without assessing its safety against a placebo control.<sup>92</sup> Nonetheless, Fluzone (IIV3) was used as the control in the trials relied upon to license Afluria (IIV3) in 2007 and Fluzone (IIV4) in 2013 for children.<sup>93</sup> Shortly thereafter, Fluzone (IIV4), Fluarix (IIV3) or Havrix were then used as the controls in the clinical trials supporting the licensure of FluLaval (IIV4).<sup>94</sup> This entire pyramid scheme rests on the safety of Fluzone (IIV3) which was licensed for pediatric use based on a trial without any control, let alone a placebo control.<sup>95</sup>

Similarly, Fluarix (IIV4) was licensed for children in 2012 based on a trial using Prevnar 13, Havrix and/or Varivax as controls; Fluarix (IIV4) was then used as the control to license Afluria (IIV4) in 2016.<sup>96</sup> This means Afluria (IIV4) was licensed because it was deemed as safe as Fluarix (IIV4), and that vaccine was licensed because it was deemed as safe as Prevnar 13, Havrix, or Varivax. However, the latter two were licensed without a placebo control; and Prevnar 13 was licensed because it was as safe as Prevnar, but that vaccine was only licensed because it was as safe as “an investigational meningococcal group C conjugate vaccine.” Hence, at bottom, none of those vaccines had its safety profile established based on any placebo-controlled clinical trial. On this basis alone the ethics of recommending routine injection of these vaccines into children is questionable.

---

<sup>87</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf>

<sup>88</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf>

<sup>89</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf>

<sup>90</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM584762.pdf>

<sup>91</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>

<sup>92</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619664.pdf> (Researchers did conduct one efficacy trial for Fluzone (IIV3) long after it was licensed which found that “the rate of hospitalization was actually higher in the vaccine group than in the placebo group” with 60% more vaccinated than unvaccinated children being hospitalized for insertion of ear draining tubes. <https://www.ncbi.nlm.nih.gov/pubmed/14506120>)

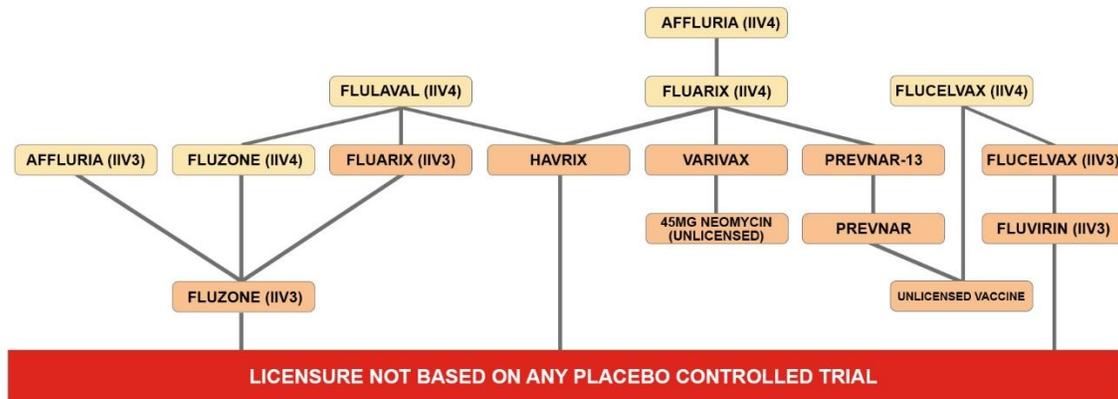
<sup>93</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM263239.pdf> (placebo control only used in adult trials but never in trials to license this vaccine for children); <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM356094.pdf>

<sup>94</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619548.pdf>

<sup>95</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM619664.pdf>

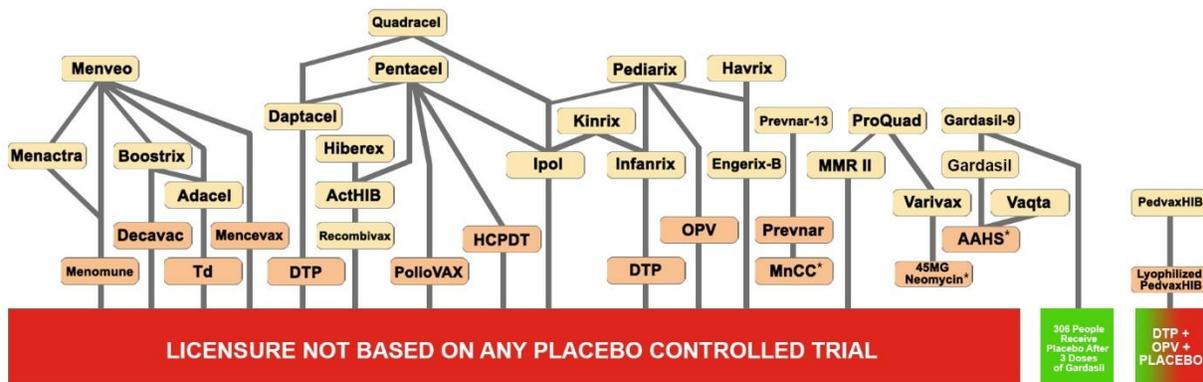
<sup>96</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM220624.pdf> (44% and 45% of the Fluarix (IIV4) and comparator vaccine group, respectively, reported an unsolicited adverse event within 28 days and 3.6% and 3.3%, respectively, reported a serious adverse reaction)

The following diagram highlights in yellow each flu shot recommended for injection into children during the 2018-2019 flu season; and each descending line shows the control(s) used to license the vaccine above<sup>97</sup>:



As the above diagram makes clear, HHS did not rely on a single placebo-controlled trial to license any flu shot HHS recommends for injection into every child over 6 months of age during the upcoming flu season.

The above examples demonstrate how HHS licenses vaccines by relying on a pyramid of other vaccines that were each licensed without being properly safety tested in a placebo-controlled trial. The diagram below highlights in yellow each vaccine HHS's childhood vaccine schedule lists for routine use (except for influenza vaccines already depicted in the diagram above), and each descending line shows the control(s) used to license the vaccine above:



\*Unlicensed

As is clear, at the bottom of this pyramid there is not a single placebo-controlled trial relied upon to license any vaccine in this pyramid scheme (with the exception of Gardasil-9 in which 306 individuals received a saline injection after three shots of Gardasil).

<sup>97</sup> <https://www.cdc.gov/flu/protect/vaccine/vaccines.htm>

It is deeply troubling that HHS permits pharmaceutical companies to use “active controls” in clinical trials for new vaccines when none of the “control vaccines” were themselves licensed based on a placebo-controlled trial. This creates layers of assumptions regarding safety that resemble a pyramid scheme. Tracing back the pre-licensure clinical trial for each vaccine used as an active control, one finds that the initial vaccine in the “safety chain” was either licensed without any control group or assessed against another vaccine, including vaccines, such as DTP, which were withdrawn from use due to safety concerns.

*(iv) HHS Summarily Dismisses Claims of Vaccine Harm*

The lack of a placebo in clinical trials is even more troubling because, when parents assert that a vaccine injured their child, HHS regularly denies these assertions by stating that no cause and effect has been established between vaccination and the alleged injury. But as HHS is well aware, *without* a placebo control trial, cause and effect is very difficult and often impossible to establish.<sup>98</sup> Therefore, no matter how many or what type of vaccine injuries are reported, HHS and manufacturers can and do hide behind the claim that “a cause and effect relationship with the vaccine has not been established.”<sup>99</sup>

This avoidance of proper research is reflected in the package insert for each pediatric vaccine. As required by federal law, each package insert lists the serious adverse events reported by doctors and consumers *after* licensure of the vaccine.<sup>100</sup> Federal law is also clear that this list should include “*only* those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.”<sup>101</sup> Appendix B to this letter provides a partial (yet long) list of reported post-licensure reactions listed on pediatric vaccine package inserts, including numerous neurological, brain and immune system disorders.

Instead of these serious adverse event reports resulting in a call to action by HHS to finally conduct long-term studies that could reasonably establish if these adverse events are causally related to vaccination, the response has been the opposite. HHS continues with growing intransigence to hide behind the claim that no causation has been proven. HHS even requires that every vaccine package insert include the following disclaimer before the list of vaccine-related adverse events reported by doctors and consumers post-licensure:

---

<sup>98</sup> <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html> (“establishing evidence for cause and effect on the basis of case reports and case series alone is usually not possible,” rather, researchers need “to compare the incidence of the event among vaccinees with the incidence among unvaccinated persons”); <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3505292/> (The entire advantage of a randomized placebo-controlled trial “is the ability to demonstrate causality i.e., cause-effect relationship.”); <https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html> (The Vaccine Adverse Events Reporting System (VAERS) is unable “to determine causation” because “there is a lack of an unvaccinated group for comparison in VAERS.”)

<sup>99</sup> *Ibid.*

<sup>100</sup> [21 C.F.R. 201.57](#)

<sup>101</sup> [21 C.F.R. 201.57](#)

In addition to reports in clinical trials, worldwide voluntary reports of adverse events received for [vaccine brand] since market introduction of this vaccine are listed below. This list includes serious adverse events or events which have a suspected causal connection to components of [vaccine brand] or other vaccines or drugs. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.<sup>102</sup>

But without carrying out placebo controlled clinical trials, which can determine causation statistically, (and by ignoring existing experimental studies in animal models aimed at establishing the underlying biological mechanisms of potential vaccine injuries,) HHS can, and apparently will, continue to hide behind this disclaimer indefinitely.

As reflected in Appendix B, there is a consistent theme of autoimmunity and neurological disorders running across the serious post-licensure adverse events reported in vaccine package inserts. Yet, HHS refuses to require placebo-controlled clinical trials to determine if any of these events are actually caused by vaccination. HHS claims doing so would be unethical for clinical trials evaluating the safety of an experimental vaccine when there is already a vaccine licensed for the same disease because it would leave a child that could be vaccinated for that disease unvaccinated. This ethical concern however rings hollow, because if ethics were a real concern, HHS would require placebo-controlled trials before licensing each new experimental vaccine where no vaccine yet exists for the infection it is intended to prevent. For example, before licensing the first Hepatitis A or Varicella vaccines as discussed above.

Conducting a placebo-controlled clinical trial will leave a clearly defined group of children unvaccinated only during the duration of the trial in a controlled setting where they can be monitored.<sup>103</sup> In contrast, injecting a vaccine into millions of children in an uncontrolled setting without first having any placebo-controlled trial safety data is, to any objective reasonable observer, grossly unethical conduct.<sup>104</sup> In a comparable situation where the baseline of safety for the “active control” had not been established, researchers from the University of Oxford explained:

---

<sup>102</sup> <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm075057.pdf>

<sup>103</sup> There are already hundreds of thousands of children that are completely unvaccinated in this country. <https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm> For example, there are many parents that will not vaccinate due to religious beliefs.

<sup>104</sup> <https://history.nih.gov/research/downloads/nuremberg.pdf> (“voluntary consent ... means that the person ... should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision”)

In some trials placebos were omitted on ethical grounds. This is illogical because studies destined to produce unreliable results should themselves be considered unethical.<sup>105</sup>

As a result, the only “ethical” thing to do at this point is for HHS to comprehensively and impartially fund truly neutral third-parties to conduct placebo-controlled trials for each vaccine and the entire HHS childhood vaccine schedule.

By refusing to conduct any placebo-controlled studies – even for new vaccines for diseases for which no vaccine exists yet – HHS provides itself a convenient way to consistently discount even widespread reported claims of vaccine injury by simply claiming causation has not been proven, knowing full well causation will likely never be proven – one way or another – without a placebo-controlled trial.<sup>106</sup>

The near universal failure to employ a placebo control group in pediatric vaccine clinical trials is scientifically and morally indefensible. The importance of a placebo control group is no doubt why HHS felt compelled to address that point first in its lengthy response letter. And now that HHS knows it was incorrect to claim that prior to licensure “many pediatric vaccines have been investigated in clinical trials that included a placebo,” we expect that HHS will address this serious shortcoming by actually conducting appropriate placebo-controlled trials.

## **B. Duration of Safety Review**

In our letter we also questioned the length of time vaccine trials gather and assess adverse reactions, noting as examples that the two Hepatitis B vaccines injected into infants assessed adverse reactions for only four<sup>107</sup> and five<sup>108</sup> days, respectively, and that the only stand-alone polio vaccine reviewed safety for a mere 48 hours.<sup>109</sup> In response, HHS’s letter seeks to create the false impression that the safety review period for pediatric vaccine clinical trials occurs over an extended period of time, stating:

In addition, there appears to be a misunderstanding regarding the term “solicited” adverse events. Typically, in vaccine trials,

---

<sup>105</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1113953/>

<sup>106</sup> <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html> (“establishing evidence for cause and effect on the basis of case reports and case series alone is usually not possible,” rather, researchers need “to compare the incidence of the event among vaccinees with the incidence among unvaccinated persons”); <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3505292/> (The entire advantage of a randomized placebo-controlled trial “is the ability to demonstrate causality i.e., cause-effect relationship.”); <https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html> (The Vaccine Adverse Events Reporting System (VAERS) is unable “to determine causation” because “there is a lack of an unvaccinated group for comparison in VAERS.”)

<sup>107</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>

<sup>108</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>

<sup>109</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM133479.pdf>

the incidence of certain specific clinical findings that might be expected after vaccination is monitored for a short period of time after vaccination. Because these events are pre-specified, they are considered to be “solicited” events. In addition, other unexpected or severe adverse events, which may occur over a longer period of time following vaccination, are also analyzed and evaluated by FDA, but because these events are not predicted prior to initiation of the study, these are not called “solicited” adverse events.<sup>110</sup>

There was no misunderstanding regarding “solicited” versus “unsolicited” adverse events in our initial letter. The duration that solicited *or* unsolicited adverse events are tracked in pediatric vaccine clinical trials is typically far too short to detect adverse effects beyond a few days or weeks of vaccination. This is no doubt why HHS vaguely refers to “short period” versus “longer period” without actually specifying the duration of the so-called “longer period.” As HHS knows, the “longer period” is still often only days or weeks, or at most a few months, instead of the several years needed to assess the actual safety profile after injecting a baby.

Whether reviewing solicited or unsolicited events, vaccine clinical trials are almost always far too short to capture developmental delays, autoimmune issues, and other chronic conditions that are likely to be diagnosed only years after vaccination.

**(i) *Safety Review Periods in Clinical Trials for Pediatric Vaccines are Too Short to Detect Most Chronic Health Conditions***

HHS’s own publications leave no doubt as to the incredibly short safety review period for almost all vaccines on HHS’s childhood vaccine schedule.

On the *first day of life*, HHS’s schedule instructs that all newborns receive a Hepatitis B vaccine.<sup>111</sup> The two Hepatitis B vaccines licensed in the United States for newborns are Recombivax HB (Merck) and Engerix-B (GSK).<sup>112</sup> Both were licensed based on clinical trials which reviewed so-called solicited and unsolicited reactions for no longer than *five days after vaccination*.<sup>113</sup> As required by HHS’s own regulations<sup>114</sup>, the clinical trial experience upon

---

<sup>110</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>111</sup> HHS purposely shifted the burden of this vaccine from those at risk, such as intravenous drug users, to all newborns. <https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>

<sup>112</sup> <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/us-vaccines.pdf>

<sup>113</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>; <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>

<sup>114</sup> [21 CFR 201.57\(c\)\(7\)](https://www.fda.gov/oc/ohrt/21-cfr-201.57-c-7)

which the licensure of each vaccine is based must be summarized in its package insert, and the inserts for these two vaccines explain as follows:

*“In three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose.”*<sup>115</sup>

*“In 36 clinical studies, a total of 13,495 doses of ENGERIX-B were administered to 5,071 healthy adults and children who were initially seronegative for hepatitis B markers, and healthy neonates. All subjects were monitored for 4 days post-administration.”*<sup>116</sup>

Putting aside that the number of babies in these trials is unclear, five days is not long enough to assess the safety profile of these products. Moreover, without a placebo control, these trials do not even provide an actual safety profile for the five days in which safety was purportedly reviewed.

At *two months of life*, HHS’s schedule instructs that babies be injected with the Hepatitis B, Hib, DTaP, IPV, and PCV 13 vaccines.<sup>117</sup> The safety review period of so-called solicited and unsolicited adverse reactions in the trials relied upon to license these vaccines were also too short to capture any resulting chronic health conditions. This is confirmed by HHS’s own documentation for each:

Target Disease	Product Name (Manufacturer)	Duration of Safety Review After Injection	
		Solicited Reactions	Unsolicited Reactions
Hepatitis B	Recombivax HB (Merck) <sup>118</sup>	5 days	5 days
	Engerix-B (GSK) <sup>119</sup>	4 days	4 days
Hib	ActHIB (Sanofi) <sup>120</sup>	3 days	30 days
	PedvaxHIB (Merck) <sup>121</sup>	3 days	3 days
	Hiberix (GSK) <sup>122</sup>	4 days	31 days
DTaP	Infanrix (GSK) <sup>123</sup>	8 days	28 days
	Daptacel (Sanofi) <sup>124</sup>	14 days	6 months
Poliovirus	Ipol (Sanofi) <sup>125</sup>	3 days	3 days

<sup>115</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf> (emphasis added)

<sup>116</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf> (emphasis added)

<sup>117</sup> <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

<sup>118</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm110114.pdf>

<sup>119</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf>

<sup>120</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf>

<sup>121</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm253652.pdf>

<sup>122</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm179530.pdf>

<sup>123</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf>

<sup>124</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm103037.pdf>

<sup>125</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm133479.pdf>

Pneumococcal	Prevnar 13 (Wyeth) <sup>126</sup>	7 days	6 months
Combination Vaccines	Pediarix (GSK) <sup>127</sup>	8 days	30 days + phone call at 6 months
	Pentacel (Sanofi) <sup>128</sup>	7 days	60 days + phone call at 6 months

Again, without a placebo controlled clinical trial, which none of the above had, the actual safety profile of each vaccine cannot be assessed even for the limited duration that its safety was reviewed. Moreover, even assuming placebo controls were used, tracking safety for (at most) a mere 6 months after injecting a 2-month old baby will not reveal if the vaccine caused autoimmune, neurological or developmental disorders that are likely to only be apparent or diagnosed after the child is a few years of age.

At *four months of life*, HHS's vaccine schedule instructs that babies again be injected with the Hib, DTaP, IPV, and PCV 13 vaccines.<sup>129</sup> The above table shows the issues with these vaccines' testing durations.

At *six months of life*, HHS's vaccine schedule instructs that babies again be injected with the Hepatitis B, Hib, DTaP, IPV, and PCV 13 vaccines.<sup>130</sup> In addition, HHS's schedule also lists the influenza vaccine already discussed above.<sup>131</sup>

As early as *twelve months of life*, HHS's vaccine schedule provides that babies again be injected with Hib and PCV13 vaccines, as well as receive the MMR, Varicella and Hepatitis A vaccines.<sup>132</sup> As for MMR, its package insert does not describe, as would be required by federal law, a single clinical trial of the MMR vaccine upon which its licensure is based.<sup>133</sup>

As for Varicella, its clinical trial, which used an injection of 45 mg of neomycin as a control (as discussed above), only assessed safety for a period of weeks.<sup>134</sup> As for the two Hepatitis A vaccines, solicited reactions for both were gathered for approximately two weeks and unsolicited reactions for approximately a month and Havrix conducted a six month non-obligatory follow-up telephone call.<sup>135</sup> Even this limited vaccine safety monitoring reveals nothing about the actual safety profile of these products since there was

<sup>126</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm201669.pdf>

<sup>127</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM241874.pdf>

<sup>128</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm109810.pdf>

<sup>129</sup> <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

<sup>130</sup> <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

<sup>131</sup> <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

<sup>132</sup> <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

<sup>133</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123789.pdf>. See footnote 31.

<sup>134</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142812.pdf> (Greater than 1 percent of children had one or more of these reactions: upper respiratory illness, cough, irritability/nervousness, fatigue, disturbed sleep, diarrhea, loss of appetite, vomiting, otitis, contact rash, headache, malaise, abdominal pain, nausea, eye complaints, chills, lymphadenopathy, myalgia, lower respiratory illness, allergic reactions, stiff neck, heat rash/prickly heat, arthralgia, dermatitis, constipation, itching.)

<sup>135</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224555.pdf>

<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110049.pdf>

no placebo control used in their clinical trials. And even if a placebo was used, a single six month follow-up phone call will not reveal the developmental, neurological or autoimmune issues that will only become apparent after a baby is at least a few years old.

In sharp contrast to the short safety testing periods for vaccines, most drugs have pre-licensure safety review periods which last years. For example, the drugs Enbrel<sup>136</sup>, Lipitor<sup>137</sup>, and Botox<sup>138</sup> had safety review periods of 6.6 years, 4.8 years and 51 weeks, respectively, and each had an actual placebo control group. And these drugs are typically for adults, not infants and children.

Moreover, even though safety review periods for vaccines typically lasted only days or weeks, the efficacy review period for vaccines often lasted years.<sup>139</sup> The “efficacy review” typically tracks antibody levels to assess how well the new vaccine will likely prevent the target infection. This review often lasts years because the biological changes in the body a vaccine seeks to achieve, typically production of vaccine strain antibodies, often require multiple injections over a period of months or years followed by monitoring efficacy for at least a few years.<sup>140</sup> Vaccine safety should be tracked at least as long as vaccine efficacy because it can take years for chronic conditions causally linked to or suspected to be caused by vaccines to become apparent. As HHS has explained: “because the childhood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, long-term adverse events may be more biologically plausible than short-term events.”<sup>141</sup>

Indeed, scientific findings, including by HHS, clearly refute the assumption that any adverse outcome of vaccination, especially when vaccinating babies during the first six months of life, will be apparent fairly immediately.<sup>142</sup> Yet this assumption underlies the design for assessing safety in the clinical trials relied upon to license pediatric vaccines. At the very least, since efficacy is already being tracked for years, safety should also be tracked for the same duration.

It is common sense that if HHS licenses vaccines without safety data extending beyond a few days, weeks or months, it is scientifically impossible to ascertain if babies will develop immunological, developmental or neurological disorders beyond these short safety review periods. There is no justifiable reason why HHS refuses to examine whether giving 29 vaccine doses by one year of age can lead to health issues at 5 years of age. As the Institute

<sup>136</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/103795s5503lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf)

<sup>137</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020702s056lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf)

<sup>138</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/103000s5302lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf)

<sup>139</sup> <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>

<sup>140</sup> <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>; <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>

For example, pursuant to HHS’s vaccine schedules, every person is to receive a diphtheria containing vaccine at the following ages: 2-months, 4-months, 6-months, 15-months, 4-years, 11-years, and then every ten years until death.

<sup>141</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>142</sup> *Ibid.*; <https://www.ncbi.nlm.nih.gov/pubmed/22235051>

of Medicine admitted: science still does not know “if there is a relationship between [the numerous known] short-term adverse events following vaccination and long-term health issues.”<sup>143</sup>

(ii) *HHS’s “Solicited” v. “Unsolicited” Scheme Further Conceals Actual Safety Profile*

Moreover, unlike almost all drugs, HHS permits pharmaceutical companies to use preset lists of adverse reactions they ask their researchers to monitor and evaluate in vaccine clinical trials – so called “solicited” adverse reactions.<sup>144</sup> Asking about certain “solicited” adverse reactions undoubtedly creates a bias in favor of parents reporting those adverse reactions, rather than reporting “unsolicited,” but more serious, adverse reactions. The reason for this approach appears to be that HHS and pharmaceutical companies are trying to institutionalize a few adverse events, such as injection site soreness, as the only adverse events that are caused by vaccination. This “don’t ask, and hope they don’t tell” policy is troubling.

Having a pre-set list of adverse reactions that are “solicited” by researchers institutionalizes and legitimizes HHS and the pharmaceutical industry’s customary practice of accepting a very small number of minor reactions as being “caused” by vaccines. This allows the “unsolicited” reports made by subjects and their parents, many of which would likely fall outside the short review period, to be easily relegated to a broad wastebasket category, such as “new medical condition.” This practice leaves the pharmaceutical industry entirely free and indeed highly likely to reject these “unsolicited” reactions as unrelated to vaccination or consider them idiosyncratic medical events based on a preexisting genetic predisposition or other latent tendency, and therefore “coincidental” and unrelated to the vaccine.

The problems created by the solicited vs. unsolicited categories are not merely abstract concerns. To the contrary, the trials conducted for the HPV vaccine, Gardasil, provide a ready example of how this dual category structure biases researchers against finding that unsolicited adverse reactions are caused by the vaccine. When Gardasil was tested for safety in clinical trials in Denmark, many participants repeatedly advised clinicians conducting the trials that after vaccination they could no longer engage in various basic life functions due to numerous brain and immune dysfunction symptoms.<sup>145</sup> These “unsolicited” Gardasil vaccine reactions, however, were discarded by the clinical trial researchers, who were paid by the pharmaceutical company seeking a license for Gardasil.<sup>146</sup>

---

<sup>143</sup> <https://www.nap.edu/read/13563/chapter/5#45>

<sup>144</sup> <https://www.ncbi.nlm.nih.gov/pubmed/16231957> (“Spontaneous (unsolicited) collection of adverse event data is used in most pharmaceutical trials.”)

<sup>145</sup> <https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html>

<sup>146</sup> <https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html>

The researchers could discard this data because, despite being an entirely new vaccine for a new disease, no placebo control was used.<sup>147</sup> As a result, the pharmaceutical company paid researchers used their “judgment,” not the scientific method, to decide if any complications were related to the vaccine.<sup>148</sup>

Even more troubling, these researchers actually told women reporting serious life altering reactions that, “This is not the kind of side effects we see with this vaccine” – an inexplicable and unscientific response for researchers conducting clinical trials of a new vaccine.<sup>149</sup> The only reason this fact came to light was because of a thorough eight-month long investigation by Slate (a strongly pro-vaccine news outlet) which sought out and found the clinical trial patients and matched them with their clinical trial records.<sup>150</sup>

*(iii) HHS Gives False Impression it Determines Whether Each Reported Adverse Reaction is Related to the Vaccine on Trial*

As this incident with Gardasil shows, even if pediatric vaccine clinical trials did gather sufficient medical data to assess safety, the determination of whether an adverse event reported during the clinical trial is associated with the vaccine under review is left to the pharmaceutical company paid researchers conducting the clinical trial.<sup>151</sup> Nevertheless, HHS’s letter seeks to mislead the reader by stating:

Serious adverse events are always evaluated by FDA to determine potential association with vaccination regardless of their rate of incidence in the control group.<sup>152</sup>

However, because pharmaceutical companies and their paid researchers determine if each reported adverse event in a trial is related to the vaccine, HHS’s assertion that “[s]erious adverse events are always evaluated by the FDA to determine potential association with vaccination” is disingenuous.

Ironically, if placebo control groups were used, then there would be no need for a case-by-case determination regarding whether each reported “unsolicited” adverse reaction is related to the vaccine under review. It is only because of the scientifically and morally

---

<sup>147</sup> <https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html>

<sup>148</sup> <https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html>

<sup>149</sup> <https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html>

<sup>150</sup> <https://slate.com/health-and-science/2017/12/flaws-in-the-clinical-trials-for-gardasil-made-it-harder-to-properly-assess-safety.html>

<sup>151</sup> For example, in the clinical trial for ActHIB there was no control group and 3.4% of the babies receiving this vaccine had a serious adverse event within 30 days of vaccination; HHS nonetheless licensed this vaccine because the trial investigators working for ActHIB’s manufacturer decided none of them were related to the vaccine. <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm109841.pdf> (“within 30 days ... (3.4%) participants [babies] experienced a serious adverse event” but “[n]one was assessed by the investigators as related to the study of vaccines”)

<sup>152</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

defunct refusal to require placebo-controlled trials that there is a need to rely on the “judgment” of pharmaceutical company paid researchers to decide if the “unsolicited” adverse event is related to the vaccine.<sup>153</sup>

This adds a very dangerous bias into what is already unreliable (no placebo control) and limited (duration too short) safety data from vaccine clinical trials. Pharmaceutical companies have a powerful financial incentive to minimize any safety concerns to ensure licensure since they have almost no liability for vaccine injuries but yet stand to typically earn billions of dollars from each newly licensed pediatric vaccine. As explained by Dr. Marcia Angell<sup>154</sup>, currently a professor in the Center for Bioethics, Harvard School of Medicine, and member of the Institute of Medicine, and former editor-in-chief of the *New England Journal of Medicine*:

Clinical trials are also biased through designs for research that are chosen to yield favorable results for sponsors. ... In short, it is often possible to make clinical trials come out pretty much any way you want, which is why it’s so important that investigators be truly disinterested in the outcome of their work. ...

It is no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of *The New England Journal of Medicine*. ...<sup>155</sup>

Dr. Angell also points out that, “Most of the big drug companies have settled charges of fraud,” including GSK and Merck, explaining that the legal “costs, while enormous in some cases, are still dwarfed by the profits generated by these illegal activities, and are therefore not much of a deterrent.”<sup>156</sup>

### **C. Conclusion to HHS’s Claims Regarding Vaccine Clinical Trials**

Best scientific research practices should not be bent or broken to allow HHS to approve pediatric vaccines. With all drugs, the pharmaceutical industry remains accountable for safety and liable in civil court for injuries caused by the drugs they put on the market. Hence, during pre-licensure clinical trials testing experimental drugs,

---

<sup>153</sup> The false and misleading claims regarding clinical trials undercut any basis for relying on the following conclusory assertion in HHS’s letter: “Please be assured that vaccine safety is carefully examined regardless of whether there is a placebo included in the clinical trials.”

<sup>154</sup> <http://bioethics.hms.harvard.edu/person/faculty-members/marcia-angell>

<sup>155</sup> <https://www.nybooks.com/articles/2009/01/15/drug-companies-doctors-a-story-of-corruption/>

<sup>156</sup> <https://www.nybooks.com/articles/2009/01/15/drug-companies-doctors-a-story-of-corruption/>

pharmaceutical companies at least have a financial incentive to their shareholders to ascertain each drug's safety profile – to determine if its liability exposure exceeds its likely revenue stream – otherwise after licensure they could face losses that exceed the drug's expected sales. This is likely why pharmaceutical companies conduct long-term placebo-controlled trials before seeking licensure for even short-acting, minor or cosmetic prescription or over-the-counter drugs.<sup>157</sup>

In contrast, pharmaceutical companies do not have liability for injuries caused by most of their vaccine products. Therefore, in line with their fiduciary duty to their shareholders, they have a financial incentive to get a new vaccine licensed by HHS as fast as possible with as little review of the vaccine's safety profile as possible. Newly licensed or even longstanding vaccines recommended by HHS for routine use by all children, such as Gardasil, Prevnar 13, or MMR, generate billions of dollars in revenue annually.<sup>158</sup> If it turns out that the vaccine causes serious harm, and a parent can prove it in Vaccine Court (over the defense mounted by the DOJ representing HHS), the claim is paid by the Federal Government using funds obtained from an excise tax collected from vaccine consumers – not paid by pharmaceutical companies.<sup>159</sup> Thus, pharmaceutical companies have a financial disincentive to identify safety issues that would prevent licensure and literally no incentive to identify safety issues after licensure.

This is precisely why the 1986 Act, simultaneous with granting vaccine makers financial immunity, made HHS responsible for vaccine safety.<sup>160</sup> Yet, HHS has abandoned this duty by not requiring long-term placebo-controlled clinical trials. Without such trials, the actual safety profile of each pediatric vaccine, or any combination thereof, cannot be determined before they are – pursuant to HHS's childhood vaccine schedule – injected into millions of American children. Once that happens, HHS becomes utterly conflicted from funding or conducting research that may find that a vaccine HHS previously licensed and recommended does, in fact, cause significant harm to more than a few children.

Indeed, admitting after licensure that a vaccine causes a certain serious harm would eliminate HHS's ability to defend itself against claims alleging such harm in Vaccine Court, which could amount to billions or even trillions of dollars in financial liability. It would also tarnish HHS's reputation and reduce the public's trust in HHS because, unlike drugs, HHS spends billions of dollars annually purchasing, distributing and vigorously promoting childhood vaccines.<sup>161</sup> This creates a serious conflict of interest within HHS that prevents it

---

<sup>157</sup> For example, the weight loss drug, Belviq (only indicated for adult use), was safety tested in a placebo-controlled trial for two years before being licensed. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/022529lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022529lbl.pdf)

<sup>158</sup> <https://investors.pfizer.com/financials/annual-reports/default.aspx>; <https://investors.merck.com/financials/sec-filings/default.aspx>; <https://www.gsk.com/media/4751/annual-report.pdf>; <https://www.sanofi.com/en/investors/reports-and-publications/>

<sup>159</sup> 42 U.S.C. § 300aa-11; 42 U.S.C. § 300aa-15

<sup>160</sup> 42 U.S.C. § 300aa-11; 42 U.S.C. § 300aa-27

<sup>161</sup> <https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf?language=es>

from rationally evaluating post-licensure reports of adverse events. It is therefore critical for HHS to have a clear and robust picture of the actual safety profile of each vaccine and the vaccination schedule *before* it is recommended and promoted by HHS to the public.

For example, Engerix B, manufactured by GSK, was originally licensed for children in the late 1980s based on an uncontrolled trial that only reviewed safety for five days (as discussed above).<sup>162</sup> Engerix B had to be reapproved by HHS almost twenty years later after the preservative used in the vaccine was changed.<sup>163</sup> The vaccine otherwise remained identical to what had been approved twenty years prior.<sup>164</sup> In the reapproval clinical trial report submitted by GSK to HHS in 2005, more than half of the babies reported an adverse event within 3 days of receiving this vaccine and 55 of the 587 babies in the study reported a serious adverse event.<sup>165</sup> That means 9.4% of the babies experienced a serious adverse event. Absent a placebo control group, however, it was left to GSK's paid researchers to decide whether these adverse events were caused by the vaccine.<sup>166</sup> Unsurprisingly, the GSK researchers declared the adverse events were not caused by its vaccine, and the vaccine was reapproved.<sup>167</sup> If HHS had overruled that finding, it could serve as an admission it previously licensed, recommended and widely promoted a vaccine that caused numerous serious adverse events in American babies, thereby creating buckling financial liability as well as serious reputational damage to HHS. This conflict makes it unlikely HHS will ever admit after licensure, due to at least willful blindness, that a vaccine causes any serious widespread harm.

This structural conflict at HHS is dangerous. There should be no compromise when it comes to the health of children, especially babies and newborns. The American public deserves nothing short of long-term placebo-controlled trials to know the true adverse event rate, without any bias.<sup>168</sup>

The bottom line is that when vaccines are licensed and recommended to be injected into every American child, apart from certain reactions, such as a sore arm, occurring within days of the vaccination, HHS does not know the safety profile of these products. As even HHS's own paid experts, the IOM, explain: "Because [vaccine] trials are primarily ... for determination of efficacy, conclusions about vaccine safety derived from these trials are

---

<sup>162</sup> <https://web.archive.org/web/20170723025206/http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244522.pdf>

<sup>163</sup> <https://web.archive.org/web/20170723025206/http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244522.pdf>

<sup>164</sup> <https://web.archive.org/web/20170723025206/http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM244522.pdf>

<sup>165</sup> [Ibid.](#)

<sup>166</sup> [Ibid.](#)

<sup>167</sup> [Ibid.](#)

<sup>168</sup> This is in fact what the *Nuremberg Code* demands. <https://history.nih.gov/research/downloads/nuremberg.pdf> ("The voluntary consent of the human subject is absolutely essential. This means that the person ... should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision.")

limited.”<sup>169</sup> HHS apparently proceeds nonetheless to license, recommend and promote these products based on its *a priori* assumption of and belief in their safety. This should be concerning because if HHS’s “belief” is incorrect, it could have negative consequences for the health of current and future generations of American children.

Please respond to all points above and answer the questions in Appendix A.

## II. SAFETY OF INJECTING BABIES WITH HEPATITIS B VACCINE

In our opening letter, we asked that HHS “Please list and provide the safety data relied upon when recommending babies receive the Hepatitis B vaccine on the first day of life.”<sup>170</sup>

### A. Safety Data for Hepatitis B Licensure is Plainly Deficient

HHS begins its response by stating: “Data relied upon in licensing infant use of hepatitis B vaccine is summarized in the respective package insert.”<sup>171</sup> It is troubling that HHS responds to the above request by citing the package inserts when our opening letter explained that these precise package inserts provide that their safety was not monitored for longer than five days after injection.<sup>172</sup> As a result, HHS’s response merely affirms the concerns we expressed in our original letter that the Hepatitis B vaccine was inadequately tested for safety prior to licensure.

Recombivax HB’s package insert asserts it was deemed safe for children based on a clinical trial in which 147 infants and children (up to 10 years of age) were monitored for five days after vaccination.<sup>173</sup> This trial is useless for assessing the safety of this vaccine for pediatric use (let alone for babies on the first day of life) because the sample size is too small, the safety review period is too short, and there is no placebo control. The safety information in the package insert for Engerix-B is just as inadequate since the clinical trial for this vaccine also had no placebo control and only monitored safety for four days after vaccination.<sup>174</sup>

These package inserts plainly do not support the safety of administering these products to babies. Hence, HHS’s assertion that the “Data relied upon in licensing infant use of hepatitis B vaccine is summarized in the respective package insert” is very troubling.

---

<sup>169</sup> <https://www.nap.edu/read/13563/chapter/4>

<sup>170</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

<sup>171</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>172</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>;

<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM224503.pdf>

<sup>173</sup> <https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf>

<sup>174</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf>

## B. Safety of Hepatitis B Recommendation for Babies Plainly Deficient

Aside from the package inserts, HHS's response points to only one other identifiable document to support its claim that the Hepatitis B vaccine is safe for babies – a report from the Advisory Committee on Immunization Practices (ACIP) that HHS asserts it relied upon for its “recommendation for all children to receive these vaccines.”<sup>175</sup> Sadly, as with the package inserts, this ACIP report does not support the safety of these vaccines for babies or children. A copy of the report is cited in a footnote to this sentence.<sup>176</sup>

The ACIP report cites seven studies to support its recommendation that every baby in this country receive Hepatitis B vaccine injections at 1-day, 1-month, and 6-months of life.<sup>177</sup> Two of the cited studies only included adult homosexual males and therefore provide no useful data to evaluate the safety of injecting newborns.<sup>178</sup> The third was a retrospective study that did not use either of the Hepatitis B vaccines licensed for infants in the United States, excluded children that did not complete the vaccine series and lacked a placebo control.<sup>179</sup> The fourth was a retrospective study of potential neurological events from the Hepatitis B vaccine based on reports submitted to a passive surveillance system.<sup>180</sup> This study is also useless for assessing the safety of administering the Hepatitis B vaccine to infants because the study involved “virtually all” adults and did not provide any separate results for infants or children.<sup>181</sup> Moreover, its conclusions regarding safety are pure speculation because, as study authors explained, “underreporting is a well-recognized problem of such surveillance systems” and the “magnitude of underreporting of neurological events after hepatitis B vaccination is unknown.”<sup>182</sup> This once again drives home the need for a placebo-controlled trial for each pediatric vaccine prior to licensure.

The three remaining studies relied upon to support the safety of the Hepatitis B vaccine cited in the ACIP report were clinical trials. But none of these clinical trials are useful for understanding the safety of injecting Hepatitis B vaccine into babies.<sup>183</sup> First, none of them had a placebo control.<sup>184</sup> Second, none of these trials assessed safety for longer than seven days after vaccination.<sup>185</sup>

---

<sup>175</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>176</sup> <https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>

<sup>177</sup> <https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>

<sup>178</sup> <https://www.ncbi.nlm.nih.gov/pubmed/6810736>; <https://www.ncbi.nlm.nih.gov/pubmed/6997738>

<sup>179</sup> Chen D-S. Control of hepatitis B in Asia: mass immunization program in Taiwan. In: Hollinger FB, Lemon SM, Margolis HS, eds. Viral hepatitis and liver disease. Baltimore: Williams & Wilkins, 1991:716-9.

<sup>180</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2962488>

<sup>181</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2962488>

<sup>182</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2962488>

<sup>183</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2952812>; <https://www.ncbi.nlm.nih.gov/pubmed/2943814>;

<https://www.ncbi.nlm.nih.gov/pubmed/2528292>

<sup>184</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2952812>; <https://www.ncbi.nlm.nih.gov/pubmed/2943814>;

<https://www.ncbi.nlm.nih.gov/pubmed/2528292>

<sup>185</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2952812>; <https://www.ncbi.nlm.nih.gov/pubmed/2943814>;

<https://www.ncbi.nlm.nih.gov/pubmed/2528292>

Indeed, one study had 122 infants and monitored safety for only 7 days.<sup>186</sup> Another study had 79 children monitored for 5 days.<sup>187</sup> Remarkably, in this study 18 percent of the children experienced a systemic or serious adverse reaction (fatigue/weakness, diarrhea, etc.), but, absent a placebo control, the pharmaceutical company paid researchers were left to decide whether or not these reactions were related to the vaccine.<sup>188</sup> The final study had 3,000 infants and children but *only* monitored safety on the day of and the third day after vaccination.<sup>189</sup> As HHS is well aware, autoimmune, neurological and developmental disorders will often not be diagnosed until after babies are a few years old.<sup>190</sup> The ACIP report even acknowledges that “systematic surveillance for adverse events [in infants] has been limited.”<sup>191</sup>

As this shows, even though we asked for the science to support the safety of injecting every newborn with the Hepatitis B vaccine starting on the first day of life, the studies HHS has provided do not support such safety and would not be sufficient to license these products for veterinary use in farm animals. For example, prior to licensure of a vaccine for use in chickens, “Daily observation records are required for at least 21 days after vaccination.”<sup>192</sup>

### C. Urgent Need for Placebo-Controlled Trial of Hepatitis B Vaccine

The need to assess the safety of each Hepatitis B vaccine in robust clinical trials is manifest. The following is a list of the reported post-marketing adverse reactions added to the package insert for Engerix-B because Merck had a “basis to believe there is a causal relationship between the drug and the occurrence of the adverse event”<sup>193</sup>:

Abnormal Liver Function Tests; Allergic Reaction; Alopecia;  
Anaphylactoid Reaction; Anaphylaxis; Angioedema; Apnea;  
Arthralgia; Arthritis; Asthma-Like Symptoms; Bell’s Palsy;  
Bronchospasm; Conjunctivitis; Dermatologic Reactions;  
Dyspepsia; Earache; Eczema; Ecchymoses; Encephalitis;

<sup>186</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2952812>

<sup>187</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2943814>

<sup>188</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2943814>

<sup>189</sup> <https://www.ncbi.nlm.nih.gov/pubmed/2528292>

<sup>190</sup> For example, according to the CDC, even for a common neurological disorder such as ADHD, “5 years of age was the average age of diagnosis for children reported as having severe ADHD.” <https://www.cdc.gov/ncbddd/adhd/features/key-findings-adhd72013.html> As another example, learning disabilities, a group of common developmental issues, are often “identified once a child is in school.” <https://www.nichd.nih.gov/health/topics/learning/conditioninfo/diagnosed> Even asthma, a very common autoimmune condition, whose symptoms are obvious, for children under 5 years of age “diagnosis can be difficult because lung function tests aren’t accurate before 5 years of age” and “[s]ometimes a diagnosis can’t be made until later, after months or even years of observing symptoms.” <https://www.mayoclinic.org/diseases-conditions/childhood-asthma/diagnosis-treatment/drc-20351513>

<sup>191</sup> <https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>

<sup>192</sup> [https://www.aphis.usda.gov/animal\\_health/vet\\_biologics/publications/memo\\_800\\_204.pdf](https://www.aphis.usda.gov/animal_health/vet_biologics/publications/memo_800_204.pdf)

<sup>193</sup> 21 C.F.R. 201.57

Encephalopathy; Erythema Multiforme; Erythema Nodosum; Guillain-Barré Syndrome; Hypersensitivity Syndrome (serum sickness-like with onset days to weeks after vaccination); Hypoesthesia; Keratitis; Lichen Planus; Meningitis; Migraine; Multiple Sclerosis; Myelitis; Neuritis; Neuropathy; Optic Neuritis; Palpitations; Paralysis; Paresis; Paresthesia; Purpura; Seizures; Stevens-Johnson Syndrome; Syncope; Tachycardia; Tinnitus; Transverse Muscular Weakness; Thrombocytopenia; Urticaria; Vasculitis; Vertigo; Visual Disturbances.<sup>194</sup>

And these are the reported post-marketing adverse reactions for Recombivax HB added to its package insert because GSK had a basis to conclude each has a causal relationship with that vaccine:

Agitation; Alopecia; Anaphylactic/Anaphylactoid Reactions; Arthralgia; Arthritis; Arthritis Pain In Extremity; Autoimmune Diseases; Bell's Palsy; Bronchospasm; Constipation; Conjunctivitis; Dermatologic Reactions; Ecchymoses; Eczema; Elevation Of Liver Enzymes; Encephalitis; Erythema Multiforme; Erythema Nodosum; Exacerbation Of Multiple Sclerosis; Febrile Seizure; Guillain-Barré Syndrome; Herpes Zoster; Hypersensitivity Reactions; Hypersensitivity Syndrome (serum sickness-like with onset days to weeks after vaccination); Hypesthesia; Increased Erythrocyte Sedimentation Rate; Irritability; Lupus-Like Syndrome; Migraine; Multiple Sclerosis; Muscle Weakness; Myelitis Including Transverse Myelitis; Optic Neuritis; Peripheral Neuropathy; Petechiae; Polyarteritis Nodosa; Radiculopathy; Seizure; Stevens-Johnson Syndrome; Somnolence; Syncope; Systemic Lupus Erythematosus (SLE); Tachycardia; Thrombocytopenia; Tinnitus; Urticaria; Urticaria; Uveitis; Vasculitis; Visual Disturbances.<sup>195</sup>

These post-marketing reactions reveal a consistent pattern of autoimmune, neurological and other chronic disorders that would appear or only be diagnosed years after vaccinating a baby. Nevertheless, instead of investigating these adverse events in methodologically sound clinical trials, HHS responds to these post-marketing reports of chronic life-long injuries by saying that “causation has not been proven,” knowing full well that causation is highly unlikely to be proven, one way or another, until a placebo-controlled trial of sufficient duration is conducted.

<sup>194</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf>

<sup>195</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm110114.pdf>

By approving, recommending and aggressively promoting use of the Hepatitis B vaccine for all infants, HHS created a liability-free captive market for Merck and GSK by ensuring millions of babies every year will be injected with their Hepatitis B products. Since HHS's recommendation in 1991 for the universal pediatric use of these products, these companies have generated over \$10 billion in sales from this vaccine.<sup>196</sup> Yet, HHS's response makes clear that it lacked the clinical trial safety data necessary to support its licensure and aggressive marketing of this product for use in all babies.

It is deeply troubling that, despite repeated assurances by HHS that the safety science for this vaccine is robust and complete, when we demanded to actually see this science, HHS was unable to produce it because it apparently does not exist.

Please respond to the above and the specific questions listed in Appendix A.

### III. THE VACCINE ADVERSE EVENT REPORTING SYSTEM

Between 2013 and 2018, the Vaccine Adverse Event Reports System (VAERS), operated by HHS, has received 261,294 reports of adverse vaccine events, including 2,081 deaths, 5,477 permanent disabilities, and 20,778 hospitalizations.<sup>197</sup> As HHS is aware, "fewer than 1% of vaccine adverse events are reported" because reporting to VAERS is voluntary.<sup>198</sup> We therefore asked in our opening letter why, after Harvard developed a system for spontaneously creating vaccine adverse event reports, "HHS failed to cooperate with Harvard to automate VAERS reporting?"<sup>199</sup> HHS's response does not answer this question.

In 2006, an HHS agency, the Agency for Healthcare Research and Quality, provided a \$1 million grant to create a spontaneous reporting system to VAERS at Harvard Pilgrim Health Care.<sup>200</sup> The result was the successful creation of a system at Harvard Pilgrim which automatically created adverse vaccine event reports:

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions ... were identified.<sup>201</sup>

---

<sup>196</sup> <https://www.thomsonone.com/>

<sup>197</sup> <https://wonder.cdc.gov/vaers.html>

<sup>198</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>199</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

<sup>200</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>201</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

After automating the spontaneous creation of adverse event reports at Harvard Pilgrim, its developers asked the CDC to take the final step of linking VAERS with the Harvard Pilgrim system so that these reports could be automatically transmitted into VAERS.<sup>202</sup> One would expect the CDC to rush to take this final step given that the preliminary data from this project showed that over only a three-year period, there were 35,570 reportable reactions in just 376,452 vaccine recipients.<sup>203</sup> Instead, the CDC refused to cooperate. As the Harvard researchers explained:

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.<sup>204</sup>

Given HHS's statutory mandate to assure safer vaccines, it should have moved forward quickly with implementing the spontaneous VAERS reporting system developed by Harvard -- not refused to even communicate with the Harvard Medical School researchers being funded by HHS.

We therefore asked why HHS did not cooperate in implementing the spontaneous VAERS reporting system, and HHS's response incongruously states that doctors may "submit reports directly online" or "download and complete the writable and savable VAERS 2.0 form and submit it using an electronic document upload feature."<sup>205</sup> This does not answer our question. Nor does it address the basic issue that VAERS is a voluntary passive reporting system and history has shown that clinicians do not fill out VAERS reports with any regularity, resulting in only a minuscule number of adverse vaccine events being reported.<sup>206</sup> It also does not correct the problem that VAERS is a passive reporting system, thus limiting its usefulness in making determinations about vaccine safety.<sup>207</sup> The fact that HHS has refused to automate this process leads to the question of whether the decision to keep VAERS as a passive reporting system is intentional in order to hamper its ability to provide reliable information regarding the rate at which a given injury occurs after a given vaccine.

These issues with VAERS have been highlighted for over 30 years and could be easily addressed by implementing automated reporting systems at hospitals and health clinics so

---

<sup>202</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>203</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>204</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>205</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>206</sup> <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf> "Reasons for clinical under-reporting might include failure to associate an acute health event to recent vaccines, lack of awareness of VAERS, the misperception that only serious events should be reported, and lack of time to report." <https://www.ncbi.nlm.nih.gov/pubmed/26060294> (cited by HHS)

<sup>207</sup> <https://vaers.hhs.gov/about.html>; <https://vaers.hhs.gov/data/dataguide.html>

that reports are electronically generated based on patients' medical records and submitted to VAERS automatically. This would also assure reporting from a known sample size and thus convert VAERS from a passive to an active reporting system, thereby permitting more reliable conclusions to be drawn from the analysis of the VAERS database. But, as discussed above, the CDC refused to cooperate with Harvard to implement such a system in 2007.

The 2015 study cited in HHS's letter shows that HHS continues to refuse to cooperate to implement an automated system.<sup>208</sup> HHS claims that this three-year-old study shows that the "CDC is developing the next generation of spontaneous reporting mechanisms for the VAERS."<sup>209</sup> This claim is at best disingenuous.

The program described in this 2015 study, which the CDC created to generate "spontaneous reporting," makes clear the CDC is desperate to avoid any actual spontaneous reporting.<sup>210</sup> Despite the fact that this program does spontaneously generate vaccine adverse events reports from patients' medical records, the CDC does not permit this program to automatically submit these reports to VAERS.<sup>211</sup> Instead, it emails each report to the patient's doctor and asks the doctor to review and decide whether to submit the report to VAERS.<sup>212</sup> This requirement is backwards.

The purpose of VAERS is to identify previously unknown associations between a vaccine and a condition (ICD-9/10 code). A doctor will, of course, be unlikely to affirm that a reaction is related to a vaccine without a known clinical precedent, the very evidence VAERS is intended to compile. Unsurprisingly, in the eight-month period it tested this new program, the system generated 1,385 vaccine adverse event reports but doctors who received these reports only clicked to submit a grand total of 16 of them to VAERS.<sup>213</sup>

Moreover, the CDC designed this program to even prevent it from generating reports for any conditions (ICD-9/10 code) the CDC predetermined are not associated with a vaccine.<sup>214</sup> The CDC also prevents the program from generating any reports for an adverse event or health condition that the patient had experienced prior to vaccination, thereby eliminating reports of any instance where the vaccine worsened or caused a relapse of a preexisting condition.<sup>215</sup> Hence, the *only* reports the program can generate are for adverse events the CDC deems permissible to associate with a vaccine.<sup>216</sup>

---

<sup>208</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26060294>

<sup>209</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>210</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26060294>

<sup>211</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26060294>

<sup>212</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26060294>

<sup>213</sup> Doctors failed to transmit reports reflecting harms that even HHS accepts are caused by vaccines; doctors affirmatively selected to not transmit 209 reports, which reflects the institutionalized belief about what injuries are caused by vaccines; and for the remaining 1,176 reports, nearly 85% of all reports, there was no clinical response. <https://www.ncbi.nlm.nih.gov/pubmed/26060294>

<sup>214</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26060294>

<sup>215</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26060294>

<sup>216</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26060294>

In short, the CDC has assured that its vaccine reaction reporting program will only generate reports for injuries the CDC deems acceptable to associate with a vaccine, and then creates the hurdle of requiring busy clinicians to review and click to affirmatively submit a report, which they are highly unlikely to do for the reasons discussed above.

When one considers that the CDC long-ago developed and championed the use of electronic systems that track the movement of each vaccine from its manufacture to its administration, as well as the vaccination status of every child in each state, there is little excuse for not similarly championing the use of long ago developed programs for automatically generating and transmitting adverse reactions reports to VAERS.<sup>217</sup>

We therefore ask – again – for HHS to explain “why HHS failed to cooperate with Harvard to automate VAERS reporting?” as well as address the issues raised above and provide responses to the specific questions in Appendix A.

#### **IV. VACCINE-INJURY PAIRS IN 1994 AND 2011 IOM REPORTS**

In our opening letter, we asked HHS to provide the studies it has conducted to determine if there is a causal relationship between vaccination and what HHS claims are the 173 most commonly claimed injuries following vaccination.<sup>218</sup>

HHS’s answer points to a recent 740-page review it conducted in 2014, entitled *Safety of Vaccines Used for Routine Immunization in the United States*, which HHS claims is “the most comprehensive review to date of published studies on the safety of routine vaccines recommended for children in the United States.”<sup>219</sup> However, this report simply reaffirms that HHS has still not conducted studies to determine whether almost any of the 173 most commonly claimed injuries from vaccines (as determined by HHS) are caused by vaccines.

Worse, as discussed below, this 2014 “comprehensive review” of vaccine safety by HHS reveals that HHS does not understand the actual safety profile of its childhood vaccine schedule.

##### **A. HHS’s Paid Expert, the IOM, Finds Vaccine Safety Has Been Neglected**

In 1991 and 1994, at HHS’s request and in compliance with a congressional mandate in the 1986 Act, the Institute of Medicine (IOM) of the National Academy of Sciences appointed committees to examine the scientific literature and other evidence that could

---

<sup>217</sup> <https://www.cdc.gov/vaccines/programs/vtrcks/about.html>; <https://www.cdc.gov/vaccines/programs/iis/index.html>

<sup>218</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

<sup>219</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

either prove or disprove a causal link between commonly reported serious health problems following administration of vaccines recommended by HHS for children. The first report, *Adverse Effects of Pertussis and Rubella Vaccines*, was published in 1991, and the second report, *Adverse Effects Associated with Childhood Vaccines*, was published in 1994.

The 1994 report evaluated 54 commonly reported serious injuries and vaccination for Diphtheria, Tetanus, Measles, Mumps, Polio, Hepatitis B, and Hib.<sup>220</sup> The IOM located sufficient science to support a causal connection between these vaccines and 12 serious injuries, including death, thrombocytopenia, and GBS.<sup>221</sup> The IOM, however, found that the scientific literature was insufficient to conclude whether or not these vaccines caused 38 other commonly reported serious injuries, including:

Arthritis, Aseptic Meningitis, Demyelinating diseases of the central nervous system, Insulin-Dependent Diabetes Mellitus, Myelitis, Neuropathy, Residual Seizure Disorder, Sensorineural Deafness, Sudden Infant Death Syndrome, Sterility, Transverse Optic Neuritis<sup>222</sup>

The IOM lamented that: “The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern.”<sup>223</sup>

Fifteen years later, in 2011, HHS paid the IOM to review the available science regarding whether there is a causal relationship between vaccination and what HHS asserted are the 158 most common injuries claimed to occur from vaccines for Varicella, Hepatitis B, Tetanus, Measles, Mumps, and Rubella.<sup>224</sup> The IOM located science to support a causal relationship with 18 of these injuries, including pneumonia, meningitis, MIBE, and febrile seizures.<sup>225</sup> The IOM, however, found the scientific literature insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

Acute Disseminated Encephalomyelitis, Afebrile Seizures, Amyotrophic Lateral Sclerosis, Arthralgia, Autoimmune Hepatitis, Brachial Neuritis, Cerebellar Ataxia, Chronic Headache, Chronic Inflammatory Demyelinating Polyneuropathy, Chronic Urticaria, Encephalitis, Encephalopathy,

---

<sup>220</sup> <https://www.nap.edu/read/2138/chapter/2#12>

<sup>221</sup> <https://www.nap.edu/read/2138/chapter/2#12>

<sup>222</sup> <https://www.nap.edu/read/2138/chapter/2#12>

<sup>223</sup> <https://www.nap.edu/read/2138/chapter/12>

<sup>224</sup> <https://www.nap.edu/read/2138/chapter/12>

<sup>225</sup> <https://www.nap.edu/read/13164/chapter/2#3>

Erythema Nodosum, Fibromyalgia, Guillain-Barré Syndrome, Hearing Loss, Immune Thrombocytopenic Purpura, Infantile Spasms, Juvenile Idiopathic Arthritis, Multiple Sclerosis, Neuromyelitis Optica, Optic Neuritis, Polyarteritis Nodosa, Psoriatic Arthritis, Reactive Arthritis, Rheumatoid Arthritis, Seizures, Small Fiber Neuropathy, Stroke, Sudden Infant Death Syndrome, Systemic Lupus Erythematosus, Thrombocytopenia, Transverse Myelitis<sup>226</sup>

Thus, out of the 158 most common serious injuries claimed to have been caused by one or more of these vaccines, the IOM found that for over 86% of those the science simply had not been performed to determine if there is a causal relationship between the vaccine and the injury.<sup>227</sup>

We therefore asked in our opening letter for HHS to identify the studies it has undertaken to determine whether there is a causal relationship between the 173 vaccine-injury pairs for which this question remained unanswered in the 1994 and 2011 IOM Reports.

#### **B. HHS’s “Comprehensive Review” of Vaccine Safety is Deeply Troubling**

To support it has studied these vaccine-injury pairs, HHS, as noted above, points to its 2014 review entitled *Safety of Vaccines Used for Routine Immunization in the United States*.<sup>228</sup> But, the 2014 HHS review reached the same conclusion that there is insufficient evidence to conclude whether – save for four – there is a causal relationship between the 173 vaccine-injury pairs from the 1994 and 2011 IOM Reports.<sup>229</sup> It is therefore incredible that HHS would cite this report as proof it has conducted the scientific studies necessary to rule out or confirm a causal relationship for these vaccine injury pairs.

Far more troubling, if the 2014 HHS review is “the most comprehensive review” of the published literature on vaccine safety, as HHS claims, then this review should cause grave concern within HHS and the public regarding vaccine safety.

First, this so-called “comprehensive” review only looked at certain narrow vaccine-injury pairs pre-selected by HHS.<sup>230</sup> This narrow approach reveals nothing about the actual safety profile of these pediatric vaccines on HHS’s childhood vaccine schedule. The only

<sup>226</sup> <https://www.nap.edu/read/13164/chapter/2#3>

<sup>227</sup> <https://www.nap.edu/read/13164/chapter/2#3>

<sup>228</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>229</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/> (HHS’s 2014 review also added the following vaccine-injury pairs to the list of what it asserts are the most commonly claimed vaccine injuries: spontaneous abortion from HPV vaccine and meningitis from MMR vaccine.)

<sup>230</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

way to actually know the true safety profile of HHS's childhood vaccine schedule or any individual vaccine on that schedule is a placebo-controlled trial of sufficient size and duration. This could provide an actual safety profile of each pediatric vaccine and HHS's childhood vaccine schedule. Instead of this basic trial design used for all drugs to understand their safety profile, HHS's approach is to work backwards by putting forth a self-selected smattering of vaccine-injury pairs, and if HHS cannot find a study proving the vaccine causes the injury (because no study was performed or adequately designed to find a causal relationship), it deems the vaccine safe.<sup>231</sup> This approach entirely ignores the scientific method and is transparently unsound because it begins with the *a priori* assumption that vaccines are safe and then relies upon a "comprehensive review" of self-selected, scarce and incomplete post-licensure vaccine literature to validate this assumption if it cannot find proof of harm.<sup>232</sup>

Second, after HHS assumed safety and narrowed the review to certain vaccine-injury pairs, the review then eliminated almost all studies showing that vaccines cause harm by excluding 20,312 of the 20,478 studies it identified as related or potentially related to vaccine safety.<sup>233</sup> The handful of studies that HHS did include for review were overwhelmingly studies in which a pharmaceutical company funded and/or authored (usually both) a review of its own vaccine.<sup>234</sup>

For example, it excluded all individual case reports despite the fact that practitioners can typically only afford to publish (typically instances of immediate and obvious vaccine injuries) in this form.<sup>235</sup> HHS excluded all experimental studies which could actually explain the biological mechanisms of how vaccines can cause injury or death.<sup>236</sup> HHS even excluded animal studies which – because experimentation with animals does not have ethical restrictions applicable to human research – often provide the best available scientific evidence of how vaccines can harm immune function, the brain and other tissue.<sup>237</sup>

The result is that this review included only 97 studies that are applicable to children<sup>238</sup>, 77 of which were directly funded and/or authored (typically both) by the very vaccine manufacturer whose vaccine(s) the study reviews.<sup>239</sup> As for the remaining 20 studies, almost all were funded and/or authored by agencies and/or individuals that directly or indirectly receive funding from the manufacturer whose vaccine(s) the study reviews.<sup>240</sup>

---

<sup>231</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>232</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>233</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>234</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>235</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>236</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>237</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/> (HHS also excluded all studies using VAERS, one of the few resources available to study vaccine safety without pharmaceutical type funding.)

<sup>238</sup> The 2014 HHS review lists the study, Zaman K. et al. (2012), twice in Table 22 and the study, Khatun S. et al. (2012), twice in Table 25.

<sup>239</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>240</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

For example, HHS *excluded* an actual randomized, double-blind, placebo-controlled study which compared the rate of respiratory infections between controls receiving a placebo (saline injection) and subjects receiving inactivated influenza vaccine (TIV).<sup>241</sup> This non-pharma-funded nine-month study carefully tracked influenza-like illness symptoms through “symptom diaries and telephone calls,” and “illness reports in any household member triggered home visits, during which nasal and throat swab specimens were collected.”<sup>242</sup> The result:

There was no statistically significant difference in the risk of confirmed seasonal influenza infection between recipients of TIV or placebo. ... However, participants who received TIV had higher risk of ARI [acute respiratory illness] associated with confirmed noninfluenza respiratory virus infection (RR, 4.40; 95% CI, 1.31–14.8).<sup>243</sup>

This meant both groups had a similar rate of influenza, but the vaccinated group had 440% more cases of noninfluenza acute respiratory illness.<sup>244</sup> It appears that getting the flu shot may have significantly “reduced immunity to noninfluenza respiratory viruses.”<sup>245</sup>

While this well designed and executed study reflecting serious negative impact of vaccination on health was *excluded* from HHS’s comprehensive vaccine safety review, this review *included* a study funded by GSK and conducted by GSK employees which nonsensically compared 199 infants receiving PHiD-CV, DTPa, HBV, IPV and Hib (test group) with 101 infants receiving DTPa, HBV, IPV and Hib (control group).<sup>246</sup> Ironically, this study found that 4.5% of test infants and 5.9% of control infants had one or more serious adverse reactions following vaccination, but HHS accepted GSK’s unsubstantiated and self-serving conclusion that none were “considered to be causally related to [GSK’s] vaccination.”<sup>247</sup>

Third, having limited the review of vaccine safety for children to 97 studies, HHS then claims that 59 of these studies compared “vaccinated versus unvaccinated children or adolescents”<sup>248</sup> The following is a break-down of these 59 studies by vaccine type: Rotavirus (34 studies), HPV (13 studies), Influenza (6 studies), Hib (3 studies), Meningococcal (2

---

<sup>241</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>242</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>243</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>244</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>245</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>246</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23432812>

<sup>247</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23432812>

<sup>248</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

studies), and Varicella (1 study).<sup>249</sup> We commend HHS for making clear it understands there is a critical importance of comparing vaccinated and unvaccinated children to scientifically evaluate and understand vaccine safety. It is, however, unfortunate that HHS mislabels these studies as comparing “vaccinated versus unvaccinated children or adolescents” when the unvaccinated cohort is not really unvaccinated.<sup>250</sup>

For example, HHS lists two studies involving the meningococcal vaccine as comparing “vaccinated versus unvaccinated children.”<sup>251</sup> However, in one study the test group and control group both received a meningococcal vaccine, and in the other study the test group received seven vaccines and the control group received six vaccines.<sup>252</sup> Claiming these two studies compared “vaccinated versus unvaccinated children” is misleading. The following table details these two studies and highlights the rate of serious adverse events (SAEs) that are ignored because the control group, wrongly labeled “unvaccinated,” is used as the baseline for what is deemed “safe”:

Vaccine & Manufacturer	Funding	Study	Test Group	Control Group	Finding
Meningococcal MCV4 (Sanofi)	Funded by <b>Sanofi</b> & authors include <b>Sanofi</b> employees	Khalil, M. et al. 2012 (Saudi Arabia)	MCV4 (151 children who received MPSV4 as babies)	MCV4 (85 children who did not receive MPSV4 as babies)	1.3% and 2.4% of the children in the subject and control group, respectively, had a serious adverse reaction (SAE)
Meningococcal MenACWY (Novartis)	Funded by <b>Novartis</b> & authors include <b>Novartis</b> employees	Klein, N.P. et al. 2012 (Three countries)	MenACWY, DTaP, IPV, Hib, HBV, IPV, PCV7, RV, V & MMRII (≈1000 babies)	DTaP, IPV, Hib, HBV, IPV, PCV7, RV, V & MMRII (≈500 babies)	75% of subject and 76% of control babies had an AE and “SAEs were reported with similar frequency among groups”

Similarly, the following table summarizes every purported “vaccinated versus unvaccinated” study that HHS could identify regarding the Hib vaccine (injected per HHS at 2, 4, 6 and 12 months of age) and again highlights the rate of serious adverse events that are ignored because the control group, wrongly labeled “unvaccinated,” is used as the baseline for what is deemed “safe”:

Vaccine & Manufacturer	Funding	Study	Test Group	Control Group	Finding
Hib - OPMC (Merck)	Funded by <b>Merck</b> & authors include <b>Merck</b> employees	Santosham M. et al., 1991 (U.S.)	OPMC, DTP, and OPV (2,588 infants)	DTP and OPV (2,602 infants)	4% of infants in each group were hospitalized within 30 days of vaccination
Hib - PHiD-CV (GSK)	Funded by <b>GSK</b> & authors include <b>GSK</b> employees	Huu, T.N. et al. 2013 (Vietnam)	PHiD-CV, DTPa, HBV, IPV & Hib (199 infants)	DTPa, HBV, IPV & Hib (101 infants)	4.5% and 5.9% of infants in the subject and control groups, respectively, reported a SAE

<sup>249</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>250</sup> The rotavirus vaccine is given orally, not injection, and hence not considered. Nonetheless, the 35 rotavirus studies HHS states compare “vaccinated with unvaccinated children” actually compare children receiving oral drops of rotavirus with children receiving oral drops of the following vaccine ingredients: Polysorbate 80, Sucrose, Citrate, Phosphate, Dextran, Sorbitol, Amino acids, Dulbecco’s Modified Eagle Medium, Calcium Carbonate, and/or Xanthan. <https://www.ncbi.nlm.nih.gov/books/NBK230057/table/results.t19/?report=objectonly>

<sup>251</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>252</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

Hib - PRP-OMP, POP-T, and HbOC (various)	No conflicts declared	Capeding M. R. Z. et al., 1996 (Philippines)	Hib, BCG, OPV, DTP and HBV (130 infants)	BCG, OPV, DTP and HBV (44 infants)	Admits that because “vaccines were administered simultaneously with other ... vaccines ... it is not possible to attribute the systemic reactions to any individual vaccine used in the study.”
--	-----------------------	--	--	------------------------------------	---

Similarly, for the six influenza vaccine studies listed by HHS as comparing “vaccinated with unvaccinated children,” only four involved an injection of influenza vaccine,<sup>253</sup> and only one of these can be properly labeled as comparing “vaccinated with unvaccinated children.” This one placebo-controlled study involved HIV-infected children and, while it provided almost no useful safety data because it only monitored safety for three days, it demonstrates that it is ethically permissible to use a saline placebo in a vaccine trial.

Vaccine & Manufacturer	Funding	Study	Test Group	Control Group	Finding
Flu - TIV (Sanofi)	Funded by Sanofi and authors include Sanofi employees	Englund J. A. et al., 2010 (U.S.)	TIV, DTaP, Hib, PNC, IPV, & HepB (915 babies)	Placebo, DTaP, Hib, PNC, IPV & HepB (460 babies)	Only collected “SAEs using previously defined criteria,” yet within 28 days 1.9% of subject and 1.5% of control babies had a SAE
Flu - TIV (unknown)	None disclosed	Gotoh K. et al., 2011 (Japan)	TIV or no TIV (38 liver transplant recipients)	TIV (63 healthy children)	Safety not compared between subject and control groups
Flu - TIV (Sanofi)	None disclosed	Greenhawt, M.J. et al. 2012 (U.S.)	TIV (14 children)	TIV thirty minutes after saline injection (17 children)	Both groups had comparable adverse event rates
Flu - Vaxigrip (Sanofi)	Sponsored by Bristol-Myers Squibb	Madhi, S.A. et al. 2013 (South Africa)	TIV (203 HIV infected children)	Placebo - Saline (200 HIV-infected children)	Adverse events only collected for 3 days post-vaccination

As for the 13 studies regarding HPV vaccine labeled by HHS as “vaccinated versus unvaccinated,” all – except for one study with a control group of 17 HIV-positive girls – use other vaccines or an injection of the aluminum adjuvant contained in the HPV vaccine as a control.<sup>254</sup> The table below reveals high rates of serious injuries and chronic illness reported by the HPV vaccine recipients, which were dismissed as not being a vaccine safety issue because the rates were similar to those reported in the “spiked” control group. It is noteworthy that unlike most of the vaccines in the tables above, the HPV vaccines were studied in adolescent and older women who, unlike children or babies, are able to clearly express if they are experiencing a serious adverse reaction, such as neurological issues.

<sup>253</sup> Two studies involved LAIV administered via nasal spray. In both, a pharmaceutical company reviewed its own product. One involved 20 immunocompromised children with cancer in which 10 received LAIV and 10 received a placebo with .5 mL of sucrose-phosphate buffer and no SAEs were reported since the pharmaceutical company’s funded researchers did not consider them related to LAIV. (Halasa N. et al., 2011 (U.S.)) The other compared 261 children receiving LAIV with 65 children receiving placebo of .5 mL sucrose-phosphate buffer and being offered LAIV after 28 days which negated reaching safety conclusions. (Mallory R. M. et al., 2010 (U.S.))

<sup>254</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

Vaccine & Manufacturer	Funding	Study	Test Group	Control Group	Finding
HPV - Gardasil (Merck)	Funded by Merck and authors include Merck employees	Moreira Jr E. D. et al., 2011 (18 countries)	Gardasil (2,020 boys and men)	225 ug of AAHS (2,029 boys and men)	"systemic AE was generally comparable between the vaccine and placebo group (31.7% vs. 31.4%, respectively)"
HPV - Cervarix (GSK)	Funded by GSK and authors include GSK employees	Roteli-Martins C. M. et al., 2012 (Brazil)	Cervarix (223 girls and women)	500 ug Aluminum Hydroxide (213 girls and women)	24.6% of subjects and 15.5% of controls had a SAE, new onset of chronic disease or medically significant condition
HPV - Cervarix (GSK)	Funded by GSK and authors include GSK employees	Schwarz, T.F. et al. 2012 (5 countries)	Cervarix (1,035 girls)	Havrix and, after delay, Cervarix (1,032 girls)	38.8% of subjects and 32.4% of controls had a SAE, new onset of chronic disease or medically significant condition
HPV - Cervarix (GSK)	Funded by GSK and authors include GSK employees	Sow, P. S. et al. 20131 (Africa)	Cervarix (450 girls and women)	500 ug Aluminum Hydroxide (226 girls and women)	75.2% of subjects and 69.3% of controls reported a "Medically significant condition"
HPV - Gardasil (Merck)	Funded by Merck and authors include Merck employees	Block S. L. et al., 2010 (global)	Gardasil (11,792 people aged 9-23)	AAHS (9,092 aged 16-23) Gardasil minus AAHS and antigens (596 aged 9-15)	Between 9% and 14% of subjects and controls each had vaginal candidiasis, bacterial vaginosis, urinary tract infection and vaginal discharge
HPV - Cervarix (GSK)	Funded by GSK and authors include GSK employees	De Carvalho N. et al., 2010 (Brazil)	Cervarix (222 women)	500 ug Aluminum Hydroxide (211 women)	9.9% of subjects and 8.6% of controls had a SAE or medically significant AE
HPV - Gardasil (Merck)	Funded by Merck and authors include Merck employees	Giuliano A. R. et al., 2011 (18 countries)	Gardasil (2,020 males)	225 or 450 ug of AAHS (2,029 males)	14.1% of subjects and 14.6% of controls had a systemic adverse event within 15 days
HPV - Cervarix (GSK)	None declared	Khatun S. et al., 2012 (Bangladesh)	Cervarix (50 girls)	Nothing given (17 girls)	Vomiting occurred in 8% of subjects after 1st dose, 10% after 2nd dose, and 32% after 3rd dose
HPV - Cervarix (GSK)	Funded by GSK and authors include GSK employees	Kim S. C. et al., 2011 (Korea)	Cervarix (149 women)	500 ug Aluminum Hydroxide (76 women)	"fatigue, myalgia and headache was frequent in both groups" and 22.8% of subjects and 13.2% of controls reported a medically significant adverse condition(s)
HPV - Gardasil (Merck)	Authors include Merck employees	Levin M. J. et al., 2010 (U.S.)	Gardasil (96 HIV positive children)	"identical placebo" (30 HIV positive children)	7% of subjects and controls had grade 3 or 4 event w/n 14 days, and 15 AEs were not graded
HPV - Gardasil (Merck)	Funded by Merck and authors include Merck employees	Li R. et al., 2012 (China)	Gardasil (302 people)	225 or 450 ug of AAHS (298 people)	42.7% of subjects and 39.9% of controls had systemic adverse event
HPV - Gardasil (Merck)	Funded by Merck	Kang, S. et al. 2008 (Korea)	Gardasil (117 females)	225 ug of AAHS (59 females)	31.6% of subjects and 44.1% of controls had systemic adverse reaction within 14 days
HPV - Gardasil (Merck)	Funded by Merck and authors include Merck employees	Clark, L.R. et al. 2013 (global)	Gardasil (373 women)	225 ug of AAHS (393 women)	49% of subjects and 41% of controls had systemic reactions, both had similar rate of SAEs

The above tables make clear that HHS is misleading the public when it labels these studies as “vaccinated versus unvaccinated” because the control group in each study almost always received another vaccine and/or an active ingredient found in the vaccine.<sup>255</sup>

Little comfort should be derived from the fact that the rate of serious adverse events is the same in an experimental vaccine test group and a control group receiving another vaccine or toxic substance, especially when that rate is higher than what would be expected in the general population. For example, it is troubling that a serious adverse event rate of over 30% (or even 2% of babies) is dismissed just because it occurred in both the subject and control groups, especially where the control group received another vaccine or toxic substance.

These outcomes of these purported “vaccinated versus unvaccinated” studies should be cause for concern regarding vaccine safety, not used as proof of safety.

Finally, it is evident that the real goal of HHS’s “comprehensive review” was *not* about providing good scientific evidence to reassure the public that the vaccines on HHS’s childhood vaccine schedule are safe. As the introduction to the review makes clear, it was about assuring high vaccine uptake, even at the expense of throwing away objectivity and basic scientific principles to produce a report that provides only the superficial appearance of vaccine safety for the public.<sup>256</sup> Indeed, the review begins by focusing upon and bemoaning that “vaccination rates remain well below established Healthy People 2020 targets for many vaccines” and that “Increasing vaccination rates remains critically important.”<sup>257</sup> HHS even laments in its review that “public concerns about vaccine safety continue to persist” despite “the rigorous processes new vaccines must undergo before receiving approval” and that they meet “stringent criteria for safety.”<sup>258</sup> HHS’s predetermined objective and conclusion is thus made clear from the outset of its review.

Despite its predetermined conclusion regarding vaccine safety and the limitations placed on the inclusion of studies as discussed above, the 2014 review still found that vaccines can cause babies and children to develop numerous serious adverse reactions, such as febrile seizures, arthralgia (pain in the joints), thrombocytopenic purpura (the immune system attacking the body’s own platelets), meningitis (inflammation of the membranes surrounding the brain and spinal cord), and encephalitis (inflammation of the brain).<sup>259</sup>

---

<sup>255</sup> As for the one purported “vaccinated versus unvaccinated” varicella (chicken pox) vaccine study, it compared a test group of 54 children with systemic lupus erythematosus that either received or did not receive varicella with a control group of 28 healthy children that received varicella. (Weinberg, A. et al. 2010 (U.S.).)

<sup>256</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>257</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>258</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>259</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

Given all of the foregoing issues with the 2014 review, it is not surprising that HHS's response letter only cites an executive summary of this review.<sup>260</sup> The full text of this review, which HHS understandably wanted to avoid publicizing as part of its response, is available at the URL in the footnote to this sentence.<sup>261</sup>

### C. Studies Published After HHS's 2014 Review Reaffirm the Above Concerns

Apart from the 2014 review, HHS's response provides a link to the CDC website which HHS states contains a "list of CDC vaccine safety publications" which "address several of the vaccine-injury pairs that have been identified in the reports mentioned above."<sup>262</sup> These studies, however, add little to closing the gap regarding whether a causal relationship exists for the 173 vaccine-injury pairs from the 1994 and 2011 IOM Reports.

The studies published prior to August 2013 should have been swept up by HHS's 2014 "comprehensive review" (discussed above), which HHS asserts encompassed all vaccine safety studies prior to August 2013.<sup>263</sup> As for studies published after August 2013, those based on VAERS data cannot be used to determine causation for any vaccine-injury pair because according to HHS: "A major limitation of VAERS data is that VAERS cannot determine if the adverse health event reported was caused by the vaccination."<sup>264</sup> What remains are only 6 non-VAERS studies published after August 2013 on the CDC webpage cited by HHS which analyze any of the relevant vaccine-injury pairs from the 1994 and 2011 IOM reports.<sup>265</sup>

HHS's response to our letter sought to mislead the public into believing it has conducted studies to fill the vaccine safety science gaps identified by the IOM between 1991 and 2013, when this is clearly not the case. HHS's response and its 2014 "comprehensive

---

<sup>260</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>261</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>262</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>263</sup> <https://www.ncbi.nlm.nih.gov/books/NBK230053/>

<sup>264</sup> <https://wonder.cdc.gov/vaers.html>. HHS also explains that VAERS cannot be used "to determine causation" because "there is lack of an unvaccinated group for comparison in VAERS." <https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html>. Also, since VAERS is a passive reporting system, the absence of adverse event reports in VAERS cannot establish safety. <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

<sup>265</sup> Five of these six studies were conducted using the VSD and the issues with the VSD are discussed below in Section IX; and the authors in half of these studies received funding from the pharmaceutical companies whose vaccines were being reviewed. The six studies are: (1) Hambridge (2014) - Reviewed risk of seizures, but expressly excluded all unvaccinated children and instead compared the rate of seizures within 2 days or between 7 to 10 days of vaccination (depending on vaccine) with the rate of seizures during the next 14 days plus the 14 days starting four weeks before vaccination. It found an increased risk of seizures from some vaccines. (2) Rowhani-Rahbar (2013) - Compared risk of seizures 7 to 10 days after vaccination with the risk in days 1 to 6 plus 11 to 42 after vaccination between MMRV alone or MMR and V concurrently but separately. (3) Klein (2015) - Also compared MMRV alone with MMR and V concurrently but separately. (4) McCarthy (2013) - Evaluated influenza vaccine, but excluded reactions on the day of vaccination for most conditions, had no unvaccinated control, and comingled data for children and adults with the exception of seizures. As for seizures, only included seizures occurring within one day of vaccination and excluded complex febrile seizures. (5) Kawai (2014) - Also reviewed influenza vaccine, had same issues as McCarthy, plus excluded all reactions occurring during outpatient visits when vaccines are administered. (6) Daley (2014) - Compared receipt of DTaP-IPV as single injection with receipt of DTaP and IPV at same time in separate injections and excluded most reactions during outpatient visits.

review” provide further evidence that it has failed to fulfill and cannot be trusted to fulfill its critical statutory vaccine safety duties.

Please respond to the above points with relevant studies, and please provide answers to the specific questions raised in Appendix A.

## V. FAILURE TO IDENTIFY CHILDREN SUSCEPTIBLE TO VACCINE INJURY

In our opening letter we noted that the IOM in 1994 asserted that it “was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not” and hence urged that “research should be encouraged to elucidate the factors that put certain people at risk.”<sup>266</sup> We also pointed out that in 2013, the IOM acknowledged this research still had not been conducted, stating that it

found that evidence assessing outcomes in sub populations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited.<sup>267</sup>

We thereafter asked that HHS “advise when [it] intends to begin conducting research to identify which children are susceptible to serious vaccine injury” and “[i]f HHS believes it has commenced this research, please detail its activities regarding same.”<sup>268</sup>

We appreciate that HHS’s response appears to acknowledge that this is an important area of study by asserting that “HHS is currently supporting several initiatives that focus on advancing research” that would identify which children are susceptible to serious vaccine injury.<sup>269</sup> Unfortunately, the two sources HHS cites do not support that it is actually conducting this research.

HHS first cites the “About Us” page for the Human Immunology Project Consortium (HIPC).<sup>270</sup> To be sure, this webpage asserts that “the HIPC program will ... establish predictors of vaccine safety in different populations.”<sup>271</sup> But, none of the projects listed on the “HIPC Projects” webpage nor the 64 HIPC-funded studies within the associated

---

<sup>266</sup> <https://www.nap.edu/read/2138/chapter/12#307>. See also <https://www.nap.edu/read/1815/chapter/9>

<sup>267</sup> <https://www.nap.edu/read/13563/chapter/9#130>. See also <https://www.nap.edu/read/13164/chapter/5#82>

<sup>268</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

<sup>269</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>270</sup> <https://www.immuneprofiling.org/hipc/page/showPage?pg=sci-about>

<sup>271</sup> <https://www.immuneprofiling.org/hipc/page/showPage?pg=sci-about>

ImmuneSpace database are aimed at establishing the predictors of susceptibility to vaccine injury in the general United States pediatric population.<sup>272</sup>

While HIPC has studiously avoided supporting projects that could identify which children should not receive one or more vaccines due to increased risk of vaccine injury, it has supported projects aimed at identifying biomarkers of inter-subject variability in vaccine immunogenicity (*i.e.*, the ability of recipients to produce a better immune response to a currently licensed vaccine, such as the Hepatitis B vaccine), even though similar tools could be utilized to search for predictors of increased risk of injury from those same vaccines.<sup>273</sup> The ImmuneSpace database even contains studies intended to *expand* the use of vaccines in subgroups where those vaccines are currently contraindicated for use.<sup>274</sup> Thus, HHS's assertion that the HIPC program is conducting studies to identify which children are susceptible to vaccine injury was incorrect.

The second source HHS cites does not fare much better.<sup>275</sup> It provides a list of the five vaccine safety studies HHS has directly funded since 2015, two of which relate to identifying which children would be injured by a vaccine.<sup>276</sup> The first "aims to identify inherited, immunologic, and clinical factors that may predict the occurrence of febrile seizures after measles vaccination" and the second "aims to analyze the genetic determinants of the immune response following yellow fever vaccination among individuals who experience serious adverse events."<sup>277</sup>

Funding only two studies in three years aimed at assessing which children are likely to be vaccine injured is far too slow a pace.<sup>278</sup> There are also serious issues with these studies.

The principal investigator for the measles vaccine febrile seizure study, Dr. Nicole P. Klein, received \$1,706,230.28 in funding from the manufacturer of the measles vaccine, Merck, between 2015 and 2017.<sup>279</sup> Selecting someone who receives millions of dollars in funding from Merck to conduct a study about the safety of a Merck vaccine raises serious concern about the study author's objectivity. If Dr. Klein were to produce and publish findings that were adverse to Merck's interests, she may place her future funding from Merck in jeopardy. This conflict should have been obvious to HHS prior to selecting Dr. Klein to conduct this study.

---

<sup>272</sup> <https://www.immuneprofilng.org/hipc/page/showPage?pg=projects>; <https://www.immunespace.org/>

<sup>273</sup> <https://www.immuneprofilng.org/hipc/page/showPage?pg=projects>

<sup>274</sup> For example, a live varicella vaccine, which is currently contraindicated per the CDC's guidelines for immunocompromised children, is being studied in renal transplant recipients. ImmuneSpace project SDY357, *VZV Evaluation of the Safety and Immunogenicity of Varivax (Live-Attenuated Varicella-Zoster Virus Vaccine) in Pediatric Renal Transplant Recipients*.

<sup>275</sup> <https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html>

<sup>276</sup> <https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html>

<sup>277</sup> <https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html>

<sup>278</sup> <https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html>

<sup>279</sup> <https://openpaymentsdata.cms.gov/physician/1081946/payment-information>

As for the yellow fever study, that vaccine is *not* a routine childhood vaccine in the U.S. and the resources for this study – especially when only two studies are being funded in three years – would have been far better spent assessing biomarkers for predicting which children are at increased risk of suffering injuries from childhood vaccines routinely used in the United States. For example, HHS could have financed studies seeking to identify biomarkers that would predict which children are likely to experience one or more of the following serious injuries that HHS concedes are caused by one or more routinely administered childhood vaccines: brachial neuritis, encephalopathy, encephalitis, chronic arthritis, thrombocytopenia, and Guillain- Barré syndrome.<sup>280</sup>

Between 2015 and 2017, HHS spent over \$14 billion purchasing and promoting the universal use of HHS recommended vaccines.<sup>281</sup> During this same time period, HHS certainly could and should have funded more than two studies seeking to identify which children should be excluded from receiving one or more vaccines in order to prevent a serious vaccine injury.<sup>282</sup> This research should also not be conducted by individuals who receive funding from the pharmaceutical company whose vaccine product is being reviewed.

## **VI. UNSUPPORTED CLAIM THAT “VACCINES DO NOT CAUSE AUTISM”**

HHS declares on its website that “Vaccines Do Not Cause Autism.”<sup>283</sup> Our letter therefore asked for the studies that HHS relies upon to make this claim.<sup>284</sup> HHS’s response, however, fails to provide a single study to support its claim that *none* of the vaccines given to children by one year of age cause autism.<sup>285</sup> HHS’s 2014 “comprehensive review” of vaccine safety even expressly stated it could not identify a single study to support that DTaP or Hepatitis B vaccines do not cause autism.<sup>286</sup> HHS nonetheless continues to contend that “vaccines do not cause autism” when its own “comprehensive review” concedes it cannot scientifically support this claim.

This section will first review the points made in our opening letter regarding vaccines and autism which HHS failed to address and then go through each of the five citations HHS provides to support its claim that “vaccines do not cause autism.”

---

<sup>280</sup> <https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf>

<sup>281</sup> <https://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf?language=es>

<sup>282</sup> <https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html>

<sup>283</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>; <https://www.hhs.gov/programs/topic-sites/autism/index.html>

<sup>284</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

<sup>285</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>286</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

### A. Vaccines-Autism Points from Opening Letter Unrebutted by HHS

As explained in our opening letter, HHS paid the IOM to conduct a review regarding whether, among other things, there is a causal relationship between autism and the DTaP vaccine.<sup>287</sup> In 2011, the IOM published its review and stated it could not locate a single study supporting that DTaP vaccine does not cause autism.<sup>288</sup> The IOM therefore concluded:

The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism.<sup>289</sup>

In fact, the only study the IOM could locate regarding whether DTaP vaccine causes autism concluded there *was* an association between DTaP and autism.<sup>290</sup>

Our opening letter further asserted that, like the DTaP vaccine, there are also no published studies showing that autism is not caused by vaccines for Hepatitis B, Rotavirus, Hib, Pneumococcal, Polio, Influenza, Varicella, or Hepatitis A – each of which HHS’s vaccine schedule recommends babies receive, typically multiple times, by six months of age.<sup>291</sup> HHS’s response fails to provide a single study to rebut the foregoing.

We further asserted that HHS has failed to address the science that does support a link between vaccines and autism.<sup>292</sup> We gave the example that HHS has not addressed a study which found a 300% increased rate of autism among newborns receiving the Hepatitis B vaccine at birth compared to those that did not.<sup>293</sup> Nor did HHS address two pilot studies recently published out of the School of Public Health at Jackson State University which showed vaccinated children had a 420% increased rate of autism compared to unvaccinated children, and vaccinated preterm babies had an even higher rate.<sup>294</sup> We also pointed out that there is a compelling body of science that supports a clear connection between aluminum adjuvants in vaccines and autism, even citing a complete write-up summarizing the studies supporting same.<sup>295</sup> Yet, HHS failed to directly or substantively address any of the foregoing.

---

<sup>287</sup> <https://www.nap.edu/read/13164/chapter/2#2>

<sup>288</sup> <https://www.nap.edu/read/13164/chapter/12#545>

<sup>289</sup> <https://www.nap.edu/read/13164/chapter/12#545>

<sup>290</sup> <https://www.nap.edu/read/13164/chapter/12#545> (Ironically, this study was discarded “because it provided data from a passive surveillance system [VAERS] and lacked an unvaccinated comparison population,” which is true of much of HHS’s “safety science.”)

<sup>291</sup> <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

<sup>292</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>293</sup> [http://hisunim.org.il/images/documents/scientific\\_literature/Gallagher\\_Goodman\\_HepB\\_2010.pdf](http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf)

<sup>294</sup> <http://www.oatext.com/pdf/JTS-3-186.pdf>; <http://www.oatext.com/pdf/JTS-3-187.pdf>

<sup>295</sup> <http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf>

Moreover, we asserted that HHS's claim that "Vaccines Do Not Cause Autism" improperly relies almost exclusively upon studies examining only one vaccine, MMR (administered no earlier than one year of age), or only one vaccine ingredient, thimerosal.<sup>296</sup> HHS's response, however, did not explain why studies that exclusively evaluated one vaccine or only one vaccine ingredient, while ignoring the balance of HHS's childhood vaccine schedule, support HHS's sweeping declaration that "Vaccines Do Not Cause Autism."

As for the one vaccine HHS claims it has studied with regard to autism, MMR, we pointed out that Senior CDC Scientist, Dr. William Thompson<sup>297</sup>, has provided a statement through his attorney that HHS "omitted statistically significant information" showing an association between the MMR vaccine and autism in the first and only MMR-autism study ever conducted by HHS with American children.<sup>298</sup> Dr. Thompson, in a recorded phone call, stated the following regarding concealing this association: "Oh my God, I can't believe we did what we did. But we did. It's all there. It's all there. I have handwritten notes."<sup>299</sup> Dr. Thompson further stated on that call:

I have great shame now when I meet families with kids with autism because I have been part of the problem ... the CDC is so paralyzed right now by anything related to autism. They're not doing what they should be doing because they're afraid to look for things that might be associated. So anyway there's still a lot of shame with that. ... I am completely ashamed of what I did.<sup>300</sup>

Hence, as for MMR, the only vaccine actually studied by HHS with regard to autism, it appears HHS may have concealed an association between that vaccine and autism.<sup>301</sup> HHS's letter completely ignores this serious allegation by one of its own senior scientists.

## **B. HHS's Citations Do Not Support that Vaccines Do Not Cause Autism**

Instead, HHS's response merely provides five links in response to our request for the studies supporting that pediatric vaccines do not cause autism. The content of these five links all directly reinforce and confirm the very concerns raised in our opening letter.

<sup>296</sup> <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>297</sup> Dr. Thompson has been a scientist at CDC for nearly two generations and a senior scientist on over a dozen CDC publications at the core of many of its vaccine safety claims. <https://www.ncbi.nlm.nih.gov/pubmed>

<sup>298</sup> <http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf>

<sup>299</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

<sup>300</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

<sup>301</sup> Studies of MMR and autism are also erroneous because of healthy user bias, which has been emphasized as a serious source of error in epidemiological vaccine safety studies by CDC scientists. <https://doi.org/10.1093/oxfordjournals.aje.a116479>

The *first* link is to a document entitled “Science Summary: CDC Studies on Thimerosal in Vaccines.”<sup>302</sup> The studies in this document are plainly insufficient to support the claim that “vaccines do not cause autism” as they at best only address whether thimerosal causes autism.

The *second* link is to an IOM report from 2004 entitled “Immunization Safety Review: Vaccines and Autism.”<sup>303</sup> This report also cannot support the CDC’s claim about all vaccines because it *only* addresses the MMR vaccine and thimerosal with regard to autism. It is nonetheless noteworthy that this report was issued before the admission by Dr. Thompson that the CDC concealed an association between the MMR vaccine and autism, and it is further noteworthy that even this review stated that the IOM “committee’s conclusion did not exclude the possibility that MMR could contribute to autism in a small number of children” and that “models for an association between MMR and autism were not ... disproved.”<sup>304</sup> But, again, this report is plainly insufficient to support the claim that “vaccines do not cause autism,” as it at best only addresses whether the MMR vaccine and thimerosal cause autism.

The *third* link is a study which only looks at one vaccine component – antigens – comparing ‘*vaccinated* children’ with ‘*vaccinated* children’ with different antigen exposure.<sup>305</sup> This study again says nothing about whether any particular vaccine or HHS’s childhood vaccine schedule causes autism. This study even concedes: “ASD with regression, in which children usually lose developmental skills during the second year of life, *could* be related to exposure in infancy, *including vaccines.*”<sup>306</sup>

This antigen exposure study could have compared children receiving no-antigens, meaning no vaccines, with children receiving vaccine antigens. That would finally provide real data. Instead, the study engages in yet another nonsensical whitewash review in which it compares vaccinated children with vaccinated children, with the only real difference typically being that some children received DTaP while others received DTP.<sup>307</sup> All vaccines on the CDC childhood schedule, including DTaP, have been estimated to have between 1 and 69 antigens per dose while the DTP vaccine, no longer used in the U.S., is estimated to have 3,002 antigens per dose.<sup>308</sup> Hence, to compare antigen exposure, this study simply looks at one group of almost entirely fully vaccinated children who received DTaP with another group of almost entirely fully vaccinated children who received DTP.

---

<sup>302</sup> <https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf>

<sup>303</sup> <http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx>

<sup>304</sup> <http://nationalacademies.org/hmd/reports/2004/immunization-safety-review-vaccines-and-autism.aspx>

<sup>305</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23545349>

<sup>306</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23545349> (emphasis added)

<sup>307</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23545349>

<sup>308</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23545349>

This study further admits the manner in which it counted “antigens” is not a valid measure of the actual immunogenicity of any given vaccine:

Admittedly, this approach assumes that all proteins and polysaccharides in a vaccine evoke equivalent immune responses, whereas some proteins actually may be more likely than others to stimulate an immune response. Moreover, the calculations do not take into account the number of epitopes per antigen or the immunologic strength of each epitope.<sup>309</sup>

In addition, HHS’s antigen study only included children vaccinated in the late 1990s, despite being published in 2013, by which time the following additional vaccines had already been added to HHS’s childhood vaccine schedule: PCV13, Influenza, Hepatitis A, Meningococcal, Tdap, and HPV.<sup>310</sup>

This study further ignores the fact that while “antigens” (as defined in the study) in vaccines have decreased since the late 1990s, the amount of aluminum adjuvant, a neuro-and-cyto-toxic immune stimulant, used in vaccines has significantly *increased*. Indeed, in 1983 there was one aluminum-adjuvanted vaccine on HHS’s vaccine schedule, in 1998 there were three (Hep B, DTaP, Hib<sup>311</sup>), and by 2018 the vaccine schedule included the following aluminum-adjuvanted vaccines: (1) Hep B, (2) DTaP, (3) Hib<sup>312</sup>, (4) PCV13, (5) Hep A, (6) Tdap, and (7) HPV (and newer vaccines contain large amounts of aluminum adjuvant).<sup>313</sup> Also, the amount of aluminum adjuvant from Hep B, DTaP and Hib vaccines has increased since the late 1990s.<sup>314</sup> For example, the product with the lowest amount of aluminum for DTaP (DTP) had approximately half the amount of aluminum in 1998 as it did in 2018, and the percent of children receiving these three vaccines has increased markedly since the 1990s.<sup>315</sup> The antigen study HHS cites not only ignores the increasing amount of aluminum adjuvant included in childhood vaccines since 1999, it studiously ignores (as discussed below) the compelling body of science implicating this rising amount of aluminum adjuvant in vaccines with causing neurological dysfunction and autism.<sup>316</sup>

But even putting all these limitations aside, this antigen study says nothing about whether any particular vaccine or group of vaccines cause autism, and, at best, relates to the

---

<sup>309</sup> <https://www.ncbi.nlm.nih.gov/pubmed/23545349>

<sup>310</sup> <https://www.cdc.gov/mmwr/preview/mmwrhtml/su6201a2.htm>; <https://www.ncbi.nlm.nih.gov/pubmed/23545349> (This study also excluded children with fragile X syndrome, and thus cannot address if vaccinating children with fragile X can cause autism.)

<sup>311</sup> In 1998, 1 out of 4 licensed Hib vaccines contained aluminum. Physicians’ Desk Reference, 1998, <http://www.pdr.net>

<sup>312</sup> In 2018, 1 out of 3 licensed Hib vaccines contained aluminum. Physicians’ Desk Reference, 2018, <http://www.pdr.net>

<sup>313</sup> <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg>; <https://www.cdc.gov/mmwr/preview/mmwrhtml/00056261.htm>; <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

<sup>314</sup> Compare 1998 and 2018 editions of the Physicians’ Desk Reference. <http://www.pdr.net>

<sup>315</sup> *Ibid.*; <https://www.cdc.gov/vaccines/imz-managers/coverage/childvaxview/data-reports/index.html>

<sup>316</sup> <http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf>

potential connection between antigen exposure and autism (albeit in a study that, in its best light, is unreliable).

The *fourth* link HHS cites is the very IOM review from 2011 cited in our opening letter.<sup>317</sup> However, as we noted in our letter, the IOM could not identify a single study which supports the claim that DTaP does not cause autism.<sup>318</sup> Even more astonishing, a different part of HHS's response letter cites the 2014 "comprehensive review" which again could not identify a single study to support the claim that DTaP does not cause autism.<sup>319</sup>

HHS's 2014 review also searched for studies that would support the claim that the Hepatitis B vaccine does not cause autism and also did not find a single study to support this claim.<sup>320</sup> In fact, even after using its strict selection criteria to toss 99% of all studies out of its review, it nevertheless resulted in the inclusion of a vaccine-autism study that was *not* funded by a pharmaceutical company reviewing its own vaccine.<sup>321</sup> This study, from the Stony Brook University Medical Center, found a 300% increased rate of autism among newborns receiving the Hepatitis B vaccine at birth compared to those who did not get this vaccine at birth.<sup>322</sup> The 2014 review summarizes the results of this study as follows:

Result was significant for the risk of autism in children who received their first dose of Hepatitis B vaccine during the first month of life (OR 3.00, 95% CI 1.11, 8.13), compared with those who received the vaccination after the first month of life or not at all.<sup>323</sup>

Having found one study that showed an association, and no studies to disprove this association, HHS's review did not claim that the Hepatitis B vaccine does not cause autism.<sup>324</sup> Rather, it concluded it does not know whether the Hepatitis B vaccine causes autism.<sup>325</sup> In short, the fourth link cited by HHS in fact proves, once again, that HHS cannot claim that vaccines do not cause autism.

The *fifth* (and final) link HHS cites in its letter is the "Strategic Plan for Autism Spectrum Disorder Research" by the Interagency Autism Coordinating Committee, which is part of HHS.<sup>326</sup> Remarkably, this 196 page strategic plan outlines dozens of research

---

<sup>317</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>318</sup> <http://nationalacademies.org/HMD/Reports/2011/adverse-effects-of-vaccines-evidence-and-causality.aspx>

<sup>319</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>320</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>321</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>322</sup> [http://hisunim.org.il/images/documents/scientific\\_literature/Gallagher\\_Goodman\\_HepB\\_2010.pdf](http://hisunim.org.il/images/documents/scientific_literature/Gallagher_Goodman_HepB_2010.pdf)

<sup>323</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>324</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>325</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>326</sup> [https://iacc.hhs.gov/publications/strategic-plan/2017/strategic\\_plan\\_2017.pdf](https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf)

priorities, but does not once mention closing the vaccine safety science gap regarding whether DTaP, Hepatitis B, and every other vaccine given by one year of age cause autism.<sup>327</sup>

The strategy plan even explains that “neuroinflammation” may cause autism, but ignores the fact that neuroinflammation (a.k.a., encephalitis or encephalopathy) is a known reaction to numerous vaccines. For example, encephalitis or encephalopathy are listed as adverse reactions in the package inserts for the following vaccines injected multiple times into babies during their first few months of life: DTaP (Infanrix, Daptacel), Hepatitis B (Recombivax-HB, Engerix -B) and combination vaccines (Pediarix, Pentacel).<sup>328</sup> The strategic plan also recognizes “immune dysregulation” – which again can be caused by vaccines – may cause autism.<sup>329</sup> It also explains that current science suggests “that ASD results from subtle alterations during brain development [including during the first year of life] that affect brain structure, function and connectivity,” which have been demonstrated to occur in lab animals following injection of comparable amounts of pediatric vaccines and/or aluminum adjuvants used in pediatric vaccines.<sup>330</sup>

This strategic plan even outlines numerous large scale studies looking at a plethora of environmental exposures, but apparently none of these include looking at the exposure to vaccines.<sup>331</sup> This is despite the fact that numerous peer-reviewed studies have found that, when surveyed, between 40% and 70% of autism parents squarely blame vaccines for their child’s autism.<sup>332</sup> It would be simple to review vaccine exposures along with the hundreds of other exposures already being reviewed in these studies, but for apparently political reasons, HHS has chosen not to address this issue.

### C. Vaccine-Autism Concerns Always Broader than MMR and Thimerosal

HHS directs all conversation regarding vaccines and autism toward MMR and thimerosal, despite longstanding concerns regarding the connection between autism and other vaccines and other vaccine ingredients.<sup>333</sup> For example, the concern that pertussis containing vaccines could cause immune and brain dysfunction, including autism, was identified as a research priority in the 1986 Act. Indeed, Congress, when passing the Act,

<sup>327</sup> [https://iacc.hhs.gov/publications/strategic-plan/2017/strategic\\_plan\\_2017.pdf](https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf)

<sup>328</sup> <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm124514.pdf>;

<https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm103037.pdf>;

<https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm110114.pdf>;

<https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf>;

<https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm241874.pdf>;

<https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm109810.pdf>

<sup>329</sup> <https://onlinelibrary.wiley.com/doi/book/10.1002/9781118663721>

<sup>330</sup> [https://iacc.hhs.gov/publications/strategic-plan/2017/strategic\\_plan\\_2017.pdf](https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf); <http://vaccine-safety.s3.amazonaws.com/WhitePaper-AlumAdjuvantAutism.pdf>

<sup>331</sup> [https://iacc.hhs.gov/publications/strategic-plan/2017/strategic\\_plan\\_2017.pdf](https://iacc.hhs.gov/publications/strategic-plan/2017/strategic_plan_2017.pdf)

<sup>332</sup> <https://www.ncbi.nlm.nih.gov/pubmed/16685182>; <https://www.ncbi.nlm.nih.gov/pubmed/25398603>; <https://www.ncbi.nlm.nih.gov/pubmed/16547798>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/>

<sup>333</sup> <https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf>

directed HHS to review the scientific evidence for whether pertussis containing vaccines can cause, among other conditions, autism.<sup>334</sup> As expressly provided in the 1986 Act:

Health and Human Services shall complete a review of all relevant medical and scientific information ... on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis ... and ... Autism<sup>335</sup>

Implementing the foregoing congressional directive, HHS commissioned the IOM in 1989 to identify any and all medical and scientific literature addressing whether pertussis-containing vaccines can cause autism.<sup>336</sup> The IOM conducted this review and issued its report in 1991.<sup>337</sup> While the IOM found at least some evidence bearing on causation for the 20 conditions other than autism it reviewed, the IOM could not find a single shred of evidence to support the claim that pertussis containing vaccines do not cause autism.<sup>338</sup> This is because no studies had been conducted to determine whether pertussis-containing vaccine cause autism. This is part of why the IOM's report in 1991 said:

In the course of its review, the committee found many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. ... If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.<sup>339</sup>

Yet when HHS commissioned the IOM twenty-two years later to assess the evidence bearing on whether pertussis containing vaccines cause autism – as this remained (per HHS) one of the most commonly claimed injuries from this vaccine – the IOM again in 2011 had the same conclusion:

The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.<sup>340</sup>

HHS itself reached this same conclusion again in its 2014 “comprehensive review.”<sup>341</sup> These reports show clearly that HHS has known for 27 years that it does not have the scientific

---

<sup>334</sup> <https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf>

<sup>335</sup> <https://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf>

<sup>336</sup> <https://www.nap.edu/read/1815/chapter/1#v>

<sup>337</sup> <https://www.nap.edu/read/1815/chapter/1>

<sup>338</sup> <https://www.nap.edu/read/1815/chapter/2#7>

<sup>339</sup> <https://www.nap.edu/read/1815/chapter/9>

<sup>340</sup> <https://www.nap.edu/read/13164/chapter/12?term=autism#545>

<sup>341</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

studies to support its claim that “vaccines do not cause autism,” and has willfully chosen to remain ignorant rather than test its *a priori* assumption that vaccines do not cause autism.<sup>342</sup>

#### D. HHS’s Refusal to Study Vaccines-Autism Connection is Troubling

HHS has even remained silent and refused to seriously study the vaccine-autism connection despite the fact that HHS’s leading autism expert, Dr. Andrew Zimmerman – an expert whom HHS relied upon in the *Cedillo v. HHS* case in Vaccine Court to claim that vaccines never cause autism – has changed his expert opinion.<sup>343</sup>

Dr. Zimmerman is a former Director of Medical Research at the Center for Autism and Related Disorders at the Kennedy Krieger Institute and Johns Hopkins University School of Medicine, and is regarded as the leading national authority on autism and mitochondrial disorder.<sup>344</sup> Dr. Zimmerman testified on November 9, 2016 that vaccines can in fact cause autism and even answered “Yes” when asked under oath: “Do other people in your field, reputable physicians in your field, hold the opinion that vaccines can cause the type of inflammatory response that can lead to a regressive autism?”<sup>345</sup> Dr. Zimmerman further testified that once HHS understands and accepts the causal relationship between vaccines and autism, “it will prevent the development of autism in quite a few children.”<sup>346</sup>

Dr. Zimmerman’s similarly credentialed colleague, Dr. Richard Kelley, also provided the following very revealing testimony in a deposition under oath:

*Lawyer: Do you agree with the statement that vaccines do not cause autism?*

Dr. Kelley: No

*Lawyer: Is it generally accepted in the medical community that vaccines do not cause autism?*

Dr. Kelley: It is a common opinion.

*Lawyer: It is generally accepted in the medical field that vaccines do not cause autism?*

Dr. Kelley: I have no basis to judge that. It is most often when physicians are commenting on that they say there is no proven association.

*Lawyer: Do you know the position of the American Academy of Pediatrics about any link between vaccines and autism?*

<sup>342</sup> [https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf\\_NBK230053.pdf](https://www.ncbi.nlm.nih.gov/books/NBK230053/pdf/Bookshelf_NBK230053.pdf)

<sup>343</sup> [https://childrenshealthdefense.org/child-health-topics/righting-wrongs/request-for-office-of-inspector-general-to-investigate-fraud-and-obstruction-of-justice/#\\_ftnref1](https://childrenshealthdefense.org/child-health-topics/righting-wrongs/request-for-office-of-inspector-general-to-investigate-fraud-and-obstruction-of-justice/#_ftnref1)

<sup>344</sup> <https://books.google.com/books?isbn=1603588256>

<sup>345</sup> <https://books.google.com/books?isbn=1603588256>

<sup>346</sup> <https://books.google.com/books?isbn=1603588256>

Dr. Kelley: Yes. They also say there is no proven association.

*Lawyer: Do you agree with the position of the American Academy of Pediatrics?*

Dr. Kelley: I agree with their position as a public health measure. I don't agree with it scientifically.

*Lawyer: You are actually arguing for a link between vaccines and autism in this case, aren't you?*

Dr. Kelley: I am.

*Lawyer: And that is contrary to the medical literature, isn't it?*

Dr. Kelley: It's not contrary to the medical literature that I read. It is contrary to certain published articles by very authoritative groups who say there is no proven association in large cohort studies.

*Lawyer: Your opinion is contrary to, say, the opinion of the CDC, correct?*

Dr. Kelley: It is contrary to their conclusion. It is not contrary to their data.<sup>347</sup>

The view apparently held by HHS that "public health" demands hiding any relationship between vaccines and autism to assure high vaccine uptake, is troubling. This view (i) ignores the fact that the real "public health" emergency in the United States is that 1 in 36 children are now diagnosed with autism<sup>348</sup>, (ii) stifles research into the association between vaccines on HHS's childhood vaccine schedule and autism, and (iii) forces HHS to ignore any science that does support a vaccine-autism connection.

Indeed, HHS appears frozen when confronted with replicated peer-reviewed studies, many of which were funded by HHS, regarding immune activation and aluminum adjuvants that support a causal relationship between the receipt of vaccines containing aluminum adjuvants and the development of autism in children.<sup>349</sup> Our opening letter attached letters to HHS from world-renowned experts on the toxicity of aluminum adjuvants, each of whom strongly supported the contention that aluminum adjuvants may have a role in the etiology of autism and cited the body of science that supports their assertion.<sup>350</sup> This science reflects that: injected aluminum adjuvant is taken-up by immune cells (macrophages) at the injection site; these aluminum-adjuvant-loaded immune cells then travel through the lymph vessels to, among other places, the brain; the immune cells then unload their aluminum adjuvant cargo in the brain; and aluminum adjuvant in the

---

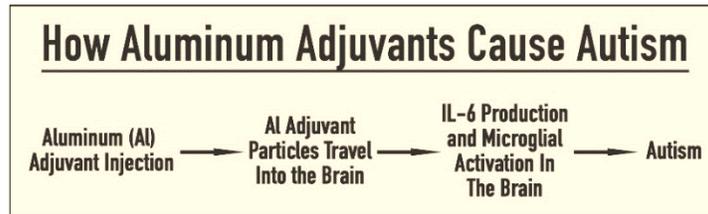
<sup>347</sup> <https://books.google.com/books?isbn=1603588256>

<sup>348</sup> <https://www.cdc.gov/nchs/data/databriefs/db291.pdf>

<sup>349</sup> <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf>

<sup>350</sup> <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf>

brain causes a release of interleukin IL-6 and microglial activation, leading to autism.<sup>351</sup>  
 Depicted in simple terms:



Despite years of vaccine safety advocacy demanding that HHS rebut, or at least address, the clear connection between aluminum adjuvant containing vaccines and autism, HHS appears unable to muster anything more than the public relations slogan – “Vaccines Do Not Cause Autism.”

On May 24, 2014, Dr. Thompson explained that the CDC is “paralyzed right now by anything related to autism ... because they’re afraid to look for things that might be associated.”<sup>352</sup> The reason for this fear may be that HHS has conceded or has been required by the Vaccine Court to pay financial compensation to at least a few dozen children where receipt of a vaccine on HHS’s childhood vaccine schedule resulted in brain, neurological and/or immune dysfunction diagnosed as autism.<sup>353</sup> The damage awards in some of these cases were in the millions of dollars.<sup>354</sup> If a single study conducted by HHS shows that even 1 in 5 cases of autism are caused, directly or indirectly, by vaccines, it would result in approximately \$1.3 trillion in liability.<sup>355</sup> Putting such potential liability into perspective, the entire federal budget in 2017 was \$3.3 trillion.<sup>356</sup> This and the decimation of HHS’s reputation if it were found that certain vaccines cause a significant fraction of autism cases, provide powerful incentives for HHS to *not* fund the basic scientific research needed to determine whether HHS’s childhood vaccine schedule is a cause of autism.

It is hard to imagine that HHS has not already internally used the databases at its disposal, such as VSD, to compare the autism rate between vaccinated and unvaccinated children. If the results showed no difference in the autism rates between these two groups of children, no doubt this study would have been published. The fact that it has not been published is very concerning. For example, HHS recently published a study using the VSD which compared vaccination rates between autistic and non-autistic children, but only looked at vaccination rates *after* an autism diagnosis.<sup>357</sup> It is hard to imagine that HHS also

<sup>351</sup> <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf>

<sup>352</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>

<sup>353</sup> <https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pehr>

<sup>354</sup> <https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pehr>

<sup>355</sup> Since approximately 3.5 million American children have autism spectrum disorder and the approximate life time cost per individual is \$1.9 million, total cost of care for just 20% of these individual is \$1.3 trillion. [www.autism-society.org/what-is/facts-and-statistics/](http://www.autism-society.org/what-is/facts-and-statistics/)

<sup>356</sup> <https://www.cbo.gov/publication/53624>

<sup>357</sup> <https://www.ncbi.nlm.nih.gov/pubmed/29582071>; <https://www.cnn.com/2018/03/26/health/vaccination-rates-children-autism-study/index.html> (lead author even concedes they “did not look at vaccination rates before the children were diagnosed with autism”)

did not internally review the vaccination rate *before* the autism diagnoses. Of course, if this comparison showed that fewer vaccines resulted in less autism, publishing such a result would call into serious doubt the competence of HHS in ensuring the safety of vaccines and its childhood vaccine schedule, as well as involve trillions of dollars in financial liability for the harm caused.

HHS's approach to this issue ignores the tens of thousands of families across this country that have attested – often in videos available online – that their best judgment based on the totality of their parental experience with their child is that vaccination caused their child's autism. Numerous peer-reviewed studies have found that, when surveyed, between 40% and 70% of autism parents squarely blame vaccines for their child's autism.<sup>358</sup> Many of these surveys explain how parents express a clear personal experience with vaccination affirming this conclusion.<sup>359</sup>

The Vaccine Information Statement (VIS) produced by HHS for every vaccine, including for DTaP, provides that other relevant information regarding the vaccine is available at the CDC website, [www.cdc.gov](http://www.cdc.gov), which in turn claims that “Vaccines Do Not Cause Autism.”<sup>360</sup> Because HHS has chosen to incorporate the CDC's website into the VIS as a resource, the information on that website regarding the relevant vaccine must, under federal law, be “based on available data and information.”<sup>361</sup> But, based on available data and information, as discussed above, HHS cannot scientifically claim that “Vaccines Do Not Cause Autism.” HHS must therefore remove this claim from the CDC website until it can produce the studies to support the claim that vaccines do not cause autism.

## **VII. HHS REFUSAL TO CONDUCT VACCINATED V. UNVACCINATED STUDY**

In our letter, we asked that HHS advise whether it will “conduct adequately powered and controlled prospective as well as retrospective studies comparing total health outcomes of fully/partially vaccinated with completely unvaccinated children?”<sup>362</sup> HHS has failed to actually respond to this question.

### **A. IOM 2013 Review Highlights Need for Vaccinated v. Unvaccinated Study**

HHS's response letter first cites the very same 2013 report by the IOM which we cited in our opening.<sup>363</sup> We cited this report because it clearly supports the need for a properly

<sup>358</sup> <https://www.ncbi.nlm.nih.gov/pubmed/16685182>; <https://www.ncbi.nlm.nih.gov/pubmed/25398603>; <https://www.ncbi.nlm.nih.gov/pubmed/16547798>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/>

<sup>359</sup> <https://www.ncbi.nlm.nih.gov/pubmed/16685182>; <https://www.ncbi.nlm.nih.gov/pubmed/25398603>; <https://www.ncbi.nlm.nih.gov/pubmed/16547798>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448378/>

<sup>360</sup> <https://www.cdc.gov/vaccines/hcp/vis/current-vis.html>; <https://www.cdc.gov/vaccinesafety/concerns/autism.html>

<sup>361</sup> 42 U.S.C. § 300aa-26

<sup>362</sup> Compare <http://icandecide.org/hhs/vaccine-safety-10-12-17.pdf> with <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>363</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

powered and controlled prospective study evaluating the health outcomes between vaccinated vs. unvaccinated children.<sup>364</sup> Indeed, HHS commissioned this review to assess the safety of HHS's early childhood vaccine schedule and hence, as explained by the IOM, its "literature searches and review were intended to identify health outcomes associated with some aspect of the childhood immunization schedule."<sup>365</sup> "Allergy and asthma, autoimmunity, autism, other neurodevelopmental disorders (e.g., learning disabilities, tics, behavioral disorders, and intellectual disability), seizures, and epilepsy were included as search terms."<sup>366</sup>

However, instead of answers, the IOM found that no studies had ever been conducted which compared the health outcomes of children receiving HHS's childhood vaccine schedule with children that had not been vaccinated:

[F]ew studies have comprehensively assessed the association between the entire immunization schedule or variations in the overall schedule and categories of health outcomes, and no study ... compared the differences in health outcomes ... between entirely unimmunized populations of children and fully immunized children. Experts who addressed the committee pointed not to a body of evidence that had been overlooked but rather to the fact that existing research has not been designed to test the entire immunization schedule. ...

[Also,] studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted.<sup>367</sup>

Even when the IOM committee expanded its search for any evidence that could help it assess the safety of HHS's childhood vaccine schedule, it stated that it "found a paucity of information, scientific or otherwise, that addressed the risk of adverse events in association with the complete recommended immunization schedule."<sup>368</sup>

Due to the lack of science regarding the safety of HHS's vaccine schedule, the best the IOM could do was conclude: "There is no evidence that the schedule is not safe."<sup>369</sup> Left unsaid, but equally true: **there is no evidence that the schedule is safe.** That HHS finds the IOM's conclusion acceptable is troubling and another clear dereliction of its vaccine safety

---

<sup>364</sup> <https://www.nap.edu/read/13563/chapter/1>

<sup>365</sup> <https://www.nap.edu/read/13563/chapter/2#5>

<sup>366</sup> <https://www.nap.edu/read/13563/chapter/2#5>

<sup>367</sup> <https://www.nap.edu/read/13563/chapter/2#5>

<sup>368</sup> <https://www.nap.edu/read/13563/chapter/6?term=paucity#70>

<sup>369</sup> <https://www.nap.edu/read/13563/chapter/2#12>

duties. Just because HHS refuses to conduct the scientific studies necessary to establish if there is harm does not mean that no harm exists.

Equally troubling is that despite acute adverse events such as persistent crying or extreme lethargy in recently vaccinated babies that can last for days, the IOM acknowledges that science does not yet even know “if there is a relationship between short-term adverse events following vaccination and long-term health issues.”<sup>370</sup> Without properly-controlled prospective long-term studies it is not possible to know whether acute vaccine reactions, including the more serious ones like brain inflammation and encephalitis, are causing long-term neurological damage (that takes the form of, for example, increasingly common developmental delays and behavioral disorders).

It is therefore remarkable that HHS cites the IOM report from 2013 as support for *not* conducting a longer-term properly powered and controlled study that would finally compare all health outcomes in vaccinated and unvaccinated children.

#### **B. HHS’s Desperation to Avoid Any Valid Vaccinated v. Unvaccinated Study**

Hiding behind a claim that it would be unethical to conduct such a study is also without merit. Putting aside that it is unethical for HHS to continue promoting its childhood vaccine schedule as proven safe when HHS lacks the scientific studies necessary to validate the safety of its childhood vaccine schedule, there are ways to “ethically” conduct a vaccinated versus unvaccinated study. As we pointed out in our opening letter, the very IOM report from 2013 asserts it “is possible to make this comparison [between vaccinated and unvaccinated children] through analyses of patient information contained in large databases such as VSD.”<sup>371</sup>

In response, HHS has not published this study. Given the numerous studies HHS publishes each year using the VSD, it is difficult to imagine that if such a study showed no health differences or that vaccinated children were healthier than unvaccinated children, HHS would not have already published that study.

Tellingly, instead of using the VSD to publish the relatively simple study comparing health outcomes between vaccinated and unvaccinated children, HHS instead spent a tremendous amount of resources to publish a 64-page white paper regarding conducting such studies using the VSD.<sup>372</sup>

---

<sup>370</sup> <https://www.nap.edu/read/13563/chapter/5#45>

<sup>371</sup> <https://www.nap.edu/read/13563/chapter/2#13>

<sup>372</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

This white paper, prominently cited by HHS in its response letter, acknowledges that many chronic disorders children are experiencing today in epidemic numbers are biologically plausible outcomes from exposure to HHS's pediatric vaccination schedule but have not yet been properly studied.<sup>373</sup> While we should be encouraged by such an open admission, the white paper is revealing regarding HHS's approach to vaccine safety.

#### i. White Paper Guided by Pharmaceutical Company Insiders

First, this white paper was guided by pharmaceutical company insiders. As the white paper authors explain:

Guided by subject matter expert engagement, we outlined a 4 staged approach for identifying exposure groups of undervaccinated children, developed a list of 20 prioritized outcomes, and described various study designs and statistical methods that could be used to assess the safety of the schedule.<sup>374</sup>

The subject matter experts relied upon to draft the white paper had serious financial and other conflicts of interest. For example, the first subject matter expert listed is Dr. Stanley Plotkin.<sup>375</sup> Dr. Plotkin earned millions of dollars in employment, consulting, and royalties from Merck, GSK, Sanofi and Pfizer (which, combined, manufacture nearly every vaccine on HHS's childhood vaccine schedule) including serving on the boards of the following for-profit pharmaceutical companies involved in vaccine development (while working on the white paper): Dynavax Technologies, VBI Vaccines, Mymetics, Inovio Biomedical Corp, CureVacAG, SynVaccine, GeoVax Labs, GlycoVaxyn AG, Adjuvance Technologies, BioNet Asia, Adcombia Biosciences, and Hookipia Biotech.<sup>376</sup> Three of the four other subject matter experts involved in creating the white paper were similarly conflicted.<sup>377</sup>

---

<sup>373</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>374</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>375</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>376</sup> <https://openpaymentsdata.cms.gov/physician/510771/summary>; <http://www.vaxconsult.com/cv-page/>; <https://patents.google.com/patent/US6290968B1/en>; <https://www.royaltypharma.com/royalty-pharma-acquires-royalty-interest-in-rotateq-from-the-childrens-hospital-foundation-for-182-million>; <http://people.equilar.com/bio/stanley-plotkin-dynavax-technologies/salary/91882>; <https://www.vbivaccines.com/about/scientific-advisory-board/>; <https://globenewswire.com/news-release/2009/09/09/404297/172906/en/Mymetics-Corporation-Announces-the-Appointment-of-Dr-Stanley-Plotkin-as-Chairman-of-the-Scientific-Advisory-Board-and-Election-of-New-Members.html>; <https://www.acommanagementpartners.com/news-events/client-news/post/1713/vaccine-pioneer-joins-inovio-biomedicals-scientific-advisory-board/>; <http://www.curevac.com/company/scientific-advisory-board/>; <https://www.synvaccine.com/about2>; <https://finance.yahoo.com/news/geovax-reports-2017-first-quarter-130000205.html>; <http://www.bionity.com/en/news/107511/glycovaxyn-ag-appoints-dr-stanley-plotkin-to-supervisory-board.html>; <http://adjuvancetechnologies.com/management-team/>; <http://www.jkdaily.com/articles/2628/20160322/asian-biotech.htm>; <http://www.abcombibio.com/advisors>; <http://hookipabiotech.com>

<sup>377</sup> Walter A. Orenstein: <https://www.ncbi.nlm.nih.gov/pubmed/18589064>; <https://www.ncbi.nlm.nih.gov/pubmed/16533116>. Edgar K. Marcuse: <https://www.ncbi.nlm.nih.gov/pubmed/10432034>. M. Alan Brookhart: <https://www.ncbi.nlm.nih.gov/pubmed/28370957>.

Despite the foregoing, the authors of the white paper state that the “White Paper study team had no conflicts of interest to declare.”<sup>378</sup>

The subject matter experts even gathered for a closed-door meeting with HHS to craft the white paper in Atlanta, Georgia in February 2014. Yet, the HHS authors excluded parents and parent organizations concerned about vaccine safety, admitting that the white paper study team “did not engage any parents or parental groups throughout the process.”<sup>379</sup>

Bias is evident in the first paragraph of the white paper. Instead of stating its goal is to assess the actual safety of the vaccine schedule, the authors assert that “Maintaining high vaccination coverage within the population is critical” and that the enemy of this goal is “concern about the safety of vaccines,” and in particular “the safety of vaccines given to young children.”<sup>380</sup>

HHS even falsely asserts, more than once, that the 2013 IOM report concluded that “the current U.S. immunization schedule was safe,” when it actually concluded: “There is no evidence that the schedule is not safe.”<sup>381</sup> Ironically, it is precisely because of the lack of evidence to support safety that the IOM “highlighted four research questions of highest priority,” with the first being “how do child health outcomes compare between fully vaccinated and unvaccinated children.”<sup>382</sup>

## ii. White Paper Expertly Designed to Support Status Quo

HHS was thus forced into a corner by the very report it commissioned from IOM. It now had to answer “how do child health outcomes compare between fully vaccinated and unvaccinated children.”<sup>383</sup> But, the HHS officials and pharmaceutical company representatives who created this white paper are plainly concerned about revealing the health outcome differences between vaccinated and unvaccinated children. The authors dissuade such a comparison and suggest study parameters that would, among other things, result in eliminating the healthiest nonvaccinated subjects from any study.

A vaccinated versus unvaccinated study to assess the safety of HHS’s childhood vaccine schedule should be straightforward. Such a study should compare the incidence of all adverse health conditions (ICD-9/10 codes) in vaccinated and unvaccinated children.

---

<sup>378</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>379</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>380</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf) (The white paper also asserts that “new knowledge generated about adverse events” should be used by “policy makers when weighing all available evidence about the benefits and risks of vaccination,” when it should have said that this knowledge should be used to reduce/eliminate the risk of any identified adverse reaction.)

<sup>381</sup> <https://www.nap.edu/read/13563/chapter/2#12>

<sup>382</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>383</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

Instead, the white paper only puts forth a handful of carefully culled conditions. It does this by first limiting its list to conditions that HHS and the pharmaceutical industry have previously studied.<sup>384</sup> Meaning, their prior bias was already built into the white paper's initial limited list of only 75 conditions.<sup>385</sup>

The authors then discarded those health conditions they deemed lacked "biological and mechanistic plausibility" with vaccination.<sup>386</sup> A lack of available biological and mechanistic studies is one of the major problems the IOM has complained about for decades. Removing outcomes because available science was lacking defeated the purpose of the exercise. Even so, this winnowing process resulted in a list of 43 adverse outcomes admitted by the subject matter experts to be plausibly caused by HHS's childhood vaccine schedule – a surprising admission given HHS's assurance that vaccine safety had already been established.<sup>387</sup> These 43 outcomes included autism spectrum disorder, attention deficit disorder, and numerous other neurological and immunological disorders.<sup>388</sup> Despite finding that all 43 of these outcomes were "plausible to study relative to the childhood immunization schedule," this list was nonetheless winnowed down to 20 conditions.<sup>389</sup> For example, autism was removed based on the demonstrably untrue claim it had "been extensively studied relative to the vaccination schedule."<sup>390</sup>

A comparison of all conditions between vaccinated and fully unvaccinated children, as directed by the IOM, is what should be conducted. Among other reasons, as HHS should be aware, vaccination can cause a spectrum of unexpected adverse effects.

For example, a recent study out of the University of Hong Kong, Queen Mary Hospital, and Centre for Influenza Research compared children receiving the influenza vaccine with those receiving a saline injection in a prospective randomized double-blind study.<sup>391</sup> Both groups had a statistically similar rate of influenza, but the group receiving the influenza vaccine had a statistically significant 440% increase in the rate of non-influenza infections.<sup>392</sup> Thus, the influenza vaccine increased children's susceptibility to other respiratory viral infections.

As another example, Dr. Peter Aaby is renowned for studying and promoting vaccines in Africa and has published over 300 peer-reviewed articles and studies regarding

---

<sup>384</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>385</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>386</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>387</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>388</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>389</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>390</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>391</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>392</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

vaccination.<sup>393</sup> In 2017, he and co-authors published a study finding that infants were 10 times more likely to die by 6 months of age following their DTP vaccination than those that did not receive any vaccines during the first 6 months of life.<sup>394</sup> Children vaccinated with DTP were dying from causes never associated with this vaccine, such as respiratory infections, diarrhea, and malaria.<sup>395</sup> This indicated that while DTP's purpose is to reduce the incidence of diphtheria, tetanus, and pertussis, it actually increased mortality from other infections.<sup>396</sup> The study therefore concludes:

All currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis.<sup>397</sup>

Perhaps most concerning is that the above study was based on data from the 1980s that had been collecting dust for over 30 years.<sup>398</sup> This begs the question: what other serious vaccine injuries and non-specific adverse effects are being missed by neglecting to conduct desperately needed vaccine safety science comparing vaccinated and unvaccinated children.

Consider that there are over 420 disorders listed on package inserts of vaccines routinely administered to babies and children – a large portion of which are immune and nervous system disorders – which are *only* listed there because its manufacturer has a basis to believe there is a causal relationship between the vaccine and the occurrence of the adverse event.<sup>399</sup> Federal law is clear that this list should include “*only* those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.”<sup>400</sup> Nonetheless, the white paper guides researchers to ignore every adverse health condition that develops following vaccination other than the 20 hand-picked conditions culled by HHS and pharmaceutical company insiders.

### iii. White Paper Guides Researchers to Exclude Unvaccinated Children

The white paper then – in contravention to the primary directive of the IOM to compare health outcomes between *vaccinated* with *unvaccinated* children – advocates for comparing *vaccinated* with *vaccinated* children.<sup>401</sup> It begins by arguing that “Comparing fully vaccinated children to totally unvaccinated children would likely be highly confounded”

<sup>393</sup> <https://www.ncbi.nlm.nih.gov/pubmed/?term=PETER+AABY%5BAuthor+-+Full%5D>

<sup>394</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>

<sup>395</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>

<sup>396</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>

<sup>397</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>

<sup>398</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>

<sup>399</sup> 21 C.F.R. 201.57; <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>

<sup>400</sup> 21 C.F.R. 201.57

<sup>401</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

and, in numerous ways, derides conducting such a comparison.<sup>402</sup> The white paper then guides researchers to compare the health outcomes between fully vaccinated children and partially vaccinated children (which are typically also almost fully vaccinated).<sup>403</sup> But this is precisely the comparison that would be “highly confounded” because children are often only partially vaccinated because parents who stop vaccinating their children (and hence have partially vaccinated children) often do so because of a negative health outcome following a previous vaccination.<sup>404</sup> HHS and authors of the white paper are aware of this bias. As the authors of the white paper admit:

Parents may alter their intended immunization schedules for a child who experiences a negative health outcome, particularly if the outcome is perceived to be a result of a vaccine.<sup>405</sup>

This means that the partially vaccinated children in the VSD may be sicker than the fully vaccinated children precisely because of their prior vaccinations. It is therefore a comparison of vaccinated with partially vaccinated children that is actually “highly confounded,” but yet precisely the type of comparison the white paper strongly recommends. Such a comparison is also nonsensical since it will not answer the outstanding scientific questions that urgently need to be answered regarding the safety of HHS’s childhood vaccine schedule.

#### iv. White Paper Guides Researchers How to Obtain Desired Results

If, despite the above recommendation not to do so, a researcher does conduct a vaccinated versus unvaccinated study, the white paper guides the researcher to use certain “adjustments” to control the study’s outcome.

First, the white paper suggests that researchers “exclude unvaccinated children who had fewer than four outpatient visits during the first two years of life.”<sup>406</sup> The purported reason for this “adjustment” is to ensure that children in the VSD with no recorded vaccination are actually unvaccinated. But, this “adjustment” is unnecessary because, as the authors of the white paper admit, many VSD sites already link to their state’s centralized electronic immunization information system which tracks the vaccination status of every child in the state.<sup>407</sup> (Moreover, the authors of the white paper also admit that a “medical record review” revealed that the vaccination status was accurate for 94% of children when

---

<sup>402</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>403</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>404</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>405</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>406</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf) (emphasis added)

<sup>407</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

they had at least one V-code for vaccine refusal and that in the VSD, “1,898 (0.6%) [children] had no vaccines and at least one V-code for vaccine refusal.”<sup>408</sup>)

The transparent reason for excluding unvaccinated children who do not have at least four outpatient visits is to exclude most or all of the very healthy unvaccinated children from the study.

HHS learned the importance of excluding children without outpatient visits from its experience in a prior study in which it found “a positive association between Hib and Hep B vaccination and the incidence of asthma.”<sup>409</sup> If this result stood, it could have meant both loss of reputation for HHS and trillions of dollars of financial liability. To eliminate the association between vaccination and asthma, HHS first excluded children without at least one outpatient visit.<sup>410</sup> But when the association remained, HHS then excluded children without “at least two outpatient visits.”<sup>411</sup> The result was that the positive finding was no longer statistically significant and a loss of reputation and trillions of dollars in liability was avoided. The white paper therefore advised that researchers restrict “their study populations to children with a minimum amount of health care utilization,” such as excluding “unvaccinated children who had fewer than four outpatient visits.”<sup>412</sup> Employing this adjustment, a researcher can make almost any safety signal disappear.

In case the above is not sufficient to eliminate a vaccine safety signal, the authors of the white paper created another escape hatch. Vaccine researchers are advised to include another supposed non-vaccine-related condition in each study as a “control” outcome, and if the incidence rate of the control condition is different in vaccinated and unvaccinated children, the study can be considered confounded and discarded.<sup>413</sup> On the surface, this approach seems sensible. However, the control conditions that the authors of the white paper suggest, such as well-child visits, are clearly related to vaccination rates.

Unvaccinated children often do not regularly go to well-child doctor visits because the major reason for these visits is vaccination; in fact, when they do, one-fifth of pediatricians report dismissing these families from their practice for refusing or requesting to delay one or more vaccines.<sup>414</sup> Hence, this control condition will likely yield a different incidence rate between vaccinated and unvaccinated children, providing the researchers

---

<sup>408</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>409</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>410</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>411</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>412</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>413</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>414</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26527552>

with a reason to discard the study.<sup>415</sup> The “controls” suggested by the authors of the white paper are an apparent “insurance” to permit researchers, if the other “adjustments” they suggest do not work, to discard any study that produces concerning results about adverse health outcomes between vaccinated and unvaccinated children.

In summary, the white paper promotes the use of inappropriate study designs that will result in highly compromised studies. The authors appear dedicated to finding a desired result rather than letting the data speak for itself. They do this by narrowing studies to 20 outcome conditions, emphasizing vaccinated vs. vaccinated studies, and claiming vaccinated vs. unvaccinated studies are “highly confounded” and hence, if conducted, require adjustments to exclude healthy unvaccinated children and otherwise a “control” that permits discarding any finding that does not affirm the safety of HHS’s childhood schedule.

The results-oriented nature of the white paper makes sense when considering it originates from HHS’s Immunization Safety Office, which assists in defeating vaccine injury claims in Vaccine Court. It is plainly conflicted from providing guidance regarding or conducting this or any other vaccine safety study. If HHS really cared about vaccine safety, federal health officials would be requiring and advocating for adherence to the gold standard in scientific research – double-blind long-term placebo-controlled studies during pre-licensure trials, and straightforward vaccinated vs. unvaccinated cohort studies as a follow-up. There is little excuse for not conducting these types of studies when there are already hundreds of thousands of completely unvaccinated children in America, including over 50,000 completely unvaccinated 2-year old children.<sup>416</sup>

Moreover, HHS claims in its letter that the white paper states that the “CDC has started conducting some of the studies mentioned in the white paper.”<sup>417</sup> The white paper, however, contains no such claim.<sup>418</sup> Nonetheless, if true, it is troubling that this study is being undertaken by HHS’s Immunization Safety Office which assists in defending against vaccine injury claims and is headed by Dr. Frank DeStefano, who is accused by his fellow CDC senior scientist of fraudulently modifying results of prior vaccine studies, including to avoid liability for HHS in Vaccine Court.<sup>419</sup> To be reliable, any vaccinated vs. unvaccinated study must be conducted by individuals completely independent of HHS and otherwise completely impartial. Nobody at HHS can impartially conduct a vaccine safety study because a finding that childhood vaccines cause any serious harm would result in serious

---

<sup>415</sup> The white paper also suggests “minor injuries” as a control because “[t]here is no plausible biologic pathway by which vaccines could cause these minor injuries”; but if vaccination causes neurological disorders which render children more prone to injury, vaccinated children would have a higher rate of minor injuries. [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>416</sup> <https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm>

<sup>417</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>418</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>419</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>; <http://www.rescuepost.com/files/william-thompson-statement-27-aug-ust-2014-3.pdf>

reputational harm to HHS, would conflict with its mission to assure high vaccine uptake, and would be used as evidence against HHS in Vaccine Court where HHS is charged to defend against claims of vaccine injury.

This concern is even more acute given that HHS really does not know the actual safety profile of each childhood vaccine nor its childhood vaccine schedule. As HHS acknowledges in its white paper: “the field of vaccine schedule safety is in its infancy.”<sup>420</sup>

### C. HHS’s Bias Leaves It Unable to See Glaring Safety Signals

HHS then states that “should signals arise that there may be a need for investigation,” HHS would then conduct an appropriate vaccinated vs unvaccinated study.<sup>421</sup> Let us provide HHS with a few such signals.

A very bright vaccine safety signal is the fact that HHS knows that less than 1% of adverse events occurring after vaccination are reported to VAERS and HHS knows that there were 261,294 adverse vaccine events reported to VAERS in the last five years.<sup>422</sup>

The following finding from the School of Public Health at Jackson State University is another bright flashing vaccine safety signal: 33% of vaccinated preterm babies had a neurodevelopmental disorder while 0% of the unvaccinated preterm babies had a neurodevelopmental disorder; and another pilot study by the same group found that vaccinated children, compared to unvaccinated children (receiving no vaccines), had an increased risk of 390% for allergies, 420% for ADHD, 420% for autism, 290% for eczema, 520% for learning disabilities, and 370% for any neuro-developmental delay.<sup>423</sup>

Another clear vaccine safety signal is the body of replicated peer-reviewed studies evidencing that that aluminum adjuvant in vaccines injected into the muscle tissue of lab animals are phagocytized by macrophages, transported to their brains and cause neurological impairments.<sup>424</sup>

---

<sup>420</sup> <https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm>

<sup>421</sup> <http://icandecide.org/hhs/vaccine-safety-1-29-18.pdf>

<sup>422</sup> <https://wonder.cdc.gov/vaers.html>

<sup>423</sup> <http://www.oatext.com/pdf/IJS-3-186.pdf>; <http://www.oatext.com/pdf/IJS-3-187.pdf>

<sup>424</sup> <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf>. Macrophages phagocytize (ingest) aluminum adjuvant (AA): <https://www.ncbi.nlm.nih.gov/pubmed/15297065>; <https://www.ncbi.nlm.nih.gov/pubmed/18496530>. Macrophages transport material into the brain: <https://www.ncbi.nlm.nih.gov/pubmed/27213597>; <https://www.ncbi.nlm.nih.gov/pubmed/21348773>; <https://www.ncbi.nlm.nih.gov/pubmed/27115998>; <https://www.ncbi.nlm.nih.gov/pubmed/27213597>. AA transport to brain: <https://www.ncbi.nlm.nih.gov/pubmed/26384437>; <https://www.ncbi.nlm.nih.gov/pubmed/27908630>; <https://www.ncbi.nlm.nih.gov/pubmed/23557144>. AA causes neuro impairment: <https://www.ncbi.nlm.nih.gov/pubmed/27908630>; <https://www.ncbi.nlm.nih.gov/pubmed/19740540>; <https://www.ncbi.nlm.nih.gov/pubmed/23932735>. Macrophages infiltrate the brain in autism: <https://www.ncbi.nlm.nih.gov/pubmed/16401547>; <https://www.ncbi.nlm.nih.gov/pubmed/15546155>; <https://www.ncbi.nlm.nih.gov/pubmed/28167942>; <https://www.ncbi.nlm.nih.gov/pubmed/24951035>.

Another vaccine safety signal is that clinical trials comparing health outcomes in two vaccinated groups typically find that both groups have significant rates of serious adverse events which exceed what would be expected in the general population.<sup>425</sup> The fact that no HHS licensed vaccine, save one, has been safety tested for use in children in a placebo-controlled trial prior to licensure makes each of these safety signals burn even brighter.<sup>426</sup>

The greatest vaccine safety signal may be the ever-growing percentage of Americans refusing to vaccinate their children. According to HHS, between 2001 and 2017 the number of completely unvaccinated two-year-old children in America has increased by 433%.<sup>427</sup> One in 77 two-year old American children are now completely unvaccinated and 1 in 2 children skip one or more vaccines on HHS's childhood vaccine schedule.<sup>428</sup> This growth has occurred despite stricter vaccination laws and access to free vaccinations for lower income populations.

Parents declining one or more HHS recommended vaccinations for their children often have concerns about vaccine safety because they themselves, their children, or someone else close to them, has had a personal experience with a life-altering adverse event following vaccination.<sup>429</sup> Parents who make this informed choice, as HHS admits, are typically well-educated, and do so in the face of social stigma and exclusion; hence, they often never make this decision lightly, but rather after careful research or a personal experience with vaccine injury.<sup>430</sup>

The stated purpose of vaccination is to improve the overall quality of health of Americans and reduce mortality. Yet, the increase in HHS's childhood vaccine schedule over the last 30 years from 8 vaccine injections<sup>431</sup> to 50 vaccine injections<sup>432</sup> (plus 2 injections during pregnancy<sup>433</sup>) has occurred in lockstep with the increase in the rate of autoimmune, developmental and neurological disorders in children from 12.8% to 54%.<sup>434</sup> HHS has no explanation for why U.S. children today are plagued with a chronic disease and disability epidemic.

---

<sup>425</sup> For examples see Sections I and IV above.

<sup>426</sup> See Section I above.

<sup>427</sup> <https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm>

<sup>428</sup> <https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a4.htm>; <https://stacks.cdc.gov/view/cdc/59415>

<sup>429</sup> <https://www.ncbi.nlm.nih.gov/pubmed/25200366>

<sup>430</sup> <https://www.ncbi.nlm.nih.gov/pubmed/18816357>; <https://www.ncbi.nlm.nih.gov/pubmed/28578210>; <https://www.cnn.com/2015/02/03/health/the-unvaccinated/index.html>

<sup>431</sup> <https://www.cdc.gov/vaccines/schedules/images/schedule1989s.jpg> (OPV is given orally)

<sup>432</sup> <https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html#schedule> (Rotavirus is given orally. Assumes 4-dose Hib series, 3-dose HPV series, and no combination vaccines; but even with combination vaccines still have a total of 40 injections.)

<sup>433</sup> <https://www.cdc.gov/vaccines/pregnancy/downloads/immunizations-preg-chart.pdf>

<sup>434</sup> Compare <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg> with <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

This as yet unexplained explosion in chronic disease and disability among American children, which coincides with the rapid increase in the numbers of vaccinations given to infants and children in the first six years of life, is a neon vaccine safety signal that demands methodologically sound studies to rule out vaccines or the HHS childhood vaccine schedule as a contributing cause. It is accepted science that adverse responses to vaccination can lead to certain chronic disorders, including autoimmune, developmental and neurological disorders – it is only the rate at which this occurs that is either disputed or admittedly unknown.<sup>435</sup> Given that the incidence of chronic diseases and disabilities is at an all-time high among children, especially among babies born healthy who then regress into chronic poor health in early childhood, it is high time to determine if vaccination is a contributing factor for this decline in overall childhood health.

HHS's response fails to provide evidence that these chronic diseases and disabilities are not caused by vaccination. If HHS does not know, then HHS cannot assess whether its childhood vaccine schedule – which produces a financial windfall to pharmaceutical companies<sup>436</sup> and the HHS agencies and employees that receive royalties from childhood vaccine sales<sup>437</sup> – is causing more harm than good. As discussed above, the flawed clinical trials that HHS relies upon to license vaccines are incapable of scientifically determining whether vaccines cause any of the chronic illnesses and developmental disorders that have steadily risen among American children during the past three decades. Despite this gap in safety, and despite the growing chorus of vaccine harm from parents – which is a major reason vaccine rates are declining – HHS defiantly continues to claim there are no vaccine safety signals.

Doctors have long been trained to listen to their patients, and studies have repeatedly shown that parents are the best source of information about their children and provide highly accurate information for detecting symptoms of and addressing developmental and behavioral problems.<sup>438</sup> HHS should take heed of this age-old wisdom and listen to the growing number of parents who, as the vaccine schedule has expanded, have reported that they observed their children regress into poor health after vaccination, including losing

---

<sup>435</sup> Among other sources: <https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf>; <https://www.nap.edu/read/1815/chapter/2#7>; <https://www.nap.edu/read/2138/chapter/2#11>; <https://www.nap.edu/read/13164/chapter/2#2>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5360569/>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/>; children must “prove that the vaccine was the cause” for all off-Table vaccine injuries, <https://www.ncbi.nlm.nih.gov/nlmcatalog/101633437>, 98% of vaccine injury claims are off-Table, <http://www.gao.gov/assets/670/667136.pdf>, and partial database of off-Table vaccine injury awards, <https://www.uscfc.uscourts.gov/aggregator/sources/7>; see studies compiled in this white paper: <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf>; conditions listed in Appendix B are reported in one or more pediatric vaccine package inserts, <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>, because, as required by federal law, there is a “basis to believe there is a causal relationship between the drug and the occurrence of the adverse event,” 21 C.F.R. 201.57.

<sup>436</sup> <https://investors.pfizer.com/financials/annual-reports/default.aspx>; <https://investors.merck.com/financials/sec-filings/default.aspx>; <https://www.gsk.com/media/4751/annual-report.pdf>; <https://www.sanofi.com/en/investors/reports-and-publications/>

<sup>437</sup> <https://www.ott.nih.gov/royalty/information-nih-inventors>; <https://www.ott.nih.gov/resources>; <https://www.ott.nih.gov/reportsstats/top-20-commercially-successful-inventions>; <https://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2017.pdf>; <https://www.ott.nih.gov/news/nih-technology-licensed-merck-hpv-vaccine>; <https://www.ott.nih.gov/reportsstats/hhs-licensed-products-approved-fda>

<sup>438</sup> <https://onlinelibrary.wiley.com/doi/abs/10.1046/j.1440-1754.1999.00342.x>

previously met cognitive and physical milestones and suffering changes in personality and behavior. If HHS wants to prove them wrong, it needs to produce real science showing the actual safety of each childhood vaccine and HHS's childhood vaccine schedule. That science demands, at the very least, a properly sized and controlled prospective study comparing health outcomes in vaccinated and completely unvaccinated children.

### **VIII. HHS REFUSES TO COMMIT TO REDUCING CONFLICTS OF INTEREST**

Our opening letter asserted numerous incriminating conflicts of interest at HHS and outright misconduct by HHS officials with regard to fulfilling its critical vaccine safety duties. HHS's response letter does not contest any of these. This may be because almost all of the conflicts of interest and misconduct we referenced in our opening letter were originally identified in congressional and other governmental reports. These reports found, for example, that the "overwhelming majority of members [of HHS's vaccine licensing committee], both voting members and consultants, have substantial ties to the pharmaceutical industry"<sup>439</sup> and that the process of recommending vaccines at HHS reflected "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."<sup>440</sup> All of these findings, as noted, remained unchallenged in HHS's response.

Many of these issues arise because HHS, *on the one hand*, is required to promote universal vaccine uptake and to defend vaccines from any claim of harm in Vaccine Court and, *on the other hand*, is responsible for the conflicting duty of assuring vaccine safety. Unfortunately, HHS's vaccine uptake/defense duties have suffocated its vaccine safety duties. We therefore suggested a number of ways in which some balance between these conflicting duties could be created.

Despite not contesting the serious conflicts of interest and misconduct regarding vaccine safety at HHS, your response rejects every single suggestion. Without drastic change, HHS's critical statutory duty to ensure vaccine safety will remain buried by HHS's vaccine uptake/defense duties. Based on HHS's response, the only real solution appears clear: remove vaccine safety into an entirely independent board that has no responsibility for vaccine uptake or defense.

#### **A. HHS's Failure To Perform Its Vaccine Safety Duties**

Recent admissions by HHS bring into sharp focus HHS's failure to perform its vaccine safety duties under the 1986 Act. As HHS is aware, when Congress in 1986 granted economic immunity to pharmaceutical companies for vaccine injuries, the financial

---

<sup>439</sup> <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

<sup>440</sup> <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

incentive for pharmaceutical companies to be accountable for and assure vaccine safety was eliminated.<sup>441</sup> Recognizing the unprecedented elimination of this market force, Congress in 1986 made HHS directly responsible for virtually every aspect of assuring vaccine safety.<sup>442</sup> Congress codified this obligation in 42 U.S.C. § 300aa-27 entitled “Mandate for Safer Childhood Vaccines” (the **Mandate**).

This Mandate underpins all vaccine safety in this country and has three simple parts. The following is a copy of the entire Mandate:

**(a) General rule.** In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary [of HHS] shall— (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

**(b) Task force.** (1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control. (2) The Director of the National Institutes of Health shall serve as chairman of the task force. (3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a) of this section.

**(c) Report.** Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.<sup>443</sup>

---

<sup>441</sup> [42 U.S.C. § 300aa-10](#); [42 U.S.C. § 300aa-11](#)

<sup>442</sup> [42 U.S.C. § 300aa-27](#)

<sup>443</sup> [42 U.S.C. § 300aa-27](#)

The first part of the Mandate requires the Secretary of HHS to assure and improve every aspect of vaccine safety.<sup>444</sup> The second part creates the Task Force on Safer Childhood Vaccines (the **Task Force**), comprised of the heads of NIH, FDA and CDC, and requires the Task Force to make recommendations to the Secretary of HHS on how to improve vaccine safety.<sup>445</sup> The third part requires the Secretary of HHS to submit a report to Congress every two years, starting in 1989, detailing the improvements made to vaccine safety in the preceding two years.<sup>446</sup>

Despite these clear requirements, HHS has failed to fulfill any of its duties under the Mandate. After our repeated demands for copies of Task Force recommendations, HHS finally admitted that the Task Force was disbanded in 1998. After we were forced to file a federal lawsuit to obtain copies of biennial vaccine safety reports that HHS was supposed to submit to Congress, HHS finally admitted that it has never once prepared or filed a single report as required by the Mandate.<sup>447</sup>

When HHS fails to accomplish the simple tasks of merely making vaccine safety recommendations (required by part two of the Mandate) and preparing biennial vaccine safety reports to Congress (required by part three of the Mandate), it is unsurprising it has failed to conduct the difficult work required by part one of the Mandate to actually improve vaccine safety. Indeed, the substance of our respective letters make it evident that HHS has failed to perform its basic vaccine safety duties.<sup>448</sup>

## **B. HHS Must Demand Congress Vest Vaccine Safety in an Independent Board**

In creating our system of government, our Founding Fathers recognized that governmental entities in powerful positions inherently have a difficult time regulating themselves. Therefore, a system of checks and balances was instituted in our system of government that has served the nation well for more than two centuries. However, this system of checks and balances has been eliminated when it comes to vaccine safety.

Given that the industry has virtually no financial liability for harms caused by vaccines, and the government department responsible for ensuring vaccine safety is driven by the need to assure vaccine uptake/defense, there is no check and balance to provide any

---

<sup>444</sup> [42 U.S.C. § 300aa-27](#)

<sup>445</sup> [42 U.S.C. § 300aa-27](#)

<sup>446</sup> [42 U.S.C. § 300aa-27](#)

<sup>447</sup> <http://icandecide.org/government/ICAN-HHS-Stipulated-Order-July-2018.pdf>

<sup>448</sup> Not only has HHS abdicated its vaccine safety duties, it is apparently comfortable with its incestuous relationship with the vaccine makers it is supposed to be regulating. For example, the first HHS vaccine committee (ACIP) meeting that ICAN attended began with an honorary ceremony in which ACIP announced it had engraved the name of a decades long pharmaceutical executive, Dr. Stanley Plotkin (whose conflicts are discussed above), on the gavel used at ACIP. <https://www.youtube.com/watch?v=AsOSF5hqCQc&t=356s&index=25&list=PLvvp9iOILTQb6D9e1YZWpbUvzfpTnMKx2> ACIP even announced, to applause, that “all of us have been influenced” by Dr. Plotkin. This event speaks to the true ethos at HHS regarding pharmaceutical company involvement and influence upon HHS’s vaccine work and policy, despite the regulations HHS cites purportedly seeking to prevent such conflicts.

level of assurance regarding vaccine safety. There is only an almost militant drive by HHS to promote vaccines, require their use and defend vaccines against any claim they cause harm, including as the defendant in the Vaccine Court.<sup>449</sup>

Product liability attorneys provide a critical check in ensuring unsafe products are either improved or eliminated from the market through civil lawsuits. But when it comes to childhood vaccines, this critical check was eliminated when product liability attorneys were neutralized by the grant of economic immunity to vaccine makers for vaccine injuries.<sup>450</sup> Without economic liability for vaccine injuries, pharmaceutical companies' fiduciary duty to their shareholders to maximize profits dictates licensing and marketing as many vaccines as possible, irrespective of their safety profile.

Congress sought to fill this void in vaccine safety (which it had created) by simultaneously making HHS legally responsible to assure vaccine safety. However, in hindsight, HHS was doomed to fail in assuring vaccine safety because HHS was simultaneously given the obligation to defend against every claim in Vaccine Court and assure high vaccine uptake.<sup>451</sup>

Moreover, HHS has become a "captive agency" co-opted by the very vaccine manufacturers it is supposed to be regulating (termed "agency capture" in academia).<sup>452</sup> There is simply no government agency pushing to ensure vaccine safety. On the other hand, there are billions of dollars spent by HHS and pharmaceutical companies every year to develop and promote vaccines, conduct studies to expand vaccine use, and discredit the scientists and medical professionals who testify on behalf of vaccine injured children in Vaccine Court or raise legitimate safety concerns regarding vaccines.<sup>453</sup>

When a department, such as HHS, is responsible for both promoting an industry and for ensuring the safety of that industry's products/activities, there is well settled precedent for separating these functions. HHS can learn from these precedents. For example, to avoid

---

<sup>449</sup> <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf> (Congressional report describing how the 1986 Act gave HHS the authority to set the rules for the Vaccine Injury Compensation Program (VICP) and that HHS used this authority to change the rules of the VICP in its favor so it can more readily defeat vaccine injury claims. Indeed, the 1986 Act created a Vaccine Injury Table (the **Table**) which quickly compensated certain common vaccine injuries. If the petitioner suffered a Table injury, the burden shifted to HHS to prove the vaccine did not cause the injury. After passage of the 1986 Act, almost 90 percent of claims were Table claims and settled quickly. Soon after, in 1995 and 1997, HHS amended the Table such that 98% of new claims are off-Table. This change greatly increased the difficulty of obtaining compensation for vaccine injuries; and while HHS changed the VICP rules in its favor, "DOJ attorneys make full use of the apparently limitless resources available to them," "pursued aggressive defenses in compensation cases," "establish[ed] a cadre of attorneys specializing in vaccine injury" and "an expert witness program to challenge claims.")

<sup>450</sup> <https://www.ncbi.nlm.nih.gov/pubmed/12923993>; <https://media2.mofo.com/documents/101200-ch55.pdf>

<sup>451</sup> [42 U.S.C. § 300aa-1](#); [42 U.S.C. § 300aa-2](#); [42 U.S.C. § 300aa-10](#); [42 U.S.C. § 300aa-11](#); [42 U.S.C. § 300aa-14](#); [42 U.S.C. § 300aa-26](#); [42 U.S.C. § 300aa-27](#)

<sup>452</sup> <https://onlinelibrary.wiley.com/doi/abs/10.1111/rego.12209>

<sup>453</sup> <https://www.hhs.gov/about/budget/index.html>; <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>; <https://www.usfc.uscourts.gov/aggregator/sources/7>; <https://www.ncbi.nlm.nih.gov/pubmed/29564139>; <https://investors.pfizer.com/financials/annual-reports/default.aspx>; <https://investors.merck.com/financials/sec-filings/default.aspx>; <https://www.gsk.com/media/4751/annual-report.pdf>; <https://www.sanofi.com/en/investors/reports-and-publications/>

conflicts of interest inherent in having one department promote transportation as well as assure its safety, the responsibility for transportation safety was transferred from the Department of Transportation to the independent National Transportation Safety Board (NTSB).<sup>454</sup> Similarly, to avoid conflicts in having one department promote nuclear energy and assure its safety, the safety function was transferred to the independent Nuclear Regulatory Commission (NRC).<sup>455</sup> In the same manner, HHS should support removing vaccine safety from HHS altogether into an entirely independent board, as was done with the NTSB and NRC. In fact, using the NTSB as a model, vaccine researchers from Johns Hopkins University have advocated, as early as 2004, for removing vaccine safety from HHS and placing into an entirely independent National Vaccine Safety Board.<sup>456</sup>

There are, in fact, additional and even more compelling reasons for removing vaccine safety duties from HHS than there were for creating the NTSB and NRC. When transportation or nuclear related injuries occur, the companies causing these injuries are, to varying degrees, economically liable for the injuries. In contrast, when a vaccine injury occurs, the companies causing these injuries are effectively economically immune from liability under the 1986 Act.<sup>457</sup> Hence, unlike the NTSB and NRC, where the companies they regulate still have an economic incentive to assure safety, there is no such economic incentive for vaccine makers.<sup>458</sup> As such, unlike nuclear and transportation safety where the onus of safety still remains with industry, the onus of vaccine safety falls solely on the shoulders of HHS, making its mission to assure safety in many ways far more critical than the safety missions of the NTSB and NRC.

The NTSB and NRC also only assist victims of injury by the transportation and nuclear industries. In contrast, HHS is supposed to play the dual and conflicting roles of identifying and preventing injuries to children from vaccination while simultaneously serving as the defendant in Vaccine Court where, represented by the DOJ, it is statutorily required to defend against any claim that a vaccine injured a child, which HHS does vigorously.<sup>459</sup>

Thus, any study or admission by HHS that would support that a vaccine caused even a potential harm could be used against HHS in the Vaccine Court. Even HHS's Immunization Safety Office, which is responsible for vaccine safety, provides ongoing assistance to HHS's Division of Vaccine Injury Compensation, which is responsible for defending against claims of vaccine injury, in order to defeat claims in Vaccine Court.<sup>460</sup> It

---

<sup>454</sup> <https://www.nts.gov/about/history/pages/default.aspx>

<sup>455</sup> <https://www.nrc.gov/about-nrc/history.html>

<sup>456</sup> <https://www.ncbi.nlm.nih.gov/pubmed/15249296>

<sup>457</sup> 42 U.S.C. § 300aa-1 et seq.; *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011)

<sup>458</sup> 42 U.S.C. § 300aa-1 et seq.

<sup>459</sup> 42 U.S.C. § 300aa-12; <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>

<sup>460</sup> Advisory Committee on Immunization Practices, Transcript of October 25, 2017 Presentation "Vaccine Injury: Shoulder Injury After Vaccination" available at <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>

is amazing that the Immunization Safety Office is actually involved in fighting against, not for, families claiming their child was seriously injured by a vaccine. It is also unjust to demand that a child, who received vaccines based on HHS's vaccine schedule, prove how one or more of those vaccines caused his or her injury (i.e., prove "causation") in Vaccine Court while fighting against HHS; all while (as discussed above) HHS has not performed the science to understand how and why vaccines cause injury despite being statutorily tasked with that job.<sup>461</sup>

These structural conflicts make removal of vaccine safety from HHS far more compelling than the removal of transportation safety and nuclear safety to the NTSB and NRC.

The above is just a small part of why Congress concluded that the system at HHS for recommending and promoting vaccines reflects "a system where government officials make crucial decisions affecting American children without the advice and consent of the governed."<sup>462</sup> A December 2009 report by HHS's Office of the Inspector General again found that the "CDC had a systemic lack of oversight of the ethics program for [committee members]," and that, for example, "[m]ost of the experts who served on advisory panels in 2007 to evaluate vaccines for flu and cervical cancer had potential conflicts that were never resolved."<sup>463</sup> HHS's response letter also does not contest that CDC does accept funding from the pharmaceutical industry, directly and indirectly, despite claiming otherwise on its website, and that key vaccine program personnel are reluctant to take actions that would diminish their chances of securing lucrative private sector jobs with vaccine manufacturers.<sup>464</sup>

Many parents, physicians and scientists, as well as lawmakers, are legitimately concerned about the foregoing, including HHS's long running failure to fulfill its essential vaccine safety duties. Their concern is not rooted in a wild conspiracy or a belief of insidious intent. Rather, it is rooted in the idea that having HHS responsible for promoting vaccines and defending vaccines, including in Vaccine Court, is directly at odds with ensuring vaccine safety, especially where any finding that a childhood vaccine can cause serious harm could result in HHS having to pay damages in Vaccine Court as well as serious reputational

---

<sup>461</sup> This was not what Congress intended in passing the 1986 Act. Instead, the 1986 Act created a Vaccine Injury Table (the "Table") which was intended to permit the Vaccine Court to quickly compensate certain common vaccine injuries. [42 U.S.C. § 300aa-12](#). If the child suffered an injury on the Table, the burden shifted to HHS to prove the vaccine did not cause the injury. [42 U.S.C. § 300aa-13](#). After passage of the 1986 Act, almost 90% of claims were Table claims and quickly settled. [Stevens v. Secretary of HHS, No. 99-594V \(Office of Special Masters 2001\)](#). However, in 1995 and 1997, HHS amended the Table such that now 98% of new claims are off-Table. <http://www.gao.gov/assets/670/667136.pdf>. As a result, injured children must now almost always prove "causation" – the biological mechanism by which the vaccine injured the child. <https://www.ncbi.nlm.nih.gov/nlmcatalog/101633437> ("Persons alleging a condition not included in the table ... must prove that the vaccine was the cause.") Requiring an injured child to prove causation adds insult to injury because had HHS conducted the safety science it demands as proof in Vaccine Court, the child's injury may have been avoided altogether.

<sup>462</sup> <http://vaccinesafetycommission.org/pdfs/Conflicts-Govt-Reform.pdf>

<sup>463</sup> <https://oig.hhs.gov/oei/reports/oei-04-07-00260.pdf>; <http://www.nytimes.com/2009/12/18/health/policy/18cdc.html>

<sup>464</sup> <http://www.bmj.com/content/350/bmj.h2362>

harm. HHS has serious conflicts and powerful disincentives which create institutional gridlock that prevent HHS from initiating, admitting or publishing any research that would support a claim that any childhood vaccine or HHS's childhood vaccine schedule causes serious injury or chronic illness in children.

HHS's response letter makes clear that these concerns are not only well founded, but worse than alleged in our opening letter.<sup>465</sup>

## IX. VSD AND PRISM

HHS's response asserted that it investigates vaccine safety post-licensure using the Vaccine Safety Datalink (**VSD**) and the Post-licensure Rapid Immunization Safety Monitoring System (**PRISM**). While these could be helpful in assessing vaccine safety, that is not currently the case.

As for the VSD, instead of being used to improve safety, it is used as a tool to silence vaccine critics and expand vaccine recommendations, even for uses not licensed by the FDA. First, the VSD was once maintained at HHS but when scientists began to access the VSD to conduct studies which revealed vaccine harm, HHS purposely moved the VSD to a health industry trade association starting in 2001 to avoid having the VSD data subject to FOIA, and to otherwise assure that only the scientists and studies it approves utilize the VSD.<sup>466</sup>

Second, when a VSD study is conducted by HHS, in violation of basic scientific standards and process, the underlying raw data is almost never available for inspection by the public and other scientists.<sup>467</sup> Refusal to make this data available raises serious concerns regarding reproducibility and transparency. HHS regulations in fact provide severe penalties if researchers, using HHS funding, refuse to share data underlying their studies, but HHS does not apply this same standard to their own VSD studies.<sup>468</sup>

Third, the secret studies that HHS performs using the VSD with secret data are virtually all squarely aimed at increasing vaccine uptake, even for uses and in populations not approved by the FDA. For example, a plurality of the nineteen VSD studies conducted

---

<sup>465</sup> Our opening letter also highlighted that HHS is required to assure that any "health care provider who administers a vaccine ... shall record ... in such person's permanent medical record ... the vaccine manufacturer and lot number." (42 U.S.C. §§ 300aa-25(a)) We therefore asked in our opening letter that HHS: "Please explain what HHS has done to assure that health care providers record the manufacturer and lot number for each vaccine they administer?" HHS's response does little more than restate HHS's requirement, and does not show it does anything to enforce this requirement. This is another dereliction of HHS's vaccine safety duties. This statutory obligation could not be any clearer. If HHS will not do anything of substance to assure the simple requirement of recording lot information, so that "hot lots" can be identified, there is little hope that HHS will fulfill its far more complex vaccine safety duties.

<sup>466</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4708093/>

<sup>467</sup> <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/accessing-data.html>

<sup>468</sup> <https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information>

by HHS in 2017 involved the vaccination of pregnant women.<sup>469</sup> This is plainly in response to the HHS recommendation that influenza and Tdap vaccines be administered to every pregnant woman, despite the fact that these vaccines were not licensed by the FDA for use in pregnant women.<sup>470</sup> HHS is essentially engaging in off-label marketing that, if conducted by the vaccine manufacturer, would be illegal, and is seeking to use the VSD as an after-the-fact tool to justify this conduct.<sup>471</sup>

Fourth, the VSD must be retooled to assess the long-term impact of vaccination, which is the real concern the public has about vaccine safety. Indeed, HHS has acknowledged that the public stakeholders “have expressed more concerns about long-term than short-term health outcomes” and that “long-term health outcomes have been less well-studied in the context of vaccine safety,” but that VSD is currently geared toward assessing short-term, and not long-term, health outcomes:

The current safety surveillance systems such as the VSD, and the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system of the Food and Drug Administration (FDA), already have extensive systems in place to assess short-term outcomes ... [despite the fact] the childhood immunization schedule is essentially a long-term exposure, occurring over 18 to 24 months, [and hence] long-term adverse events may be more biologically plausible than short-term events.<sup>472</sup>

Fifth, it is highly inappropriate that VSD studies are conducted by HHS’s Immunization Safety Office which, as discussed above, is headed by an individual accused by a Senior Scientist at HHS of fraudulently modifying results of prior vaccine studies, including for the purpose of avoiding liability for HHS in Vaccine Court.<sup>473</sup>

Sixth, and critically, any VSD study intended to assure the public that vaccines are safe should be designed and performed by an organization for whom a finding that a vaccine causes a serious harm would not have significant financial and/or reputational repercussions, as it would for HHS. In fact, the very HHS office that conducts VSD studies, the Immunization Safety Office, as discussed above, actively assists in defeating vaccine injury claims in Vaccine Court.

---

<sup>469</sup> <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/publications.html>

<sup>470</sup> <https://www.cdc.gov/vaccines/pregnancy/hcp/resources.html> (advertising materials created by the CDC to promote vaccines to pregnant women); <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm> (each vaccine package inserts states, in one form or another, that the safety and effectiveness of the vaccine has not been established in pregnant women)

<sup>471</sup> <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf>

<sup>472</sup> [https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety\\_WEB.pdf](https://www.cdc.gov/vaccinesafety/pdf/WhitePaperSafety_WEB.pdf)

<sup>473</sup> <https://soundcloud.com/fomotion/cdc-whistle-blower-full-audio>; <http://www.rescuepost.com/files/william-thompson-statement-27-august-2014-3.pdf>

When HHS is ready to be transparent, it should: open the VSD to all researchers; make accessible the underlying data used for all its published studies; subject itself to the same criticism of its VSD studies as other scientists; and, not have these studies conducted by anyone or any organization that participates in defending against vaccine injury claims, is accused of scientific fraud, or has any conflict of interest with finding that a vaccine causes harm. Only then can HHS finally claim the VSD is a valid research tool for improving vaccine safety. Until then, the VSD remains an improperly wielded government tool, like the KGB's Mitrokhin Archive waiting for someone from HHS to defect and share the VSD data with the scientific community.

As for PRISM, putting aside its very limited use, instead of being used to improve vaccine safety, it is also wielded by HHS to silence vaccine critics and expand vaccine recommendations for uses not licensed by the FDA. For example, every single assessment conducted in PRISM in 2018 was conducted to provide after-the-fact support for HHS's vigorous marketing campaign aimed at assuring that every pregnant woman in America receives an influenza vaccine.<sup>474</sup> As discussed above, despite the fact the FDA has not licensed any influenza vaccine for use in pregnant women, HHS has been recommending and promoting this off-label use to pregnant women for a decade.

It is only after HHS could no longer ignore the mounting vaccine injury claims by pregnant women and independent studies finding serious safety signals regarding the risks of vaccinating pregnant women, that HHS used VSD and PRISM to "prove" the safety of its prior pregnancy vaccine use recommendation. But these efforts are plainly not about assuring vaccine safety. If that were the goal, these safety studies would have been conducted before HHS promoted administering influenza vaccine to all pregnant women. Rather, it is a transparent effort to silence recent and growing criticism of its off-label marketing of this vaccine to pregnant women. After vigorously promoting the flu shots to pregnant women for a decade, is HHS really going to publish science that requires it to backtrack and admit: "oops, sorry, actually, it is not safe to inject pregnant women with the flu shot."

Like the VSD, it is unlikely HHS will use PRISM to publish a study that confirms any serious widespread harm from vaccination. If it did, HHS would be developing the very science that would then be used against it in Vaccine Court, potentially resulting in crippling financial liability as well as loss of reputation. This is why HHS's Vaccine Safety Office, instead of working to prevent and obtain compensation for vaccine injuries and deaths, assists HHS's office responsible for fighting against the claims of vaccine injured plaintiffs

---

<sup>474</sup> <https://www.sentinelinitiative.org/vaccines-blood-biologics/assessments>

in Vaccine Court. HHS is so blind to this obvious conflict that it openly bragged about this collaboration at a public ACIP meeting held in October 2017.<sup>475</sup>

The VSD and PRISM could be useful tools for assessing vaccine safety (after the baseline safety profile of HHS's childhood vaccine schedule is established in properly sized and controlled trials), but the studies conducted with these systems must be designed and executed by individuals and organizations without conflicts of interest and bias with regard to assessing vaccine safety. Such studies should certainly not be conducted by an organization that could suffer serious financial and reputational harm if it confirms that one or more childhood vaccines can cause serious injury. For example, finding that vaccines cause 1 in 5 cases of either allergic rhinitis, ADHD, learning disabilities or neurodevelopmental delay, all of which preliminary science has shown can be caused by vaccination,<sup>476</sup> would result in trillions of dollars of liability and a loss of public confidence in HHS and its vaccine schedule.

As explained by a renowned professor in the Center for Bioethics, Harvard School of Medicine, member of the Institute of Medicine, and former editor-in-chief of the New England Journal of Medicine:

It is no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of *The New England Journal of Medicine*. ...<sup>477</sup>

For these and other reasons discussed above, it is entirely inappropriate to have HHS manage and control VSD and PRISM. These health database platforms are paid for by the American public and should be open to every scientist in this country to conduct studies without any barrier and without requiring any permission from HHS. If HHS truly believes that vaccines are "safe and effective," it should immediately make available to the public and scientific community, as it does with VAERS, the deidentified data in the VSD and let that data speak for itself.

### **Conclusion**

Instead of focusing on defending pharmaceutical companies and their products, including in Vaccine Court, HHS should be focused on protecting and defending children

---

<sup>475</sup> Advisory Committee on Immunization Practices, Transcript of October 25, 2017 Presentation "Vaccine Injury: Shoulder Injury After Vaccination" available at <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>

<sup>476</sup> <http://www.oatext.com/pdf/ITS-3-186.pdf>

<sup>477</sup> <https://www.nybooks.com/articles/2009/01/15/drug-companies-doctors-a-story-of-corruption/>

from vaccine injuries. Pharmaceutical companies are well organized and funded. Parents of current and future vaccine injured children, the citizens the Government is supposed to serve, are not.

Since vaccine products are injected dozens of times into nearly every baby and child in America and are typically required by law to attend school, they should be tested for safety prior to licensure in extremely well designed clinical trials. Instead the opposite is true. Without impeccable clinical trials—with rigorous methods, large sample sizes, true placebo controls, and extended periods of observation for vaccine injury—yielding results which demonstrate that the benefits of vaccination clearly outweigh the harms, the large-scale vaccination program in this country cannot be ethically justified.

Even absent an ethical imperative, HHS's responsibility for assuring vaccine safety is required by federal law. HHS's response letter seeks to create the impression that there exists a complete understanding of the safety profile of each pediatric vaccine and HHS's childhood vaccine schedule, and that there is almost nothing left for HHS to do to assure vaccine safety. We request that HHS carefully consider all of the information provided above, which is nearly entirely grounded in and anchored by citations to HHS's own publications.

It is our hope that HHS will rise above its internal gridlock and inherent conflicts of interest, and take this opportunity to seriously consider the safety of pediatric vaccines and its childhood vaccine schedule.

We await your response to each of the points raised above and to the questions listed in Appendix A below.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Del Bigtree', written in a cursive style.

Del Bigtree  
President

Enclosures: Appendices A and B.<sup>478</sup>

---

<sup>478</sup> Appendix A of our initial letter, dated October 12, 2017, is amended to add Hope Inc. Academy, Medical Freedom Nevada, Hope from Holly, Educate.Advocate., Autism is Medical, Inc., Oregonians for Medical Freedom, Thinking Moms Revolution, Vaccine Freedom Utah, and Your Health Freedom.

## APPENDIX A

## QUESTIONS REGARDING VACCINE SAFETY

## 1. CLINICAL TRIALS

- a. Please list each vaccine product that is currently recommended for routine use in children which was licensed for use in children based on a placebo-controlled clinical trial. For each vaccine product listed, please provide the clinical trial report supporting that a “placebo,” as defined at [www.cdc.gov/vaccines/terms/glossary.html](http://www.cdc.gov/vaccines/terms/glossary.html), was used.
- b. Please list each vaccine product that is currently recommended for routine use in children which was licensed for use in children based on a clinical trial that used an “active control” previously licensed for use in children based on a placebo-controlled clinical trial. For each vaccine product listed, please provide the clinical trial report supporting that a “placebo,” as defined at [www.cdc.gov/vaccines/terms/glossary.html](http://www.cdc.gov/vaccines/terms/glossary.html), was used.
- c. Will HHS henceforth require a placebo-controlled (saline injection) properly-powered (sufficient children) long-term (reviews safety for at least three years or until age eight, whichever is longer) clinical trial prior to licensing any new vaccine product for which no other vaccine exists for the target disease?

## 2. VACCINES INJECTED DURING THE FIRST 6-MONTHS OF LIFE

- a. For each clinical trial relied upon to license any injectable vaccine product HHS currently recommends for routine use in children between birth and six-months of age, please identify (i) the control used and (ii) the trial’s safety review period, by completing the following chart and please provide supporting documentation:

Licensed Vaccine Product	Control	Safety Review Period: Solicited Reactions	Safety Review Period: Unsolicited Reactions
Recombivax HB			
Engerix-B			
ActHIB			
PedvaxHIB			
Hiberix			
Infanrix			
Daptacel			
Ipol			
Prevnar 13			
Pediarix			
Pentacel			

- b. Please provide the clinical trial report(s) that reflect the cumulative safety profile, by ten years of age, of injecting approximately 22 vaccine doses into babies during the first six months of life, including the rate of any autoimmune, neurological or developmental disorders.
- c. Please provide the clinical trial report(s) that reflect the cumulative safety profile, by ten years of age, of injecting approximately 35 vaccine doses into babies and toddlers during the first two-years of life, including the rate of any autoimmune, neurological or developmental disorders.

**3. VACCINES INJECTED INTO PREGNANT WOMEN**

- a. Please provide the clinical trial report(s) relied upon by HHS when licensing influenza and Tdap vaccines for use by pregnant women.
- b. Is a pharmaceutical company permitted to advertise or promote the influenza or Tdap vaccines it manufactures to pregnant women? If not, why not?

**4. SPECIFIC VACCINES**

- c. Is it acceptable to inject a healthy baby with a product that contains one or more known or suspected neurotoxic or cytotoxic substances where its licensure is based on a trial that had no control and a short safety review period?
- d. Please identify and provide a copy of any placebo-controlled trial with a safety review period longer than one week that HHS relied upon when it recommended that every baby in this country receive either Recombivax HB or Engerix-B on the first day of life.
- e. Please advise if HHS disputes that during the Gardasil trials the rate of girls and women 9 through 26 years of age who reported an incident condition potentially indicative of a systemic autoimmune disorder was 2.3% in the group that received Gardasil, 2.3% in the group that received AAHS Control, and 0% for the group that received Saline Placebo.
- f. Please explain why it was considered ethical to inject controls during the clinical trials for (i) Gardasil with 225 mcg or 450 mcg of Amorphous Aluminum Hydroxyphosphate Sulfate (AAHS) when it has no known therapeutic benefit? (ii) Varivax with 45 mg of neomycin when neomycin is only licensed for topical and oral use?

## 5. POST-LICENSURE SAFETY

- a. After a Harvard Pilgrim Health Care study, conducted pursuant to a grant from an HHS agency, developed a program which automatically identified and generated reports of possible vaccine reactions, please explain why HHS failed to cooperate with Harvard to automate submission of these reports to VAERS.
- b. For each vaccine-injury pair for which the IOM, in its 1994 and 2011 reports, could not determine whether or not there is a causal relationship, please list the precise vaccine-injury pairs for which HHS has since determined whether there is a causal relationship. For each vaccine-injury pair identified, please specify HHS's finding regarding causation and provide documentary support.
- c. Please list each vaccine on HHS's childhood vaccine schedule that has been evaluated for its (i) carcinogenic potential, (ii) mutagenic potential, or (iii) potential to impair fertility. For each vaccine listed, please identify for which of these three potentials it has been evaluated and provide documentary support.
- d. Please identify the specific studies, by title, author and year, which HHS has conducted to determine specific biomarkers or other predictive criteria which can be used to identify whether a given child will suffer a serious vaccine injury.
- e. Please provide the deidentified datasets from the following study relating to autism and vaccines in which HHS was involved so that we and the scientific community can analyze the data: <https://www.ncbi.nlm.nih.gov/pubmed/?term=29582071>
- f. Please advise if HHS will forthwith provide public access to the deidentified datasets within the VSD so that all researchers can conduct vaccine safety studies without requiring any permission or approval from HHS or anyone else. Putting aside that taxpayers support the VSD, agreeing to such transparency would accord with CDC's claim that it "embraces intellectual honesty and transparency in its release of information to fully empower public decision."<sup>479</sup>
- g. The following white paper provides the peer reviewed scientific support for how aluminum adjuvants injected into the body travel to the brain, can cause IL-6 production and microglial activation in the brain, and that this in turn can cause autism: <http://icandecide.org/white-papers/ICAN-AluminumAdjuvant-Autism.pdf> Please clearly and specifically explain which steps in this chain of causation or any other aspect of this white paper HHS disputes.

---

<sup>479</sup> <https://www.cdc.gov/about/organization/communication-principles.html>

**6. CONFLICTS OF INTEREST**

- a. Please explain why HHS has never once prepared or submitted a biennial report to Congress detailing improvements in vaccine safety as required under federal law, 42 U.S.C. § 300aa-27(c).
- b. Please explain why HHS disbanded the Task Force on Safer Childhood Vaccines in 1998 when this task force is mandated to exist pursuant to federal law, 42 U.S.C. § 300aa-27(b), to provide recommendations to assist the Secretary of HHS in his/her ongoing duty to fulfill HHS's vaccine safety obligations pursuant to 42 U.S.C. § 300aa-27(a).
- c. Please explain why HHS would place the name of a pharmaceutical executive and consultant on the gavel of its premier vaccine committee, the Advisory Committee on Immunization Practices.
- d. Will you support the removal of vaccine safety duties from HHS into an entirely independent government board, similar to the National Transportation Safety Board or the Nuclear Regulatory Commission. If not, please explain why.

## APPENDIX B

The following is a *partial* list of post-licensure adverse reactions reported by consumers and physicians, and listed in the package inserts for one or more pediatric vaccines.<sup>480</sup> Pursuant to federal law, these adverse reactions are only listed if the vaccine’s manufacturer has a basis to believe there is a causal relationship between the vaccine and the occurrence of the adverse event.<sup>481</sup> Indeed, Federal law is clear that this list should include “*only* those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.”<sup>482</sup>

### Immune System Disorders

Alopecia	<i>autoimmune skin disease causing loss of hair on the scalp and body.</i>
Anaphylactic Shock	<i>rapid onset of severe allergic reaction that causes sudden drop in blood pressure and narrowing of airway that can lead to seizures, shock, and death.</i>
Angioedema	<i>potentially life-threatening swelling underneath the skin.</i>
Arthritis	<i>painful and disabling autoimmune disease that includes joint pain, swelling and progressive stiffness in the fingers, arms, legs and wrists.</i>
Autoimmune Disease	<i>disease caused by the immune system mistakenly attacking the body’s own tissue.</i>
Guillain-Barré Syndrome	<i>autoimmune disease where the immune system attacks the nerves in the legs, upper body, arms and/or face.</i>
Hemolytic Anemia	<i>red blood cells are destroyed faster than they can be replaced.</i>
Henoch-Schonlein Purpura	<i>abnormal immune response causing inflammation of microscopic blood vessels which can lead to multiple organ damage.</i>
Lupus Erythematosus	<i>autoimmune disease in which the immune system attacks multiple organs, including skin, joints, kidney, and brain.</i>
Multiple Sclerosis	<i>autoimmune disease in which the immune system attacks nerve fibers, causing them to deteriorate.</i>

<sup>480</sup> <https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm>

<sup>481</sup> [21 C.F.R. 201.57](#)

<sup>482</sup> [21 C.F.R. 201.57](#)

Myasthenia	<i>autoimmune disease causing chronic weakness of the skeletal muscles, including arms and legs, vision problems, and drooping eyelids or head.</i>
Myositis	<i>chronic muscle inflammation that damages the muscle fibers causing weakness, and may affect the arteries and blood vessels that pass through muscle.</i>
Polyarteritis Nodosa	<i>systemic vasculitis that affect medium-sized and small muscular arteries resulting in ruptures and other damage.</i>
Stevens-Johnson's Syndrome	<i>severe autoimmune reaction in which the top layer of skin is burned off and dies.</i>
Thrombocytopenia	<i>low blood platelet count which can result in easy bruising and excessive bleeding from wounds or bleeding in mucous membranes.</i>
Vasculitis	<i>inflammation of the blood vessels, potentially leading to loss of function of affected tissues and organ damage.</i>

### **Nervous System Disorders**

Acute Disseminated Encephalomyelitis	<i>acute, widespread inflammation in the brain and spinal cord that damages myelin.</i>
Ataxia	<i>brain damage resulting in loss of full control of bodily movement, impaired speech, eye movement, and swallowing.</i>
Bell's Palsy	<i>disfiguring paralysis or weakness on one side of the face.</i>
Encephalitis	<i>inflammation of the brain, which can result in permanent injury.</i>
Encephalomyelitis	<i>inflammation of the brain and spinal cord.</i>
Encephalopathy with EEG Disturbances	<i>damage or malfunction of the brain with severity ranging from altered mental state to dementia, seizures and coma.</i>
Grand Mal Convulsion	<i>loss of consciousness and violent muscle contractions.</i>
Hypotonia	<i>low muscle tone.</i>
Hypotonic-Hyporesponsive Episode	<i>sudden and unexpected loss of tone, unresponsiveness and color change.</i>
Meningitis	<i>inflammation of protective membranes covering the brain and spinal cord.</i>

Migraine	<i>sudden and severe, pounding headaches, upset stomach, and sometimes disturbed vision.</i>
Motor Neuron Disease	<i>neurological disorder that destroys motor neurons that control essential voluntary muscle activity such as speaking, walking, breathing, and swallowing.</i>
Myelitis	<i>inflammation of spinal cord that can involve nerve pain, paralysis and incontinence.</i>
Nerve Deafness	<i>hearing loss from damage to the nerve that runs from the ear to the brain.</i>
Neuralgia	<i>intense painful sensation along a nerve or group of nerves.</i>
Neuropathy	<i>nerve problem that causes pain, numbness, tingling, swelling, or muscle weakness in different parts of the body.</i>
Ocular Palsies	<i>damage to the nerve of the eye that controls eye movement.</i>
Optic Neuritis	<i>inflammation causing eye pain and partial or complete vision loss.</i>
Paralysis	<i>inability to move part or all of the body.</i>
Radial Nerve and Recurrent Nerve Paralysis	<i>nerve injury to the radial nerve that can cause weakness or difficulty moving the wrist, hand or fingers.</i>
Radiculopathy	<i>compressed or pinched nerve.</i>
Retrobulbar Neuritis	<i>inflammation and damage to the optic nerve between the back of the eye and the brain.</i>
Seizures	<i>sudden, uncontrolled body movements and changes in behavior that occur because of abnormal electrical activity in the brain.</i>
Stroke	<i>blood flow blocked to the brain or bleeding in the brain, which can lead to brain damage, long-term disability, or death.</i>
Subacute Sclerosing Panencephalitis (SSPE)	<i>progressive neurological disorder affecting the central nervous system leading to mental deterioration, loss of motor function, and ultimately leading to a vegetative state followed by death.</i>
Syncope	<i>decrease in blood flow to the brain causing a loss of consciousness and muscle strength.</i>
Transverse Myelitis	<i>inflamed spinal cord which may result in paralysis.</i>

### Other Disorders and Chronic Disorders

Aseptic Meningitis	<i>acute inflammation of the brain and spinal cord.</i>
--------------------	---

Aplastic Anemia	<i>damage to the bone marrow that slows or shuts down the production of new blood cells.</i>
Cellulitis	<i>infection of the deep tissues of the skin and muscles that cause the skin to become warm and tender.</i>
Cyanosis	<i>bluish skin discoloration due to low oxygen saturation.</i>
Death	<i>permanent end of life.</i>
Deep Vein Thrombosis	<i>formation of a blood clot in a deep vein that can break off and block blood flow to organs.</i>
Diabetes Mellitus	<i>chronic condition affecting ability to use energy from food.</i>
Dysphonia	<i>impairment in the ability to speak.</i>
Epididymitis	<i>inflammation of the testicle tube, which can lead to abscess formation, testicular pain, painful urination, tissue death, and decreased functionality of gonads.</i>
Mental Disorders	<i>unusual thoughts, perceptions, emotions, behavior, and relationship with others.</i>
Myalgia	<i>muscle pain that can become chronic.</i>
Orchitis	<i>inflammation of one or more testicles that can cause infertility, testicular atrophy, and severe pain.</i>
Pancreatitis	<i>inflammation of the pancreas due to damage by digestive enzymes.</i>
Pneumonia	<i>infection in one or both lungs.</i>
Respiratory Infection	<i>infection of the respiratory tract.</i>
Retinitis	<i>inflammation of the retina which can permanently damage the retina, leading to blindness.</i>
Rhinitis	<i>irritation and inflammation of nasal mucous membranes impacting ability to breathe properly.</i>
Sudden Infant Death Syndrome	<i>sudden death of infant in good health.</i>
Tachycardia	<i>an abnormally rapid heart rate.</i>
Uveitis	<i>inflammation of the eye leading to vision loss.</i>
Vertigo	<i>problem with the vestibular portion of the inner ear causing dizziness.</i>

# Exhibit F

## AFFIDAVIT

I, Andrew Walter Zimmerman, M. D. do hereby state under oath as follows:

1. I am a board certified, pediatric neurologist and former Director of Medical Research, Center for Autism and Related Disorders, Kennedy Krieger Institute, and Johns Hopkins University School of Medicine.
2. I was a Reviewer for the National Academy of Sciences 2004 report entitled IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM, which was prepared by the Immunization Safety Review Committee, at the request of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Institute of Medicine (IOM).
3. A copy of my curriculum Vitae is attached hereto as exhibit A and incorporated by reference.
4. In 2007, I was an expert witness for the Department of Health and Human Services in the Omnibus Autism Proceeding (O.A.P.) under the National Childhood Vaccine Injury Compensation Program.
5. With the assistance of the Department of Justice, I prepared and executed the attached expert witness opinion regarding Michelle Cedillo, on behalf of the Department of Health and Human Services in Cedillo v. H.H.S. My expert opinion in Cedillo v. H.H.S. is attached as exhibit B. It states in pertinent part as follows:

"There is no scientific basis for a connection between measles, mumps and rubella (MMR) vaccine or mercury (Hg) intoxication and autism. Despite well-intentioned and thoughtful hypotheses and widespread beliefs about apparent connections with autism and regression, there is no sound evidence to support a causative relationship with exposure to both, or either, MMR and/or Hg. Michelle Cedillo had a thorough and normal immunology evaluation by Dr. Sudhir Gupta, showing no

signs of immunodeficiency that would have precluded her from receiving or responding normally to MMR vaccine. ”

My expert opinion regarding Michelle Cedillo also states:

“Furthermore, there is no evidence of an association between autism and the alleged reaction to MMR and Hg, and it is more likely than not, that there is a genetic basis for autism in this child.”

6. On Friday June 15<sup>th</sup> 2007, I was present during a portion of the O.A.P. to hear the testimony of the Petitioner’s expert in the field of pediatric neurology, Dr. Marcel Kinsbourne. During a break in the proceedings, I spoke with DOJ attorneys and specifically the lead DOJ attorney, Vincent Matanoski in order to clarify my written expert opinion.
7. I clarified that my written expert opinion regarding Michelle Cedillo was a case specific opinion as to Michelle Cedillo. My written expert opinion regarding Michelle Cedillo was not intended to be a blanket statement as to all children and all medical science.
8. I explained that I was of the opinion that there were exceptions in which vaccinations could cause autism.
9. More specifically, I explained that in a subset of children with an underlying mitochondrial dysfunction, vaccine induced fever and immune stimulation that exceeded metabolic energy reserves could, and in at least one of my patients, did cause regressive encephalopathy with features of autism spectrum disorder.
10. I explained that my opinion regarding exceptions in which vaccines could cause autism was based upon advances in science, medicine, and clinical research of one of my patients in particular.

11. For confidentiality reasons, I did not state the name of my patient. However, I specifically referenced and discussed with Mr. Matanoski and the other DOJ attorneys that were present, the medical paper, Developmental Regression and Mitochondrial Dysfunction in a Child With Autism, which was published in the Journal of Child Neurology and co-authored by Jon Poling, M.D. Ph.D, Richard Frye, M.D., Ph.D, John Shoffner, M.D. and Andrew W. Zimmerman, M.D. A copy of which is attached as exhibit C.
12. Shortly after I clarified my opinions with the DOJ attorneys, I was contacted by one of the junior DOJ attorneys and informed that I would no longer be needed as an expert witness on behalf of H.H.S. The telephone call in which I was informed that the DOJ would no longer need me as a witness on behalf of H.H.S. occurred after the above referenced conversation on Friday, June 15, 2007, and before Monday, June 18, 2007.
13. To the best of my recollection, I was scheduled to testify on behalf of H.H.S. on Monday, June 18, 2007.
14. At the time of the above referenced conversation with the DOJ, I did not know that Hazlehurst v. HHS or Poling v. HHS were potential test cases in the OAP.
15. It is my understanding the HHS concession in Poling v. H.H.S. has become common knowledge and has been published by international news media. Among other news media coverage, I reviewed the CNN interview in which Dr. Julie Gerberding, the former head of the CDC discussed the concession by H.H.S. in Poling v. H.H.S. and the interview with Dr. Jon Poling, the father of the child whose case was conceded.
16. The summary language, "the vaccinations ....., significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder" is in essence the chain of causation that I explained to the DOJ attorneys including Vincent Matanoski during the above referenced conversations on June 15, 2007.

17. I have reviewed extensive genetic, metabolic and other medical records of William "Yates" Hazlehurst. In my opinion, and to a reasonable degree of medical certainty, Yates Hazlehurst suffered regressive encephalopathy with features of autism spectrum disorder as a result of a vaccine injury in the same manner as described in the DOJ concession in Poling v. H.H.S., with the additional factors that Yates Hazlehurst was vaccinated while ill, administered antibiotics and after previously suffering from symptoms consistent with a severe adverse vaccine reaction.

18. I have reviewed the attached portion of the transcript, of Vincent Matanoski's closing argument in Hazlehurst v. H.H.S., which is attached as exhibit D. The relevant portion of the transcript states as follows:

I did want to mention one thing about an expert, who did not appear here, but his name has been mentioned several times, and that was Dr. Zimmerman.

Dr. Zimmerman actually has not appeared here, but he has given evidence on this issue, and it appeared in the Cedillo case. I just wanted to read briefly because his name was mentioned several times by Petitioners in this matter. What his views were on these theories, and I'm going to quote from Respondent's Exhibit FF in the Cedillo case, which is part of the record in this case as I understand it.

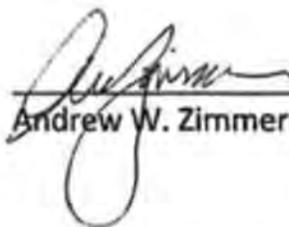
"There is no scientific basis for a connection between measles, mumps and rubella MMR vaccine or mercury intoxication in autism despite well-intentioned and thoughtful hypotheses and widespread beliefs about apparent connection with autism and regression. There's no sound evidence to support a causative relationship with exposure to both or either MMR and/or mercury."

We know his views on this issue.

19. In my opinion, the statement by Mr. Matanoski during his closing argument regarding my expert opinion was highly misleading and not an accurate reflection of my opinion for two reasons. First, Mr. Matanoski took portions of my opinion out of context. My opinion as to Michelle Cedillo was case specific. I was only referring to the medical evidence that I had reviewed regarding her. My opinion regarding Michelle Cedillo was not intended to be a blanket statement as to all children and all medical science. Second, as explained above, I specifically

explained to Mr. Matanoski and the other DOJ attorneys who were present that there were exceptions in which vaccinations could cause autism.

20. In my opinion, it was highly misleading for the Department of Justice to continue to use my original written expert opinion, as to Michelle Cedillo, as evidence against the remaining petitioners in the O.A.P. in light of the above referenced information which I explained to the DOJ attorneys while omitting the caveat regarding exceptions in which vaccinations could cause autism.

  
\_\_\_\_\_  
Andrew W. Zimmerman M.D.

State of Massachusetts

County of Worcester

Personally appeared before me, the undersigned Notary Public, Andrew Zimmerman M. D. with whom I am personally acquainted and who signed the foregoing Affidavit in my presence and, under oath stated that he had personal knowledge of the facts contained in the foregoing Affidavit and that those facts are true and correct.

Sworn and subscribed before me, the undersigned Notary Public, in and for the aforesaid State and County on this the 21<sup>st</sup> day of September, 2018.

Maxine Schmeidler  
Notary Public

My Commission expires: April 9, 2021



**MAXINE SCHMEIDLER**  
Notary Public  
Commonwealth of Massachusetts  
My Commission Expires  
April 9, 2021

**CURRICULUM VITAE**

**Date Prepared:** December 11, 2017

**Name:** Andrew W. Zimmerman, M.D.

**Office Address:** UMass Memorial Medical Center  
Dept. of Pediatrics  
55 Lake Ave. North  
Worcester, MA 01655

**Home Address:** 38 Daniels St.  
Hopedale, MA 01747

**Work Phone:** 508-856-3279

**Work E-Mail:** Andrew.Zimmerman@umassmemorial.org

**Work FAX:** 508-856-4287

**Place of Birth:** Harrisburg, PA

**Education**

1966	AB	Germanic Languages and Literatures	Princeton University
1970	MD	Medicine	Columbia University College of Physicians and Surgeons

**Postdoctoral training**

07/70-06/72	Intern, Resident	Pediatrics	C.S. Mott Children's Hospital University of Michigan Hospitals Ann Arbor, MI
07/74-06/77	Resident	Neurology	Johns Hopkins Hospital Baltimore, MD

**Faculty Academic Appointments**

01/77-08/82	Assistant Professor	Neurology Pediatrics	University of Connecticut School of Medicine
08/82-08/83	Associate Professor	Neurology Pediatrics	University of Connecticut School of Medicine
08/83-12/02	Clinical Associate Professor	Pediatrics	University of Tennessee School of Medicine

09/94-2010	Associate Professor	Neurology Psychiatry Pediatrics	Johns Hopkins University School of Medicine
10/10-present	Adjunct Associate Professor	Neurology	Johns Hopkins University School of Medicine
07/08-2012	Associate Professor	Epidemiology	Johns Hopkins Bloomberg School of Public Health
10/10-12/13	Associate Professor	Neurology Pediatrics	Harvard Medical School
12/13-present	Clinical Professor	Pediatrics & Neurology	University of Massachusetts Medical School

#### **Appointments at Hospitals/Affiliated Institutions**

01/77-08/83	Staff Physician	Pediatrics and Neurology	University of Connecticut Hospital Farmington, CT
08/83-12/02	Staff Physician	Pediatrics	University of Tennessee Hospital
08/83-08/94	Staff Physician	Pediatrics	East Tennessee Children's Hospital
08/83-08/94	Staff Physician	Pediatrics and Neurology	St. Mary's Hospital Knoxville, TN
09/94-2010	Staff Physician	Pediatric Neurology	Johns Hopkins Hospital
09/94-present	Staff Physician	Neurology and Developmental Medicine	Kennedy Krieger Institute Baltimore, MD
09/05-2010	Director of Medical Research	Center for Autism and Related Disorders	Kennedy Krieger Institute
2010-present	Courtesy Staff		Kennedy Krieger Institute
10/10-10/13	Director of Clinical Trials	Lurie Family Autism Center MGH LADDERS	MassGeneral Hospital for Children Lexington, MA
10/13 – present	Courtesy Staff	MGH Pediatric Neurology	Mass General Hospital for Children and Spaulding MGH Clinic, Sandwich, MA

**Other Professional Positions**

07/72-06/74	Clinical Associate in Pediatrics	Developmental and Metabolic Neurology Branch, NINDS, NIH
08/83-09/94	Partner	Knoxville Neurology Clinic Knoxville, TN
09/94-08/06	Chairman of Professional Advisory Board	East Tennessee Chapter Autism Society of America
2005-present	Founding Member and Chairman, Scientific Advisory Board Member, Board of Directors	Fetal Physiology Foundation <a href="http://www.fetalphysiologyfoundation.org">http://www.fetalphysiologyfoundation.org</a>
1985-2008	Examiner	American Board of Psychiatry and Neurology

**Major Administrative Leadership Positions**

07/91-08/94	Vice President of Medical Staff	East Tennessee Children's Hospital Knoxville, TN
10/03-06/06	President of Medical Staff	Kennedy Krieger Institute
09/83-08/94	Director, Oliver W. Hill Pediatric Neurology Laboratory (EEG)	East Tennessee Children's Hospital
05/85-06/96	President	Pedifutures, Inc. Oak Ridge, TN
06/06-01/07	Organizer, Autism and Immunology Conference	Autism Speaks
06/06-09/06	Symposium Organizer	Fetal Physiology Foundation
03/08-06/08	CME Conference Organizer	Fetal Physiology Foundation

**Committee Service**

1987	Panel member	NIH Consensus Development Conference on Neurofibromatosis
1996-1998	Pharmacy and Therapeutics Committee	Kennedy Krieger Institute
1998-2000	Health Information Committee	
2000-2006	Medical Staff Executive Committee	
2006-2010	Credentials Committee	

**Professional Societies**

1975	American Academy of Neurology	
1977	American Academy of Pediatrics 1998-2001	Member, Executive Committee Section on Neurology
1978	Child Neurology Society 1985-86, 1990-91 1987-88 1992-93 1998 2010 2012-15	Scientific Selection Committee Practice Committee Ethics Committee By-Laws Committee Membership Committee Scientific Selection Committee
1983	American Medical Association	
1996	Society for Neuroscience	
2001	Baltimore City Medical Society 2005-07 2005-10	Board Member Health, Education and Legislation Committee
2007	American Neurological Association 2010	Scientific Selection Committee
<b>Grant Review Activities</b>		
2005	Grant review	Scottish Rite Charitable Foundation Ad hoc member
2005-2009	Grant reviewer	Autism Speaks Ad hoc member
2007- 2009	Grant reviewer	Governor's Council for Medical Research and Treatment of Autism
2009	Grand Opportunities Grant Reviews	NIMH, NIH Ad hoc member
2009	Grant reviews	Autistica (Autism Speaks U.K.) Ad hoc reviewer
2009-2010	Grant reviewer	Fetal Physiology Foundation
2009-2010	Grant reviewer	Autism Treatment Network

2010 Ad hoc reviewer ZonMw (Dutch National Research Incentives Scheme)

### Editorial Activities

Ad hoc Reviewer:  
 New England Journal of Medicine  
 Pediatrics  
 Archives of Pediatrics  
 Journal of Pediatrics  
 Annals of Neurology  
 American Journal of Obstetrics and Gynecology  
 Journal of Autism and Developmental Disorders  
 Autism Research  
 Journal of Neuroimmunology  
 Journal of Neurovirology  
 Journal of Child Neurology  
 Biological Psychiatry  
 Brain Imaging and Behavior  
 Neurobiology of Disease  
 MIT Press (book proposal)  
 Neurotherapeutics  
 FASEB Journal

### Honors and Prizes

1966-70	E.J. Noble Foundation International Fellow	Columbia University	International Fellows Program
1970	Medical Student Research Award	Columbia University	
1977	Certificate of Excellence in Teaching	Johns Hopkins University School of Medicine	
2007	Distinguished Service Award	Baltimore Medical Society	

### Report of Funded and Unfunded Projects

1977-1979	Zinc incorporation during morphogenesis Charles H. Hood Foundation PI (\$25,000/year) The goal was to localize zinc by autoradiography in developing embryos, with emphasis on neural tube and CNS development.
1979-1982	Zinc transport in pregnancy United Cerebral Palsy Foundation

PI (\$50,000/year)

This was a study of plasma zinc and zinc transport proteins during pregnancy.

1979-1980

Histamine release in migraine

University of Connecticut Research Foundation

PI (\$20,000/year)

This was *in vitro* study of histamine release from lymphocytes of patients with migraine.

1986-1988

Cellular zinc uptake in neural tube defects

Physicians' Medical and Educational Research Foundation

University of Tennessee-Knoxville

PI (\$10,000/year)

The objective was to develop methods to determine zinc uptake by fibroblasts from patients with neural tube defects and controls.

1989

Ketamine anesthesia and PET in childhood autism

Physicians' Medical and Educational Research Foundation

University of Tennessee-Knoxville

PI (\$15,000)

This was a pilot study to replicate clinical observations of functional improvements in patients with autism following ketamine anesthesia.

1990-1994

Ketamine in autism

State of Tennessee Legislature grant

PI (\$50,000)

The objective was to study changes in behavior following ketamine anesthesia for PET and MRI in children with autism.

1996-1997

Lamotrigine in autism

Glaxo Wellcome Co.

PI (\$40,000/year)

The goal was to evaluate functional changes on treatment with lamotrigine, for its glutamate (NMDA) blocking properties.

1998

Excitatory and inhibitory neurotransmitter receptor expression and microglial status in autism

Autism Research Foundation

PI (\$10,000)

This was a pilot study to examine microglial activation in autism.

1998-1999

NCAM in autism

National Alliance for Autism Research

PI (\$75,000/year)

This was a study of Neural Cell Adhesion Molecule in autism.

- 1999-2000      CEB-1050 (amantadine) in autism  
Cerebrus, Ltd.  
Site PI in multisite study (\$30,000)  
This was a multisite study of amantadine for its glutamate blocking properties, to which our site contributed several subjects.
- 2001-2005      Fever in autism  
Cure Autism Now Foundation  
PI (\$75,000/year for 3 years)  
This was an extended study of behavioral improvements with fever in children with autism.
- 2005-2007      Maternal antibodies in autism  
National Alliance for Autism Research  
Co-PI (Harvey Singer, PI)  
This was a study of serum anti-brain antibodies in mothers of children with autism, based on preliminary data.
- 2007-2010      Maternal antibody binding to lymphocytes of offspring with autism  
The Hussman Foundation  
PI (\$50,000)  
This is a current study to examine techniques for the assessment of maternal antibody binding to lymphocytes from children with autism.
- 2008-2010      Hydroxyurea in the treatment of adolescents with autism: Preliminary safety and action study  
Anonymous Donor  
PI (\$40,000)  
This is a pilot grant for study planning and application for FDA and IRB approval for a trial of hydroxyurea in autism.
- 2011-2013      Clinical trial: Sulforaphane-rich Broccoli Sprout Extract for Autism.  
PI (\$250,000)  
This is a double blind, placebo-controlled trial to test the efficacy of sulforaphane in males with autism, 13-30 years of age.
- 2014-2016      Cytokine expression of lymphocytes in children with Autism Spectrum Disorder  
RapidLabs  
PI (\$100,000)  
A pilot study of in vitro cytokine expression in response to mitogens and new anti-inflammatory drugs.
- 2015-2018      Clinical trial: Sulforaphane treatment of children with Autism Spectrum Disorder  
Congressionally Mandated Research Program; Department of Defense  
PI (\$1,300,000)

A double blind, placebo-controlled clinical trial of sulforaphane in children with ASD, 3-12 years of age.

### **Current Unfunded Projects**

- 2008-present Maternal antibodies in autism; continuing longitudinal study of maternal antibodies to fetal brain in a cohort of mothers of children with autism.
- 2008-present Sickle cell disease and autism spectrum disorders  
This is an ongoing evaluation of CDC data from the multisite surveillance study of autism to determine if there is a decreased frequency of autism in persons with sickle cell disease.

### **Teaching of Students in Courses**

- |           |  |  |
|-----------|--|--|
| 1977-1983 | Neuroscience course<br>2 <sup>nd</sup> year medical students | University of Connecticut School of Medicine<br>1-hr lecture yearly on brain development and pediatric neurology         |
| 1995-2008 | Autism: science, clinical evaluation and treatment           | Kennedy Krieger Institute; Core course for trainees in neuropsychology, speech therapy, OT and PT; 1.5-hr annual lecture |

### **Formal Teaching of Residents, Clinical Fellows and Research Fellows**

- |           |   |  |
|-----------|---|--|
| 1983-1994 | Migraine in children<br>Treatment of epilepsy<br>Autism<br>Communication with patients<br>Neural tube and other CNS birth defects | University of Tennessee-Knoxville<br>Pediatric and family practice residents<br>1-hr lectures  |
| 2004-2008 | Medical evaluation and treatment of autism spectrum disorders   | Center for Autism and Related Disorders<br>Kennedy Krieger Institute<br>Recurring lectures to fellows, OT and SLP therapy trainees   |
| 1995-2005 | Autism and related disorders  | Johns Hopkins Hospital<br>Pediatric neurology, neurology and developmental medicine and pediatric residents<br>Biannual 1-hr lecture |
| 1997      | Evaluation of autism  | Pediatric residents' rounds  |
| 2002      | Neurology and autism  | Neurology residents' rounds  |
| 2005      | Asperger syndrome   | Invited lecture to neurology and developmental medicine fellows  |
| 2009      | Clinical observations and autism research   | Invited lecture to neurology and developmental medicine fellows  |
| 2015      | Clinical and lab research in autism: history and future   | Seminary on ASD for MDPHD students at UMass  |

**Clinical Supervisory and Training Responsibilities**

1977-1983	Inpatient and ambulatory pediatric neurology attending University of Connecticut	Daily clinic sessions and consulting service, teaching pediatric residents
1983-1994	Ambulatory pediatric neurology teaching of pediatric and family practice residents East Tennessee Children's Hospital and University of Tennessee	One session per week/1-2 monthly rotations of residents per year in office practice and hospital consultations
1994-2001	Inpatient attending Pediatric neurology service Johns Hopkins Hospital	Daily for 1 month/year
1994-2010	Ambulatory pediatric neurology Attending/Residents' clinic	One session per month
2004-2010	Ambulatory Developmental Medicine and Child Neurology Attending/Residents' clinic	One session every 6 weeks
2011-	Inpatient attending Pediatric neurology service Massachusetts General Hospital	Daily for 2 weeks/year
2010-	Ambulatory pediatric neurology	Weekly clinic sessions at MGH and 3 days/week at Lurie Center for Autism 3 sessions per week at UMass
2013-present	Resident and Student teaching in Autism (CANDO) and Pediatric Neurology Clinics	3 sessions per week + on service 1 week:4
2011-16	Supervision of Research Fellow Kanwaljit Singh, M.D.	Daily

**Formally Supervised Trainees and Faculty**

1980-1983	Jeffrey Rosenfeld, MD, PhD/Dept. of Neurology, Univ. of CA Fresno Thesis Committee member, Dept. of Neuroscience, University of CT, Storrs and Farmington, CT; published studies of copper in quaking mice.
1987-1990	Christopher A. Mann, PhD/Sleep medicine Thesis Committee member, Dept. of Psychology, Univ. of Tennessee, Knoxville; published study of topographic brain mapping as a diagnostic for ADHD

- 1991-1994 Michie O. Swartwood, PhD/Dept. of Psychology, SUNY  
Thesis Committee member, Dept. of Psychology, Univ. of TN; published study of effects of methylphenidate in ADHD
- 1991-1994 Jeffrey N. Swartwood, PhD/ Dept. of Psychology, SUNY  
Thesis Committee member, Dept. of Psychology, Univ. of TN; published study of neurophysiological differences between ADHD and Non-ADHD children
- 2002-2005 Amy E. Purcell, PhD/Attorney  
Thesis committee member, Dept. of Neuroscience, Johns Hopkins University School of Medicine
- 1997-2005 Laura K. Curran, PhD/Research Assistant, Kennedy Krieger Institute  
Thesis committee member and mentor, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health; published study of Behavioral Changes with Fever in Children with Autism
- 2007 Stephanie Darbre, MD, PhD/Elective during medical training at University of Geneva in study of cellular stress responses in autism (with AWZ and Kirby Smith, PhD); preparation for application to FDA for clinical trial of hydroxyurea in autism. Kennedy Krieger Institute and Johns Hopkins University
- 2006-2009 Katherine A. Bowers, PhD/Postdoctoral Fellow, NICHD, Epidemiology Branch  
Thesis committee member (alternate reviewer), Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health; publications being submitted on gene-environment interactions in autism.
- 2008-2012 Rebecca A. Harrington, PhD/doctoral thesis committee member  
SSRI use in pregnancy and autism in offspring  
Johns Hopkins Bloomberg School of Public Health
- 2016- Anita Panjwani /doctoral thesis committee member  
Johns Hopkins Bloomberg School of Public Health  
Sulforaphane clinical trial in ASD, in Bangladesh

**Formal Teaching of Peers (from 2002)**

- (No presentations below were sponsored by outside entities)
- 2002 Differential diagnosis of abnormal behavior (from a neurological perspective)  
Spectrum of Developmental Disabilities (CME course)  
Kennedy Krieger Institute / Johns Hopkins University School of Medicine  
Baltimore, MD
- 2003 Autism: Trends in patient management / Invited presentation  
Maryland Academy of Physician Assistants  
Baltimore, MD
- 2004 Immunology and autism / Invited presentation  
Autism Network lecture series, Kennedy Krieger Institute/Johns Hopkins

- 2005 Autism and Asperger Syndrome / Invited presentation  
Psychiatry Update; Sponsored by Johns Hopkins University  
New Brunswick, NJ
- 2006 Is autism an autoimmune disorder? / Invited presentation  
Autism Network lecture series, Kennedy Krieger Institute/Johns Hopkins
- 2006 Is there a role for the immune system in autism? / Invited presentation  
Spectrum of Developmental Disabilities (CME course)  
Kennedy Krieger Institute / Johns Hopkins University School of Medicine  
Baltimore, MD
- 2008 Maternal antibodies and autism / Invited presentation  
Autoimmunity Day / Johns Hopkins Bloomberg School of Public Health
- 2008 Selective mutism and Aicardi syndrome / Invited presentation  
Symposium on selective mutism  
American Academy of Child and Adolescent Psychiatry  
Chicago, IL
- 2012 Future directions in autism research / Invited presentation  
Special interest group in neurodevelopmental disorders  
Child Neurology Society

**Local Invited Presentations (from 2004)**

- (No presentations below were sponsored by outside entities)
- 2004 Neuropathology of autism spectrum disorders / Workshop presentation  
Epidemiology of Autism Spectrum Disorders  
Johns Hopkins Bloomberg School of Public Health
- 2006 Simulation of the beta-2 adrenergic receptor and its polymorphisms in autism  
Inaugural symposium of the Fetal Physiology Foundation  
Baltimore, MD
- 2007 Immunological aspects of autism / Invited presentation  
Workshop on autism research  
Kennedy Krieger Institute
- 2007 Autism and the environment / Invited presentation  
Workshop on autism research  
Kennedy Krieger Institute
- 2008 Fetal mechanisms in neurodevelopmental disorders / Conference organizer  
Fetal Physiology Foundation, sponsored by Kennedy Krieger Institute and  
NICHD; Johns Hopkins CME program
- 2008 Autism -- 2008 / Grand Rounds  
Department of Neurology, Johns Hopkins Hospital
- 2008 Cellular abnormalities: New approaches in autism research  
Research seminar organized for staff at Kennedy Krieger Institute  
and Johns Hopkins University  
Baltimore, MD
- 2008 Autism -- 2008 / Neurology Grand Rounds  
Johns Hopkins Hospital  
Baltimore, MD
- 2009 From hypotheses to theories in autism research / Pediatrics Grand Rounds

Johns Hopkins Hospital  
Baltimore, MD  
2009 Autism and maternal immunogenetic factors  
Baltimore Genetics Society  
Greater Baltimore Medical Center  
Baltimore, MD

**Regional, National and International Invited Teaching and Presentations (from 2002)**

(The presentations below sponsored by outside entities are so noted and the sponsors are identified)

2002 Medical and immune factors in clinical trials in autism / Invited presentation  
Symposium on clinical trials in autism; Cure Autism Now Foundation  
Santa Monica, CA

2002 Autism: An overview / Presentation to pharmaceutical company  
(Sponsored by Psychiatric Genomics, Inc.)  
Germantown, MD

2002 Neurobiology of autism / Invited presentation  
Autism symposium, Geisinger Medical Center  
Wilkes-Barre, PA

2003 Basic and clinical science of autism and related neurodevelopmental disorders  
Medical evaluation and treatment of autism spectrum disorders  
Care of the Sick Child Conference (CME)  
Arnold Palmer Children's Hospital  
Orlando, FL

2004 Autism's early signs / Invited presentation  
East Tennessee Children's Hospital  
Knoxville, TN

2004 Microglial activation in the brain in autism / Invited presentation  
The Autism Research Foundation  
Boston, MA

2004 Autism: What it is / Invited presentation  
Current Clinical Issues in Primary Care  
Hopkins/Harvard CME Program  
(Sponsored by PRI-MED)  
Washington, DC

2004 Autism: Current science and management / Invited Presentation  
Society for Pediatric Special Care Dentistry  
Banff, Canada

2005 Neuroinflammation and development of white matter / Invited presentation  
White Matter "Think Tank"  
Cure Autism Now Foundation  
Malibu, CA

2005 Immunology and autism / Invited presentation at annual conference  
Interdisciplinary Council for Development and Learning  
Washington, DC

2005 Immunology and autism / Invited presentation

- The Autism Research Foundation  
Boston, MA
- 2006 Serum antibrain antibodies in children with autism / Invited presentation  
The Autism Research Foundation  
Boston, MA
- 2006 Autism and Asperger syndrome / Grand Rounds  
Potomac Hospital  
Potomac, VA
- 2007 Clinical overview of autism / Autism Immunology Workshop (organizer)  
Autism Speaks / Cure Autism Now Foundation  
California Institute of Technology  
Pasadena, CA
- 2007 Maternal antibodies and placental-fetal IgG transfer in autism/Invited presentation  
The Autism Research Foundation  
Boston, MA
- 2008 Evidence for immune involvement in autism / Invited presentation  
Neuroimmunology, Brain Development and Mental Disorders  
NIMH Conference  
Washington, D.C.
- 2008 Placental-fetal transfer of maternal antibodies in autism / Invited presentation  
Autism Research Consortium  
Massachusetts General Hospital  
Boston, MA
- 2009 Effects of fever in autism / Invited presentation  
LADDERS Clinic, Massachusetts General Hospital  
Lexington, MA
- 2009 Fever, immune factors and synaptic function in autism / Invited presentation  
Autism symposium, Lucille Packard Children's Hospital, Stanford University  
Palo Alto, CA
- 2009 Immunological aspects of autism: Important questions  
Immunological aspects of autism: Curious findings / Invited presentations  
Weinberg Child Development Center, Safra Children's Hospital  
Sheba Tel Hashomer, Tel Aviv, Israel
- 2009 The fever effect and search for the holy grail in autism  
Effects of fever in autism: clues to pathogenesis and treatment  
Distinguished lecturers series, MIND Institute  
University of CA, Davis
- 2009 Autism: Challenge for our time / Medical staff presentation  
Anne Arundel Medical Center  
Annapolis, MD
- 2010 Fever and autism / Invited Presentation  
Workshop on effects of fever in autism  
Simons Foundation  
New York, NY
- 2010 Neurology of cognitive flexibility / Invited Presentation  
American Academy of Child and Adolescent Psychiatry

- New York, NY
- 2012 Current diagnosis, treatment and research / Invited Presentation  
Mary L. Hayleck, MD Memorial Lecture  
MedStar Union Memorial Hospital  
Baltimore, MD
- 2013 Current Autism Research; Autism Research Institute/Invited Presentation  
Annual meeting, Baltimore, MD
- 2014 Neuroinflammation in Autism/Invited Presentation  
International Child Neurology Congress, Foz do Iguassu, Brazil

#### **Current Licensure and Certification**

1994-present Maryland Medical License

2002-present Massachusetts Medical License

1976 American Board of Pediatrics

1979 American Board of Psychiatry and Neurology, with special competence in  
Child Neurology

1992 Continuing Education Recognition Certificate, American Academy of Neurology

#### **Practice Activities**

Discipline: Neurology, Pediatric neurology

1977-1983	Inpatient and outpatient	Adult neurology	On-call coverage
1977-1983	Inpatient and outpatient Consultations and follow up ambulatory care	Pediatric neurology University of CT	4 sessions per week Inpatient consultation service
1983-1994	Inpatient consultations and follow up	Adult neurology Knoxville (TN) Neurology Clinic (private practice)	1 day per week + on call
1983-1994	Inpatient and outpatient Consultations and follow up	Pediatric neurology Knoxville (TN) Neurology Clinic and Univ. of TN	5 days per week + on call
1983-1994	EEG dept. supervision	Pediatric Neurology East TN Children's Hospital, Knoxville	5 days per week + on call
1994-1997	Medical Director	Neurobehavior Unit	5 days per week

	Supervise medical care on inpatient unit	Kennedy Krieger Inst. Baltimore, MD
1994-2010	Inpatient and outpatient Ambulatory care	Pediatric neurology 4 sessions per week Kennedy Krieger Inst.
2010-2013	Outpatient care	Lurie Family Autism Center/LADDERS 4 sessions per week
2012-2013	Outpatient care	Pediatric neurology clinic/MGH 1 session/week
2013-present	Inpatient and outpatient	UMass Memorial Medical Center 4 days per week
2013-present	Volunteer Faculty	MGH Dept. of (Pediatric) Neurology Attending in Residents' Clinic 6/yr Outpatient care at Cape Cod clinic ½ day/month

### **Clinical Innovations**

Zinc nutrition in premature infants	Improvements in intravenous and oral zinc nutriture in prematurity developed nationally as the result of my study of acrodermatitis and zinc deficiency in premature infants; demonstrated anomalous zinc excretion in breast milk.
Immune dysfunction in autism	Fostered recognition of importance of immune system in autism through studies of autoimmune dysfunction in families, microglial activation in brain, maternal antibodies to fetal brain and behavioral improvements during fever.
Fever effects in autism and cell stress responses; treatment trials	Based on clinical observations of the beneficial effects of fever in some children with ASD, treatments, as well as lab studies have followed in collaboration with others, in clinical trials of sulforaphane in ASD.

### **Technological and Other Scientific Innovations**

Novel drug therapy for autism	U.S. Patent No. 4,994,467 Treating autism and other developmental disorders with NMDA receptor antagonists.
Novel use of primidone for treatment of apnea of prematurity	U.S. Patent No. 5,166,158 Method for the treatment of apnea and/or bradycardia (primidone).
Development of wireless EEG for rapid application and measurement	U.S. Patent No. 5,279,305

**Education of Patients and Service to the Community (from 2002)**

(No presentations below were sponsored by outside entities)

- 2002 Update on biology of autism  
East Tennessee Chapter, Autism Society of America  
Knoxville, TN
- 2002 Update on biology and drug therapy of autism spectrum disorders  
Cincinnati Children's Hospital  
Cincinnati, OH
- 2003 Immunology and autism / Invited presentation  
Current Trends in Autism  
Ontario, CA
- 2003 Immunology and autism: More than meets the eye / Invited presentation  
Symposium for families and professionals  
Queens University  
Kingston, Ontario
- 2004 Medical science and autism  
Parents' Day, Center for Autism and Related Disorders  
Kennedy Krieger Institute, Baltimore, MD
- 2005 Autism Research: Challenge of our time  
Maryland Chapter, Cure Autism Now Foundation  
Columbia, MD
- 2006 Effective use of medications for autism spectrum disorders  
Howard County Chapter, Autism Society of America  
Columbia, MD
- 2006 Autism research: Challenge of our time  
East Tennessee Chapter, Autism Society of America  
Knoxville, TN
- 2006 Recent trends in autism research / Invited presentation  
Baltimore City and County Chapter, Autism Society of America  
Baltimore, MD
- 2007 Immunology and autism / Invited presentation  
Association for Research in Autistic People  
Rhein-Neckar-Kraichgau; Heidelberg, Germany
- 2009 Genetic and immune abnormalities in autism / Invited presentation  
East Tennessee Chapter, Autism Society of America  
Knoxville, TN
- 2010 Autism -- 2010  
Ezra and Friends Foundation  
Vienna, VA

**Recognition**

- 1995 Distinguished service award  
East Tennessee Chapter, Autism Society of America

### Peer-reviewed Publications

1. Zimmerman, A.W. and Schmickel, R. Fluorescent bodies in maternal circulation. *Lancet (Letter)*, i:1305, 1971.
2. Zimmerman, A.W., Holden, K.R., Reiter, E.O., and Dekaban, A.S. Medroxyprogesterone acetate in the treatment of seizures associated with menstruation. *J. Peds.* 83:959-963, 1973.
3. Matthieu, J-M., Zimmerman, A.W., Webster, H deF, Ulsamer, A.G., Brady, R.O., and Quarles, R.H. Hexachlorophene intoxication: Characterization of myelin and myelin related fractions in rats during early postnatal development. *Exp. Neurol* 45:558-575, 1974.
4. Reier, P.J., Matthieu, J-M., and Zimmerman, A.W. Myelin deficiency in hereditary pituitary dwarfism: A biochemical and morphological study. *J. Neuropath Exp Neurol*, 34:465-477, 1975.
5. Zimmerman, A.W., Quarles, R.H., Webster H deF, Matthieu, J-M., and Brady, R.O. Characterization and protein analysis of myelin subfractions in rat brain. Developmental and regional comparisons. *J. Neurochem*, 25:749-757, 1975.
6. Zimmerman, A.W., Matthieu, J-M., Quarles, R.H., Brady, R.O., and Hsu, J.M. Hypomyelination in copper-deficient rats. Effects of prenatal and postnatal copper replacement. *Arch Neurol*. 33:111-119, 1976.
7. Zimmerman, A.W., Hodges, F.J., III, and Niedermeyer, E. Lennox-Gastaut syndrome and computerized tomography findings. *Epilepsia* 18:463-464, 1977.
8. Zimmerman, A.W., Kumar, A.J., Gadoth, N. and Hodges, F.J. III. Traumatic vertebrobasilar occlusive disease in childhood. *Neurology*, 28:185-188, 1978.
9. Sanders, W.M., Zimmerman, A.W., Mahoney, M. and Ballow, M. Histamine release in migraine. *Headache*, 20:307-310, 1980.
10. Holmes, C.L., Hafford, J., Zimmerman, A.W. Primary position upbeat nystagmus following meningitis. *Ann Ophthalmol*, 13:935-936, 1981.
11. Herson, V.C., Phillips, A.F., Zimmerman, A.W. Acute zinc deficiency in a premature infant after bowel resection and intravenous alimentation. *Am J Dis Child*, 135:968-969, 1981.
12. Hersh, J.H., Bloom, A.S., Zimmerman, A.W., Dinno, N.D., Greenstein, R.N., Weisskopf, B., and Reese, A.H. Behavioral correlates in the Happy Puppet Syndrome: A characteristic profile? *Devel Med Child Neurol*, 23:792-800, 1981.

13. Zimmerman, A.W., Hambidge, K.M., Lepow, M.L., Greenberg, R.T., Stover, M.L. and Casey, C.E. Acrodermatitis in breast-fed premature infants: Evidence for a defect of mammary zinc secretion. *Pediatrics*, 69:176-183, 1982.
14. Holmes, G., Rowe, J., Hafford, J., Schmidt, R., Testa, M. and Zimmerman, A.W. Prognostic value of the electroencephalogram in neonatal asphyxia. *Electroencephalogr Clin Neurophysiol* 53:60-72, 1982.
15. Simon, R.H., Zimmerman, A.W., Tasman, A., and Hale, M.S. Spectral analysis of photic stimulation in migraine. *Electroencephalogr Clin Neurophysiol*, 53:270-276, 1982.
16. Holmes, G.L., Blair, S., Eisenberg, E., Schneebaum, R., Margraf, J. and Zimmerman, A.W. Tooth brushing-induced epilepsy. *Epilepsia* 23:657-661, 1982.
17. Levinson, E.D., Zimmerman, A.W., Grunnet, M.L., Lewis, R.A. and Spackman, T.J. Cockayne Syndrome. *J Comput Assist Tomogr* 6:1172-1174, 1982.
18. Simon, R.H., Zimmerman, A.W., Sanderson, P. and Tasman, A. EEG markers of migraine in children and adults. *Headache* 23:201-205, 1983.
19. Holmes GL and Zimmerman AW: Temporomandibular joint pain-dysfunction syndrome: A rare cause of headaches in adolescents. *Dev Med Child Neurol* 25:601-605, 1983.
20. Rosenfeld J, Zimmerman AW and Friedrich, VL Jr. Altered brain copper and zinc levels in quaking mice. *Exp Neurol* 82:55-63, 1983.
21. Grunnet ML, Zimmerman AW, Lewis RA: Ultrastructure and electrodiagnosis of peripheral neuropathy in Cockayne syndrome. *Neurology* 33:1606-1609, 1983.
22. Zimmerman AW, Rowe DW: Cellular zinc accumulation in anencephaly and spina bifida. *Z für Kinderchirurgie* 38 (suppl II): 65-67, 1983.
23. Zimmerman AW: Hyperzincemia in anencephaly and spina bifida: A clue to the pathogenesis of neural tube defects? *Neurology* 34:443-450, 1984.
24. Zimmerman AW, Dunham BS, Kaplan BM, Nochimson DJ and Clive JM: Zinc transport in pregnancy. *Am J Obstet Gynecol* 149:523-29, 1984.
25. Holmes GL, Weber DA, Koczko N, Zimmerman AW: Relationships of endocrine function to inhibition of kindling. *Developmental Brain Research* 16:55-59, 1984.
26. Holmes, GL, Kloczko, N, Weber, DA, Zimmerman AW: Anticonvulsant effect of hormones on seizures in animals. In *Advances in Epileptology: XVth Epilepsy International Symposium*, ed Porter, R.V. Raven Press, New York, 1984, pp 265-268

27. Reeve, A., Schulman, S.A., Zimmerman, A.W., Cassidy, S.B. Methylphenidate therapy for aggression in a man with ring 22 chromosome. *Arch Neurol* 42:69-72, 1985.
28. Zimmerman, A.W., Banta J.V., Garvey, J.S. and Horak, E. Urinary excretion of zinc and metallothionein in children with spina bifida. *Pediatric Neurology* 1:23-27, 1985.
29. Madigan, R.R., Eisenstadt, M.L., Dougherty, J.H., Zimmerman, A.W. et al. A new technique to improve cortical-evoked potentials in spinal cord monitoring: A ratio method analysis. *Spine* 12:330-335, 1987.
30. Joshi, J.G., Cho, S., Fleming, J., Sczekan, S., Zimmerman, A.W. The effect of long term intake of low levels of aluminum on enzyme activity and brain ferritin./ Meeting on Trace Metals, Aging and Alzheimer's Disease, September 22-25, 1983. DHEW (NIH).
31. Cassidy, S.B., Sheehan, N.C., Farrell, D.F., Grunnett, M.L., Holmes, G.L. and Zimmerman, A.W. Connatal Pelizaeus-Merzbacher disease: An autosomal form. *Pediatric Neurology* 3:300-305, 1987.
32. Grunnet, M.L., Leicher, C., Zimmerman, A., Zalneraitis, E., and Barwick, M. Primary lateral sclerosis in a child. *Neurology* 39:1530-1532, 1989.
33. Zimmerman, A.W. and Lozzio, C.B. Interaction between selenium and zinc in the pathogenesis of anencephaly and spina bifida. *Z Kinderchir* 44 (Suppl 1): 48-50, 1989.
34. Myer, E., Morris, D.L., Brase, D.A., Dewey, W.L. and Zimmerman, A.W. Naltrexone therapy of apnea in children with elevated cerebrospinal fluid beta-endorphin. *Ann Neurol* 27:75-80, 1990.
35. McCarthy, V.P., Zimmerman, A.W., Miller, C.A. Central nervous system manifestations of parainfluenza virus type 3 infections in childhood. *Pediatr Neurol* 6:197-201, 1990.
36. Mann, C.A., Lubar, J.F., Zimmerman, A.W., Miller, C.A. and Muenchen, R.A. Quantitative analysis of EEG in boys with attention deficit hyperactivity disorder (ADHD): Controlled study with clinical implications. *Pediatric Neurology*, 8:30-36, 1992.
37. Miller CA, Gaylord M, Lorch V, Zimmerman AW: The use of primidone in neonates with theophylline resistant apnea. *AJDC* 147:183-186, 1993.
38. Zimmerman AW, Goss KC, Speckhart FH: Vestibular stimulatrion: A new device for off vertical axis rotation. *Inf Young Children* 6:56-67 1993.
39. Anderson ME, Zimmerman AW, Tayidi R, Frye V. Ergonovine toxicity in a newborn. *J Perinatol* 14:128-130, 1994.

40. Potter NT, Meyer MA, Zimmerman AW, Eisenstadt ML, Anderson IJ: Molecular and clinical findings in a family with dentatorubral-pallidoluysian atrophy. *Ann Neurol* 37:273-277, 1995.
41. Zimmerman AW, Bradley NN, Thornton DS, Zimmerman LN: Communication with patients: Skills that enhance healing. *J Tennessee Med Assn* 88:177-180, 1995.
42. Swartwood MO, Swartwood JN, Lubar JF, Timmermann DL, Zimmerman AW, Muenchen RA: Methylphenidate effects on EEG, behavior, and performance in boys with ADHD. *Pediatr Neurol* 18:244-250, 1998.
43. Hodes ME, Zimmerman AW, Aydanian A, Naidu S, Miller NR, Garcia Oller JL, Barker B, Aleck KkA, Hurley TD, Dlouhy SR: Different mutations in the same codon of the proteolipid protein gene, *PLP*, may help in correlating genotype with phenotype in Pelizaeus-Merzbacher disease/X-linked spastic paraplegia (PMD/SPG2). *Am J Med Genet* 82:132-139, 1999.
43. Comi AM, Zimmerman, AW, Frye VH, Law PA, Peeden JN: Familial clustering of autoimmune diseases and evaluation of medical risk factors. *J Child Neurol* 14:388-394, 1999.
44. Martin ER, Menold MM, Wolpert CM, Bass MP, Donnelly SL, Raven SA, Zimmerman A, Gilbert JR, Vance JM, Maddox LO, Wright HH, Abramson RK, DeLong GR, Cuccaro ML, Pericak-Vance MA: Analysis of linkage disequilibrium in gamma-aminobutyric acid receptor subunit genes in autistic disorder. *Am J Med Genet* 96:43-48, 2000.
45. Meyer MA, Zimmerman AW, Miller CA. Temporal lobe epilepsy presenting as panic attacks: detection of interictal hypometabolism with positron emission tomography. *J Neuroimaging* 10:120-122, 2000.
46. Belsito KM, Law PA, Kirk KS, Landa RJ, Zimmerman AW: Lamotrigine therapy for autistic disorder: A randomized, double-blind, placebo-controlled trial. *J of Autism and Developmental Disorders* 31:175-181, 2001 .
47. Purcell AE, Rocco MM, Lenhart JA, Hyder K, Zimmerman AW, Pevsner J: Assessment of neural cell adhesion molecule (NCAM) in autism. *J of Autism and Developmental Disorders* 31:183-194, 2001.
48. King BH, Wright DM, Handen BL, Sikich L, Zimmerman AW, McMahon W, Cantwell E, Davanzo PA, Dourish CT, Dykens EM, Hooper SR, Jaselskis CA, Leventhal BL, Levitt J, Lord C, Lubetsky MJ, Myers SM, Ozonoff S, Shah BG, Snape M, Shernoff EW, Williamson K, Cook EH Jr. Double-blind, placebo-controlled study of amantadine hydrochloride in the treatment of children with autistic disorder. *J Am Acad Child Adolesc Psychiatry* 40:658-665, 2001.

49. Purcell AE, Jeon OH, Zimmerman AW, Blue ME, Pevsner J: Postmortem brain abnormalities of the glutamate neurotransmitter system in autism. *Neurology* 57:1618-1628, 2001.
50. Pizzini F, Fatemi AS, Barker PB, Nague-Poetscher LM, Horska A, Zimmerman AW, Moser HW, Bibat G, and Naidu S: Proton MR spectroscopic imaging in Pelizaeus-Merzbacher disease. *AJNR Am J Neuroradiol* 24:1683-1689, 2003.
51. Anderson GW, Zimmerman AW, Akshoomoff N, Chugani DC: Autism clinical trials: Biological and medical issues in patient selection and treatment response. *CNS Spectrums* 9:57-64, 2004.
52. Vargas DL, Nascimbene C, Krishnan C, Zimmerman AW, Pardo CA: Neuroglial activation and neuroinflammation in the brain of patients with autism. *Ann Neurol* 57:67-81, 2005.
53. Zimmerman AW, Jyonouchi H, Comi AM, Connors SL, Milstien S, Varsou A, Heyes M. Cerebrospinal fluid and serum markers of inflammation in autism. *Pediatric Neurology* 33:195-201, 2005.
54. Connors SL, Crowell DE, Eberhart CG, Copeland J, Newschaffer CJ, Spence SJ, Zimmerman AW: Beta-2 Adrenergic receptor activation and genetic polymorphisms in autism: data from dizygotic twins. *J Child Neurol* 20:876-884, 2005.
55. Poling JS, Frye RE, Shoffner J, Zimmerman AW: Developmental regression and mitochondrial dysfunction in a child with autism. *J Child Neurol* 21:170-172, 2006.
56. Connors SL, Matteson KJ, Sega GA, Lozzio CB, Carroll RC, Zimmerman AW: Plasma serotonin in autism. *Pediatric Neurology* 35:182-186, 2006.
57. Singer HS, Morris CM, Williams PN, Yoon DY, Hong JJ, Zimmerman AW: Antibrain antibodies in children with autism and their unaffected siblings. *J Neuroimm.* 178:149-155, 2006.
58. Lee L-C, Zachary AA, Leffell MS, Newschaffer CJ, Matteson KJ, Tyler JD, Zimmerman AW. HLA-DR4 in Families with Autism. *Pediatric Neurology* 35:303-307, 2006.
59. Zimmerman AW, Connors SL, Matteson KJ, Lee L-C, Singer HS, Castaneda J, Pearce, DA. Maternal antibrain antibodies in autism. *Brain, Behavior and Immun* 21:351-7, 2007.
60. Cheslack-Postava K, Fallin MD, Avramopoulos D, Connors SL, Zimmerman AW, Eberhart CG, Newschaffer CJ. Beta-2 adrenergic receptor gene variants and risk for autism in the AGRE cohort. *Molecular Psychiatry* 12:283-91. Epub 2007 Jan 2.

61. Zerrate MC, Pletnikov M, Connors SL, Vargas DL, Seidler FJ, Zimmerman AW, Slotkin TA, Pardo CA. Neuroinflammation and behavioral abnormalities after neonatal terbutaline treatment in rats: implications for autism. *J Pharmacol Exp Ther* 322:16-22, 2007.
62. Woo EJ, Ball R, Landa R, Zimmerman AW, Braun MM; VAERS Working Group. Developmental regression and autism reported to the Vaccine Adverse Event Reporting System. *Autism* 11:301-10, 2007.
63. Curran LK, Newschaffer CJ, Lee L-C, Crawford SO, Johnston MV, Zimmerman AW. Behaviors associated with fever in children with autism spectrum disorders. *Pediatrics* 120(6):e1386-92, 2007.
64. Tesini D, Friedman C, Connors SL, Zimmerman AW. Autism. *J Am Dent Assoc.* 138:286-8, 2007.
65. Connors SL, Levitt P, Matthews SG, Slotkin TA, Johnston MV, Kinney HC, Johnson WG, Dailey RM, Zimmerman AW. Fetal mechanisms in neurodevelopmental disorders: Inaugural symposium of the Fetal Physiology Foundation. *Pediatric Neurology* 38:163-176, 2008.
66. Singer HS, Morris CM, Gause CD, Gillin PK, Crawford S, Zimmerman AW. Antibodies against fetal brain in sera of mothers with autistic children. *J Neuroimmunol.* 194:165-72, 2008.
67. Lee LC, Newschaffer CJ, Lessler JT, Lee BK, Shah R, Zimmerman AW. Variation in season of birth in singleton and multiple births concordant for autism spectrum disorders. *Paediatr Perinat Epidemiol.* 22:172-9, 2008.
68. Singer HS, Morris C, Gause C, Pollard M, Zimmerman AW, Pletnikov M. Prenatal exposure to antibodies from mothers of children with autism produces neurobehavioral alterations: A pregnant dam mouse model. *J. Neuroimmunol.* 211:39-48, 2009.
69. Morris CM, Zimmerman AW, Singer HS. Childhood serum anti-fetal brain antibodies do not predict autism. *Pediatr Neurol* 41:288-90, 2009.
70. Croen LA, Connors SL, Matevia M, Newschaffer CJ, Qian Y, Zimmerman AW. Prenatal exposure to  $\beta$ 2-adrenergic receptor agonists and risk of autism spectrum disorders. *J Neurodevel Disord* 3:307-15, 2011.
71. Close H, Lee L-C, Kaufmann CN, Zimmerman AW. Autism Spectrum Disorders: Co-Occurring conditions and change in diagnosis. *Pediatrics* 129:e305-16, 2012.
72. Schmidt K, Zimmerman AW, Bauman M, Ferrone C, Venter J, Spybrook J, Henry C. Brief Report: Asperger's syndrome and sibling birth order. *J Autism Dev Disord* (published online 080812).

73. Bressler J, Gillin PK, O'Driscoll C, Kiihl SF, Solomon M, Zimmerman AW. Maternal antibody reactivity to lymphocytes of offspring with autism. *Pediatric Neurology* 47:337-40, 2012.
74. Harrington RA, Lee LC, Crum RM, Zimmerman AW, Hertz-Picciotto I. Serotonin hypothesis of autism: Implications for selective serotonin reuptake inhibitor use during pregnancy. *Autism Research* 6:149-68, 2013.
75. Kadam SD, French BM, Kim ST, Morris-Berry CM, Zimmerman AW, Blue ME, Singer HS. Altered postnatal cell proliferation in brains of mouse pups prenatally exposed to IgG from mothers of children with autistic disorder. *J Exp Neurosci* 7:93-9, 2013.
76. Harrington RA, Lee LC, Crum RM, Zimmerman AW, Hertz-Picciotto I. Prenatal SSRI use and offspring with autism spectrum disorder or developmental delay. *Pediatrics* 133:e1241-8, 2014.
77. Lance EI, York JM, Lee LC, Zimmerman AW. Association between regression and self injury among children with autism. *Res Dev Disabil* 35:408-13, 2014
78. Singh K, Connors SL, Macklin EA, Smith KD, Fahey JW, Talalay P, Zimmerman AW. Sulforaphane treatment of autism spectrum disorder (ASD). *Proc Natl Acad Sci USA*. 111(43):15550-5, 2014
79. Singh K, Zimmerman AW. Sleep in Autism Spectrum Disorder and Attention Deficit Hyperactivity Disorder. *Semin Pediatr Neurol*. 2015 Jun;22(2):113-25. doi: 10.1016/j.spn.2015.03.006. Epub 2015 Mar 26. Review. PubMed PMID: 26072341.
80. Singh K, Zimmerman AW. Sulforaphane Treatment of Young Men with Autism Spectrum Disorder. *CNS Neurol Disord Drug Targets*. 2016;15(5):597-601. PubMed PMID: 27071786.
81. Choueiri RN, Zimmerman AW. New Assessments and Treatments in ASD. *Curr Treat Options Neurol*. 2017;9:6-24.

#### **Non-peer reviewed publications**

1. Zimmerman, A.W. Hormones in epilepsy: Recent research and new directions. In *Plan for Nationwide Action on Epilepsy, Vol II, Part 2*, pp. 323-322, Publication DHEW (NIH) 78-277, 1977.
2. Zimmerman, A.W. Hormones and Epilepsy. *Neurologic Clinics* 4(4), 853-61, 1986.
3. Joshi, J.G., Zimmerman, A.W. Ferritin: An expanded role in metabolic regulation. *Toxicology* 48:21-29, 1988.
4. Zimmerman, A.W., Frye, V.H., Potter, N.T. Immunological aspects

- of autism. *International Pediatrics*, 8:199-204, 1993.
5. Zimmerman, A.W., Alemzadeh, R., Eberle, A.J. Hormones in pediatric epilepsy. *International Pediatrics*, 8:272-9, 1983.
  6. Zimmerman, A.W. The learning-disabled child (hyperactivity/dyslexia). In: Johnson R.T., Griffin, J.W., *Current Therapy in Neurological Diseases*, 5th ed., St. Louis: Mosby-Year Book, Inc., 1997, pp 114-119.
  7. Zimmerman AW, Jinnah HA, Lockhart PJ. Behavioral Neuropharmacology. *Mental Retardation and Developmental Disabilities Research Reviews (MRDD)* 4:26-35, 1998.
  8. Zimmerman AW. The immune system in autism. *J Developmental and Learning Disorders* 3:3-15, 1999.
  9. Zimmerman AW, Myers SM. Magnesium, excitotoxicity, and growth of the neuropil in autism. *J Developmental and Learning Disorders* 3:147-159, 1999.
  10. Zimmerman AW, Gordon B. Neural mechanisms in autism. In: *Autism: Clinical and Research Issues*. Ed. Pasquale Accardo et al, York Press, 2000.
  11. Zimmerman AW, Bonfardin B, Myers SM. Neuropharmacological therapy in autism. In *Autism: Clinical and Research Issues*. Ed. Pasquale Accardo et al, York Press, 2000.
  12. Zimmerman AW. Commentary: Immunological treatments for autism: In search of reasons for promising approaches. *J Autism Devel. Disorders* 30:479-482, 2000.
  13. Zimmerman AW. Book Review: *The Biology of the Autistic Syndromes*, 3<sup>rd</sup> ed, by Christopher Gillberg and Mary Coleman. London: MacKeith Press, 2000. *Archives of Neurology* 59:486, 2002.
  14. Zimmerman AW. The Immune System. In: *The Neurobiology of Autism*, 2<sup>nd</sup> ed. Eds: M.L. Bauman and T. L. Kemper. Baltimore: The Johns Hopkins University Press, 2005, pp 371-386.
  15. Zimmerman AW. Autism spectrum disorders. In: *Treatment of Pediatric Neurologic Disorders*. Eds: H. S. Singer, E.H. Kossoff, A.L. Hartman and T. O. Crawford. Boca Raton, Florida: Taylor and Francis, 2005, pp. 489-494.
  16. Immunization Safety Review Committee, Institute of Medicine. *Immunization Safety Review: Vaccines and Autism (Reviewer)*. Washington, D.C.: The National Academies Press, 2004.
  17. Pardo CA, Vargas DL and Zimmerman AW. Immunity, neuroglia and neuroinflammation in autism. *Int. Rev. Psychiatry* 17:485-495, 2005.

18. Zimmerman AW. Autism. In: Johnson R.T., Griffin J.W., McArthur J.C., *Current Therapy in Neurological Disease*, 7th ed., Philadelphia: Mosby Elsevier, 2006, pp 111-114.
19. Zimmerman AW, Connors SL and Pardo CA. Neuroimmunology and Neurotransmitters in Autism. Chapter for Autism. (R. Tuchman and I. Rapin, eds.), International Child Neurology Association, 2006.
20. Bonfardin B, Zimmerman AW, Gaus V. Pervasive Developmental Disorders. In: Fletcher, R., Loschen, E., Stavrakaki, C., & First, M. (Eds.). *Diagnostic Manual -- Intellectual Disability (DM-ID): A Textbook of Diagnosis of Mental Disorders in Persons with Intellectual Disability*. Kingston, NY: NADD Press, 2007, pp 107-125.
21. Wied HM, Morrison PF, Gordon B, Zimmerman AW, Vining EP, Boatman DF. Cortical auditory dysfunction in childhood epilepsy: Electrophysiologic evidence. *Current Pediatric Reviews* 3:317-327, 2007.
22. Bukelis I, Porter FD, Zimmerman AW, Tierney E. Smith-Lemli-Opitz syndrome and autism spectrum disorder. Clinical case conference. *Am J Psychiatry* 164:11, 2007.
23. Eichler EE, Zimmerman AW. A hotspot of genetic instability in autism. *N Engl J Med* 358:737-9, 2008.
24. Zimmerman AW (Ed.). *Autism: Current Theories and Evidence*. Humana Press, 2008.
25. Witter FR, Zimmerman AW, Reichmann JP, Connors SL. In utero beta 2 adrenergic agonist exposure and adverse neurophysiologic and behavioral outcomes. *Am J Obstet Gynecol* 201:553-9, 2009.
26. Zimmerman AW, Connors SL (Eds.). *Maternal Influences on Fetal Neurodevelopment*. Springer, 2010.
27. Zimmerman, A. W., Connors, S.L. Neuroscience. Could autism be treated prenatally? *Science* 343:620-1, 2014.
28. Singh, K., Zimmerman, A.W. Sleep in Autism Spectrum Disorder and Attention Deficit Hyperactivity Disorder. *Semin Pediatr Neurol* 22:113-125, 2015.

**Abstracts and Poster Presentations (3 years)**

1. Ebens, C.L., Morris, C.M., Gause, C.D., Gillin, P, Lee, L-C, Singer, H.S., and Zimmerman, A.W. Parental age and maternal antibodies to fetal brain in autism. International Meeting for Autism Research (IMFAR) 2007.
2. Singer, H.S., Morris, C.M., Gause, C.D., Gillin, P., Lee, L-C, Zimmerman, A.W. Serum antibrain antibody differences in mothers of children with autistic disorder: A study with fetal human and rodent tissue. IMFAR 2007.

3. Priestley, B.J., Lee, L-C, Zimmerman, A.W. Effects of maternal and paternal age in singleton births with autism spectrum disorders (ASD). IMFAR 2007
4. Zimmerman, A.W., Zachary, A.A., Leffell, M.S., Matteson, K.J., Tyler, J.D., Lee, L-C. The frequencies of HLA-A and B antigens in families with autism. IMFAR, May 4, 2007
5. Zimmerman, A.W., Connors, S.L., Curran, L.K. Fever in Autism spectrum Disorders (ASD): Spontaneous reports. IMFAR, May 17, 2008.
6. Zimmerman, A.W., Lee, L.C., Baio, J., Keefer, J.R., Kirby, R.S., Newschaffer, C., Nicholas, J.S., Durkin, M., Zahorodny, W., Smith, K.D. Sickle cell disease and autism spectrum disorders. IMFAR, May 8, 2009.
7. Croen, L., Connors, S.L., Matevia, M., Newschaffer, C., Zimmerman, A.W. Prenatal exposure to beta 2-adrenergic receptor agonists and risk of autism spectrum disorders. IMFAR, May 8, 2009.
8. Harrington, R.A., Lee, L-C., Crum, R.M., Zimmerman, A.W., Hertz-Picciotto, I. Association between SSRI exposure during pregnancy with behavior and conditions among children with ASD. IMFAR, May 3, 2013.
9. Zimmerman, A.W., Singh, K., Connors, S.L. Citalopram treatment of young children with autism spectrum disorder (ASD): Correlation with maternal history of depression. International Congress of Child Neurology, Foz do Iguassu, Brazil, May 5, 2014.

### **Narrative Report**

My first passion was for the clinical care of children, then for investigation based on clinical observations in order to pursue underlying mechanisms of disease. In neurology I found a broad array of clinical and intellectual challenges. An early interest in aberrant brain development and trace metal metabolism at the University of Connecticut was followed by recognition of the importance of autism during 11 years of private practice in Knoxville, Tennessee, during which I continued to do research. First and foremost, I value direct clinical care as the foundation for investigation that leads to improved clinical care. This approach led to my appreciation of the importance of immune factors in autism, an area of research that continues to unfold. In the past several years I have been focusing on underlying cellular mechanisms that may contribute to autism and novel treatments. Over 16 years at Kennedy Krieger Institute and Johns Hopkins, I devoted 50% time to the clinical care of patients with autism and other neurodevelopmental disorders and epilepsy, 40% to research. Teaching (10%) of trainees has been a pleasure in academic environments, and I was honored to serve as president of the medical staff for 3 years. I have also co-founded the Fetal Physiology Foundation and served on the board. At MGH and the Lurie Center, I conducted a clinical trial of sulforaphane (broccoli sprouts extract) for the treatment of autism, in collaboration with Drs Kirby Smith and Paul Talalay at Johns Hopkins. This approach is based on the clinical observation of behavioral improvements in autism during

fever, and the stimulation of cellular stress responses (e.g., heat shock proteins) by sulforaphane. I moved to UMass (Worcester) in late 2013 and have been seeing patients and teaching both in the autism clinic as well as general pediatric neurology. I am currently running a clinical trial of sulforaphane in children with autism, funded by the DOD.

Clinical expertise in pediatric and behavioral neurology and innovative approaches to disease mechanisms and treatment best describe my area of excellence. I have several current collaborations with colleagues, including studies of maternal antibodies in autism, *in vitro* assays of cytotoxicity between mothers and their children with autism, epidemiological study of autism in sickle cell disease (a negative correlation) and cell signaling with genetic variants of the beta-2 adrenergic receptor. In our current clinical trial of sulforaphane in children, several collaborators are helping to study metabolic aspects of ASD as well as the effects of sulforaphane at the cellular level.

My role in teaching has included mentorship of several individuals who have entered the fields of pediatric neurology and autism. A few colleagues in neurology have become involved as leaders in autism in their areas of expertise at my urging, and have made important contributions to the field.

# Exhibit G

# AUTISM & ALUMINUM ADJUVANTS IN VACCINES

## How Aluminum Adjuvants in Vaccines Can Cause Autism



Published: August 18, 2017 (Version 1.0)

The Centers for Disease Control (CDC) asserts that vaccines and vaccine ingredients have been disproven as potential causes of autism. Statements by the CDC are generic and encompass all vaccines and vaccine ingredients. For example, the CDC states:

*“Vaccines Do Not Cause Autism”  
“There is no link between vaccines and autism.” “...no links have been found between any vaccine ingredients and autism spectrum disorder.” (CDC website, August 2017)*

These statements are not supported by available science. The CDC’s evidence supporting these statements is limited to the MMR vaccine (Taylor 2014), thimerosal preservative (Taylor 2014) and vaccine antigen exposure (DeStefano 2013).

Dr. Frank DeStefano of the CDC’s Immunization Safety Office is co-author of a paper (Glanz 2015) which states:

*“To date, there have been no population-based studies specifically designed to evaluate associations between clinically meaningful outcomes and non-antigen ingredients, other than thimerosal.”*

This statement applies to, among other vaccine ingredients, aluminum adjuvant. Studies of MMR vaccine cannot be used as evidence of safety for other vaccines, for example vaccines that contain aluminum adjuvant. The overly-broad, generic

assertions that no vaccines and no ingredients cause autism are thus not supported by scientific evidence. In fact, the CDC statements are contradicted by a large, consistent and growing body of scientific evidence, including:

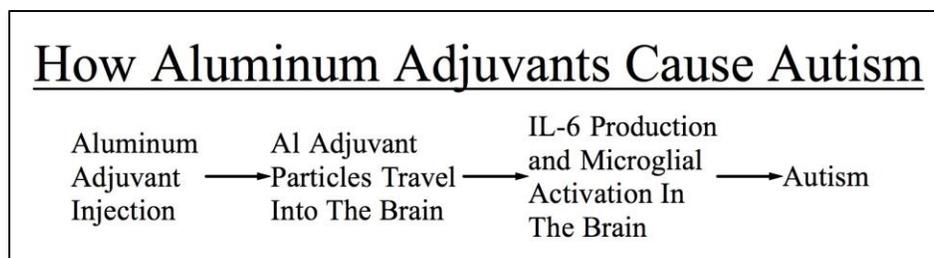
1) studies showing neurotoxic and neuroinflammatory effects (e.g. microglial activation) from dosages of aluminum adjuvants lower than or approximately equal to dosages received by infants according to the CDC vaccine schedule (Crepeaux 2017, Petrik 2007, Shaw 2013, Shaw 2009);

2) studies linking vaccines to immune activation brain injury (Zerbo 2016, Li 2015);

3) studies showing that early-life immune activation is a causal factor in autism and other neurodevelopmental disorders and mental illnesses (e.g. schizophrenia) (Meyer 2009, Deverman 2009, Estes 2016, Kneusel 2014, Careaga 2017, Meyer 2014).

The accumulating evidence indicates that vaccine-induced immune activation, and aluminum adjuvants in particular, may cause mental illnesses and neurodevelopmental disorders, including autism.

In this paper, we present scientific evidence that aluminum adjuvants can cause autism and other brain injuries. Also, we explain why the studies allegedly supporting the safety of aluminum adjuvants do not show safety for adverse neurological outcomes.



**Fig 1: Proposed mechanism for how aluminum adjuvants cause autism. Each step is supported by replicated scientific studies.**

## Immune Activation: A Cause of Autism and Mental Illness

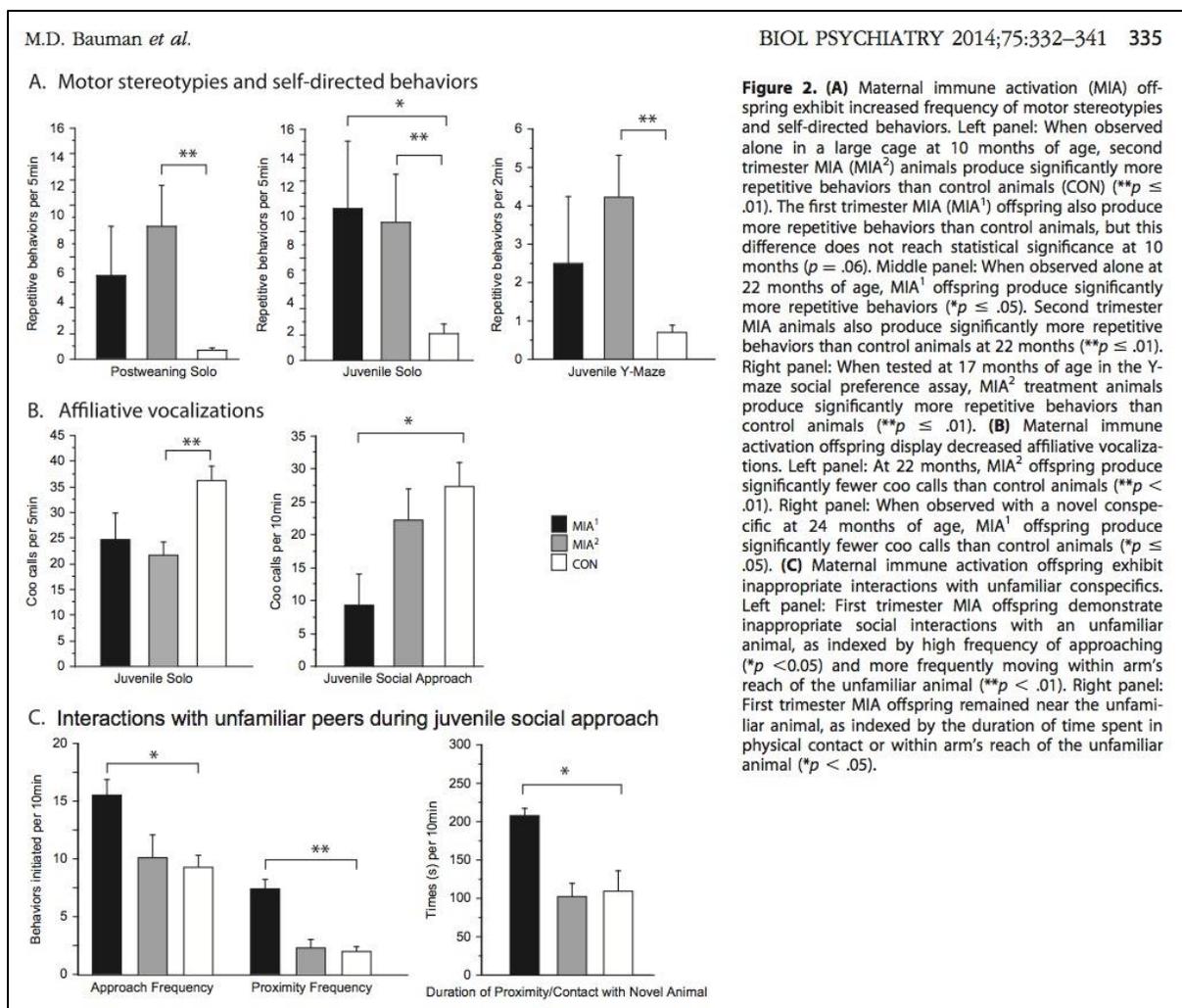
The term “immune activation” describes the activation of the cellular components of the immune system. The developing brain can be injured by immune activation, with life-long consequences (Meyer 2009, Deverman 2009, Estes 2016, Kneusel 2014, Careaga 2017, Meyer 2014). Immune activation injury is linked to autism, schizophrenia, depression and other mental illnesses or neurodevelopmental disorders. Immune activation effects on the brain are mediated by immune system signaling molecules, especially cytokines (Estes 2016, Meyer 2014, Smith 2007, Choi 2016, Pineda 2013).

It is generally accepted that immune activation (e.g., from infection) during pregnancy is a risk factor for autism and schizophrenia in the offspring (Ciaranello 1995, Atladottir 2010, Brown 2012). The intensity and duration of immune activation and cytokine expression appear to be important factors influencing autism risk (Meyer 2014). Intense immune activation is associated with greater risk of autism (Careaga 2017, Atladottir 2010). Chronic inflammation is associated with greater risk of autism (Jones 2016, Zerbo 2014). However, there is no evidence that short-duration, low-intensity

immune activation resulting from common childhood illnesses increase autism risk. Timing of immune activation in relation to stages of brain development is also an important factor (Meyer 2006, Meyer 2009).

Animal experiments have tested the effects of immune activation during pregnancy and postnatally on the development of offspring (Meyer 2009, Deverman 2009, Estes 2016, Kneusel 2014, Careaga 2017, Meyer 2014). In these experiments, pregnant animals (mice, rats and monkeys) or neonates are injected with a non-infectious immune activating substance such as “poly-IC” (which mimics a viral infection) or lipopolysaccharide (LPS, which mimics a bacterial infection). These substances cause immune system activation without infection. They induce fever and cytokine production and can have substantial effects on brain development if activation is sufficiently intense or prolonged and if exposure occurs during vulnerable developmental stages.

Immune activation has been demonstrated in mice to cause the three core behavioral symptoms of autism: decreased socialization and communication, and increased repetitive behaviors (Malkova 2012). Immune activation has also been shown to cause neuropathology (Weir 2015) and behavioral abnormalities in monkeys that resemble behaviors in human schizophrenia and autism (Bauman 2014, Machado 2015). See Fig. 2.



**Fig 2: Maternal immune activation in monkeys caused behavioral abnormalities in juvenile offspring resembling behaviors in both autism and schizophrenia. MIA<sub>1</sub> (Black)= first trimester immune activation; MIA<sub>2</sub> (grey) 2nd trimester immune activation; CON (white) saline control. From Bauman et al. 2014**

Immune activation also causes non-behavioral effects associated with human autism (citations here link immune activation with these effects):

- 1) reduction in Purkinje cells (Shi 2009);
- 2) mitochondrial dysfunction (Giulivi 2013);
- 3) increase in brain volume (from IL-6 exposure, Wei 2012(b)) and neuron density in the brain (Smith 2012);
- 4) long term chronic brain inflammation (Garay 2012); and
- 5) microbiome disruption (dysbiosis) (Hsiao 2013).

These non-behavioral similarities further support the relevance of the immune activation models to human autism. The non-behavioral (e.g., physiological) effects of immune activation have been reviewed (Labouesse 2015).

The cytokines interleukin-6 (IL-6) and interleukin-17a (IL-17) have been identified as mediating the behavioral effects of immune activation (Smith 2007, Malkova 2012, Choi 2016, Pineda 2013, Wei 2012(a), Wei 2013, Parker-Athill 2010, Wei 2016). The IL-6 findings have been replicated by different researchers using a variety of experimental methods. For example, in an experiment with

poly-IC, abnormal behavior is almost completely prevented by simultaneous administration of IL-6-blocking antibody (Smith 2007, Pineda 2013). Injection of IL-6 by itself causes abnormal behavior that closely matches behavior resulting from poly-IC immune activation (Smith 2007). Inhibition of IL-6 signaling in a genetic autism model (BTBR mice) normalized social and repetitive behavior (Wei 2016). These results demonstrate that IL-6 is responsible for causing abnormal autism-like behavior.

The Patterson laboratory at CalTech was the first to report that IL-6 is responsible for causing the autism-like behavioral effects of immune activation (Smith 2007). Two papers from this research group state:

*“IL-6 is central to the process by which maternal immune activation causes long-term behavioral alterations in the offspring.” (Smith 2007)*

*“...blocking IL-6 prevents >90% of the changes seen in offspring of poly(I:C)-injected females, showing that gene expression changes, as well as behavioral changes, are normalized by eliminating IL-6 from the maternal immune response.” (Smith 2007)*

*“IL-6 is necessary and sufficient to mediate these effects since the effects...are prevented by injection of pregnant mice with poly-IC combined with an anti-IL-6 antibody, and are mimicked by a single maternal injection of IL-6.” (Garay 2013)*

Brain exposure to elevated IL-6 by engineered virus showed that IL-6 exposure, initiated after birth, caused autism-like behaviors (Wei 2012(a)). The Wei 2012(a) paper states:

*“We demonstrated that IL-6 is an important mediator of autism-like behaviors. Mice with an elevated IL-6 in brain developed autism-like behaviors, including impaired cognition ability, deficits in learning,*

*abnormal anxiety-like trait and habituation, as well as a decreased social interaction initiated at later stages. These findings suggest that an IL-6 elevation in the brain could modulate certain pathological alterations and contribute to the development of autism.” (Wei 2012(a))*

More recent evidence shows that IL-17 acts downstream of IL-6 to cause autism-like behavioral abnormalities and atypical cortical development in mice (Choi 2016). Blocking either IL-6 or IL-17 prevents the autism-like behavior; an injection of IL-17 by itself causes the autism-like behavior (Choi 2016). IL-6 is known to induce IL-17 by promoting the development of Th17 cells which produce IL-17.

Immune activation animal models appear to be valid models for human neurological/psychiatric disorders, including autism (Estes 2016, Careaga 2017, Meyer 2014). The Estes 2016 review argues for the validity of the immune activation models to humans:

*“These MIA (maternal immune activation) animal models meet all of the criteria required for validity for a disease model: They mimic a known disease-related risk factor (construct validity), they exhibit a wide range of disease-related symptoms (face validity), and they can be used to predict the efficacy of treatments (predictive validity).” (Estes 2016)*

Evidence suggests a mediating role for IL-6 and IL-17 in human autism. For example, IL-6 is significantly elevated in the cerebellum in human autism (Wei 2011) and is highly elevated in some brain regions of some autistic individuals (Vargas 2005). Treatment of human autistics with the anti-inflammatory flavonoid luteolin improves autistic behaviors in the individuals that also experience a decline in IL-6 blood levels (Tsiloni 2015). This result is consistent with a causal role for IL-6 in human autism. Also, IL-17 is elevated in human autism (Akintunde 2015, Al-Ayadhi

2012, Suzuki 2011). Vitamin D reduces IL-17 production (Bruce 2011, Wobke 2014, Drozdenko 2014) and improves autistic behaviors in humans (Saad 2016, Jia 2015). The vitamin D findings are consistent with a causal role for IL-17 in human autism.

IL-6 functioning appears to be similar or identical in mice and humans. No mouse-human differences in IL-6 functioning are described in a 2004 review (Mestas 2004). IL-6 functioning is quite conserved across species (Brown 2014). Central nervous system development in rodents and humans is governed by the same principles (Brown 2014). Hence, the fact that IL-6 causes autism-like behavioral abnormalities in animal models deserves a presumption of validity to humans.

Immune activation is a risk factor for autism, schizophrenia and other neurological/psychiatric disorders. The cytokines IL-6 and IL-17 are responsible for mediating the autism-like behavioral effects of immune activation in the animal models. The available evidence supports a causal role for IL-6 and IL-17 in human autism.

## Maternal vs. Postnatal Immune Activation

---

The timing of immune activation is an important factor influencing effects on the brain. The developing brain is vulnerable to immune activation injury; the mature, adult brain is apparently not nearly as vulnerable. Sensitivity to immune activation likely declines as the brain matures (Meyer 2014, Meyer 2007).

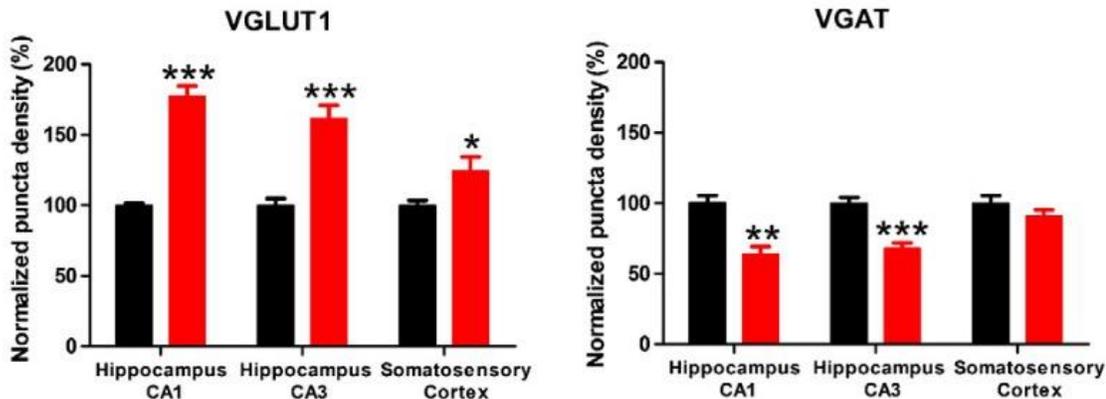
In most immune activation experiments, the offspring are exposed to immune activation during gestation (by stimulating the maternal immune system). In

contrast, most vaccines are administered postnatally. This raises the question of whether postnatal immune activation can have similar effects on the brain as maternal immune activation. Diverse evidence indicates that the brain can be adversely affected by postnatal immune activation. Postnatal immune activation experiments, human case reports, and consideration of brain development timelines suggest that the human brain is vulnerable to immune activation injury for years after birth.

In the maternal immune activation experiments, inflammatory signaling and some cytokines (e.g. IL-6) traverse the placenta into the fetus. Consequently, immune activation in the mother causes immune activation and elevated cytokines in the fetus, and in the fetal brain (Oskvig 2012, Ghiani 2011).

Postnatal immune activation can have adverse neurological effects, including increased seizure susceptibility (Chen 2013, Galic 2008), learning and memory deficits (Harre 2008), and an increase in excitatory synapse formation (Shen 2016). Seizure disorders, learning and memory dysfunction, and elevated excitatory signaling are associated with autism.

Elevated IL-6 in the brain in the postnatal period causes neuronal circuitry imbalance and mediates autism-like behaviors in mice (Wei 2012(a)). The circuitry imbalance observed in Wei 2012(a) was an excess of excitatory synapses and a deficit of inhibitory synapses. See Fig. 3. Excessive excitatory signaling is observed in human autism (Robertson 2016, Freyberg 2015). In fact, an imbalance between excitatory and inhibitory signaling (towards excess excitation) has been posited as a central characteristic of autism (Robertson 2016, Freyberg 2015).



**Fig 3: Elevation of IL-6 in the brains of mice (initiated shortly after birth) caused an increase in excitatory synapses (VGLUT<sub>1</sub>) and a decrease in inhibitory synapses (VGAT). Excessive excitatory signaling is observed in human autism. Red=Elevated IL-6; Black=Control. VGLUT<sub>1</sub>=excitatory synapses; VGAT=inhibitory synapses. \*P<0.05, \*\*P<0.01 and \*\*\*P<0.001. Adapted from Wei et al 2012(a).**

In a maternal immune activation experiment with mice (Coiro 2015), autism-relevant behavior and dendritic spine abnormalities (relevant to autism and schizophrenia) were ameliorated by administering an anti-inflammatory drug postnatally. The drug was started at birth and continued for 2 weeks, which roughly corresponds to age 2 in humans (Semple 2013). This result indicates that brain development is affected by postnatal inflammation, at times corresponding to when vaccines are given to humans.

Several case reports describe previously-healthy children that displayed sudden-onset autistic behavior during or subsequent to infection in the brain. All the cases had signs of intense brain inflammation. Here are brief descriptions:

*Delong 1981:* describes 3 children, ages 5, 7 and 11 with full-blown autistic behavior associated with brain inflammation. Brain inflammation was presumed in two cases and confirmed in one. The 5 and 7 year olds recovered completely, and the 11-year recovered partially.

*Marques 2014:* describes a previously healthy 32-month-old girl that

suffered autistic regression from a viral central nervous system infection with associated brain inflammation.

*Ghaziuddin 2002:* describes a previously healthy 11-year-old boy that suffered permanent autistic regression after sudden onset herpes brain infection with associated brain inflammation.

*Gillberg 1986:* describes a previously healthy 14-year-old girl with permanent autistic regression from herpes brain infection with associated brain inflammation.

The most parsimonious explanation for these cases is that autistic behavior resulted from intense inflammation and cytokine production in the brain. Accordingly, these cases indicate that the human brain remains vulnerable to immune activation injury well into childhood, though the vulnerability almost certainly decreases with maturation. The susceptibility of older children to inflammation-induced autistic behavior strongly suggests that younger infants, of 0-2 years of age, are also vulnerable. It is not reasonable to claim, and there is no evidence to suggest, that the age range of 0-2 years (when most vaccines are given) is uniquely resistant to immune activation

injury. All the available evidence indicates the opposite.

The immune activation experiments and case reports are consistent and indicate that immune activation and elevated cytokines in the postnatal period can cause brain injury.

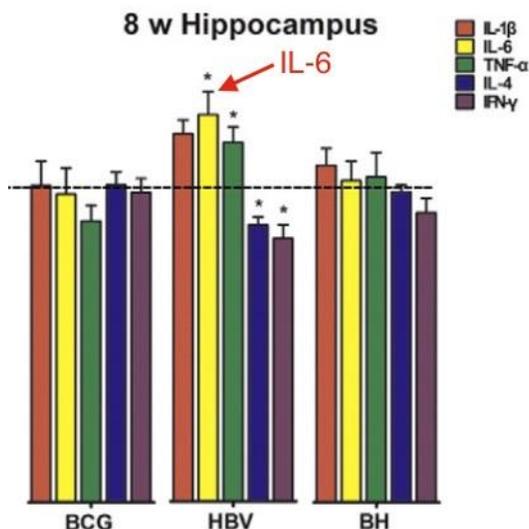
The next critical question to consider is whether vaccines can cause immune activation and elevated cytokines in the brain.

## Postnatal Vaccination Affects Brain Development in Animal Model

The first study to test the effect of postnatal vaccination on brain development was published in 2015 (Li 2015). In this

experiment, neonatal rats were administered bacillus calmette-guerin (BCG) vaccine, hepatitis B (HBV) vaccine or a combination (BCG+HBV) timed to imitate human infant vaccination schedules. BCG and HBV vaccines produced opposite effects on the brain. Specifically, BCG enhanced synaptic plasticity and long-term potentiation (LTP, the basis for learning and memory); HBV inhibited synaptic plasticity and LTP. BCG and HBV vaccines also caused opposite changes in some synapse protein levels.

HBV vaccine (but not BCG vaccine) increased IL-6 gene expression in the brain; increased gene expression likely indicates an elevation in brain IL-6. The HBV vaccine contains aluminum adjuvant, and the BCG does not contain aluminum adjuvant. Hence, the aluminum adjuvant may be the ingredient responsible for the elevated IL-6 gene expression. See Fig. 4.



**Fig. 4: Hepatitis B vaccine, but not BCG vaccine, increased IL-6 gene expression in the brain at 8 weeks after neonatal vaccination. Hepatitis B vaccine contains aluminum adjuvant; BCG vaccine does not. Elevated IL-6 causes autism-like behaviors in animal models. \*P<0.05 Adapted from Li et al 2015.**

The Li et al study showed that the vaccines caused other changes in the brain, including 1) changes in long-term potentiation (LTP) (Hep B decreased LTP), 2) changes in dendritic spines, and 3) changes in synapse protein expression. Changes in synapse

proteins and dendritic spines have been observed in human brain disorders.

Li et al. attribute the brain effects to changes in cytokine levels and immune polarization (Th1/Th2 polarization) induced by the vaccines. Aluminum adjuvants cause

Th2 polarization. Li et al. state that the results suggest vaccines can interact by way of immune activation effects:

*“...our data suggested that combinations of different vaccines can mutually interact (enhance or counteract). The mechanism of synaptic plasticity modulation through neonatal BCG/HBV vaccination may be via systemic Th1/Th2 bias accompanied by a specific profile of cytokines and neurotrophins in the brain.” (Li 2015)*

Li 2015 demonstrates that vaccines affect brain development by an immune activation mechanism. Further, since aluminum adjuvants induce Th2 activation and long term Th2 polarization, the Li 2015 results suggest that all aluminum-adjuvanted vaccines may cause adverse effects similar to the HBV vaccine. Accordingly, the Li 2015 results suggest that studies showing that immune activation causes neurological/psychiatric disorders are relevant to vaccine adverse effects.

## Vaccines Are Given During Synaptogenesis

---

Another way to answer the question of brain vulnerability to immune activation is to consider the types of brain development processes occurring when vaccines are administered. Vaccines are given primarily in the first 18 months after birth. The human brain undergoes intense and rapid development during this period. Synaptogenesis (formation of synapse connections between neurons) is especially intense in this period.

The vulnerability of the developing brain to immune activation is apparently related to the specific types of brain development processes occurring (Tau 2010, Meyer 2006, Meyer 2007). Such processes include migration (movement of neurons to

final locations in the brain), adhesion (formation of chemical-mechanical attachments between brain cells), and synaptogenesis (formation of synapse connections between neurons), among others (neurogenesis, gliogenesis, myelination etc).

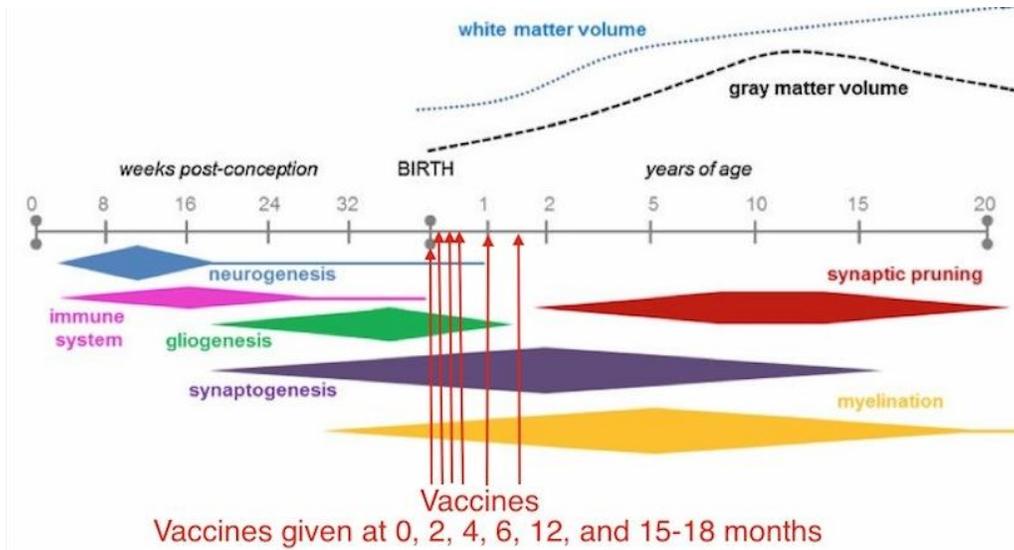
Cytokines affect brain development processes. For example, elevated IL-6 affects migration, adhesion and synaptogenesis (Wei 2011). Elevated IL-6 in the postnatal period promotes an excess of excitatory synapses and a deficit of inhibitory synapses, and mediates autism-like behaviors (Wei 2012(a)).

In humans, a dramatic increase in synaptogenesis begins around the time of birth, and continues until about age 3 (Huttenlocher 1997, Tau 2010, Stiles 2010, Semple 2013). Vaccines are administered during this intense synaptogenesis. See Figs. 5-6. Elevated brain IL-6 induced by vaccination during synaptogenesis may cause an excitatory-inhibitory imbalance, towards excitation. An excitatory imbalance has been observed in human autism (Robertson 2016, Freyberg 2015).

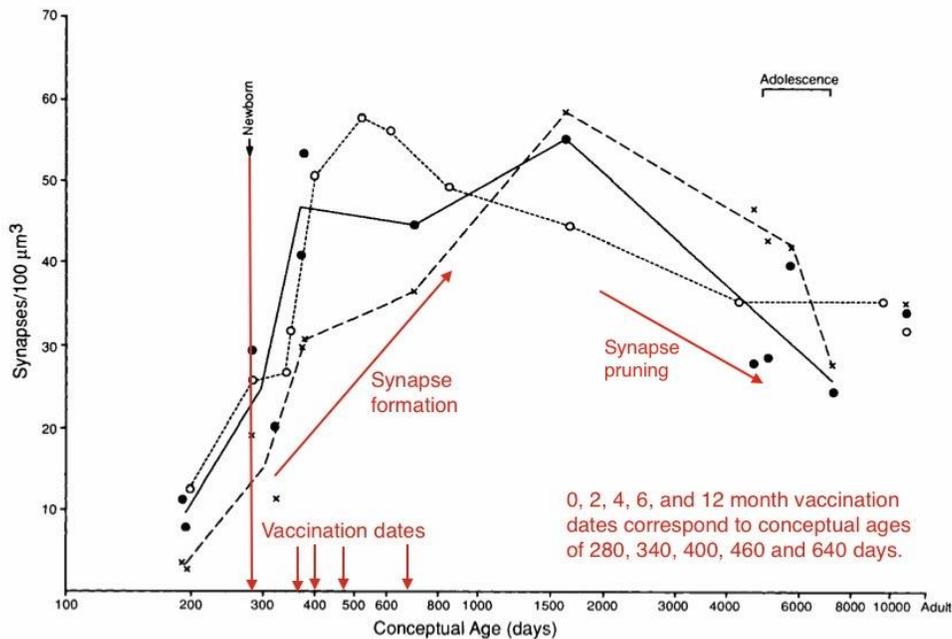
Synaptogenesis tapers off through childhood and adolescence. This fact may explain why some older children and teens can suffer autistic regression after intense brain inflammation, but apparently become less vulnerable to immune activation brain injury with age.

Intense synaptogenesis occurs at ages 0-18 months, when many vaccines are administered. Consequently, vaccines may adversely impact synaptogenesis if they induce inflammation or IL-6 in the brain.

The timing of brain development processes in humans supports the idea that the human brain is vulnerable to immune activation and cytokines in the first few years after birth, when vaccines are administered. Disruption of synaptogenesis by vaccine-induced immune activation is a particular concern.



**Fig. 5: Timeline of specific brain developmental processes in humans. Synaptogenesis is most intense during the first couple years of life, when vaccines are administered. Timing of vaccination according to the CDC vaccine schedule is shown. Elevated IL-6 during synaptogenesis may cause an excitatory-inhibitory synapse imbalance, towards excitation. Adapted from Semple 2013.**



**Fig. 2. Mean synaptic density in synapses/100 μm³ in auditory, calcarine, and prefrontal cortex at various ages. Open circles, visual cortex (area 17); filled circles, auditory cortex; x, prefrontal cortex (middle frontal gyrus).**

**Fig. 6: Measurements of synapse density in human cadavers of various ages indicate a dramatic increase in synapses in the first few years of life. Vaccines are administered during intense synapse formation. Elevated IL-6 during synaptogenesis may cause an excitatory-inhibitory synapse imbalance, towards excitation. Image adapted from Huttenlocher and Dabholkar 1997.**

## Aluminum Adjuvants: Neurotoxic At Vaccine Dosages

---

Aluminum (Al) adjuvants have an essential role in many vaccines: to stimulate immune activation. Without Al adjuvants, these vaccines would have greatly reduced efficacy.

Aluminum adjuvants comprise sub-micron particles (primary particles) of aluminum compounds, typically  $\text{Al}(\text{OH})_3$ ,  $\text{AlPO}_4$ ,  $\text{Al}_2\text{SO}_4$  or mixtures. The primary particles are typically agglomerated into larger particles with sizes of about 2-20 microns (Harris 2012). The Al adjuvant materials have low solubility in water and body fluids. Al adjuvant particles are biopersistent and can remain in the body for months or years (Flarend 1997, Khan 2013, Gherardi 2001).

Aluminum ingested in the diet has low oral absorption (about 0.3%), is rapidly excreted by the kidneys, is (mostly) excluded from the brain by the blood-brain barrier, and is in a solubilized,  $\text{Al}^{3+}$  ionic form (not particulate). These defenses are adequate for protecting the brain from natural levels of aluminum exposure. These protective mechanisms are unable to protect the brain from injected aluminum adjuvant particles. Al adjuvant particles are too large to be removed by the kidneys, and are carried across the blood-brain barrier by macrophages.

Dosages of aluminum adjuvants received by infants according to the CDC vaccination schedule are:

### **Birth (Hep B):**

74 mcg/kg (250 mcg for 3.4 kg infant)

### **2 month:**

245 mcg/kg (1225 mcg for 5 kg infant)

### **4 month:**

150 mcg/kg (975 mcg for 6.5 kg infant)

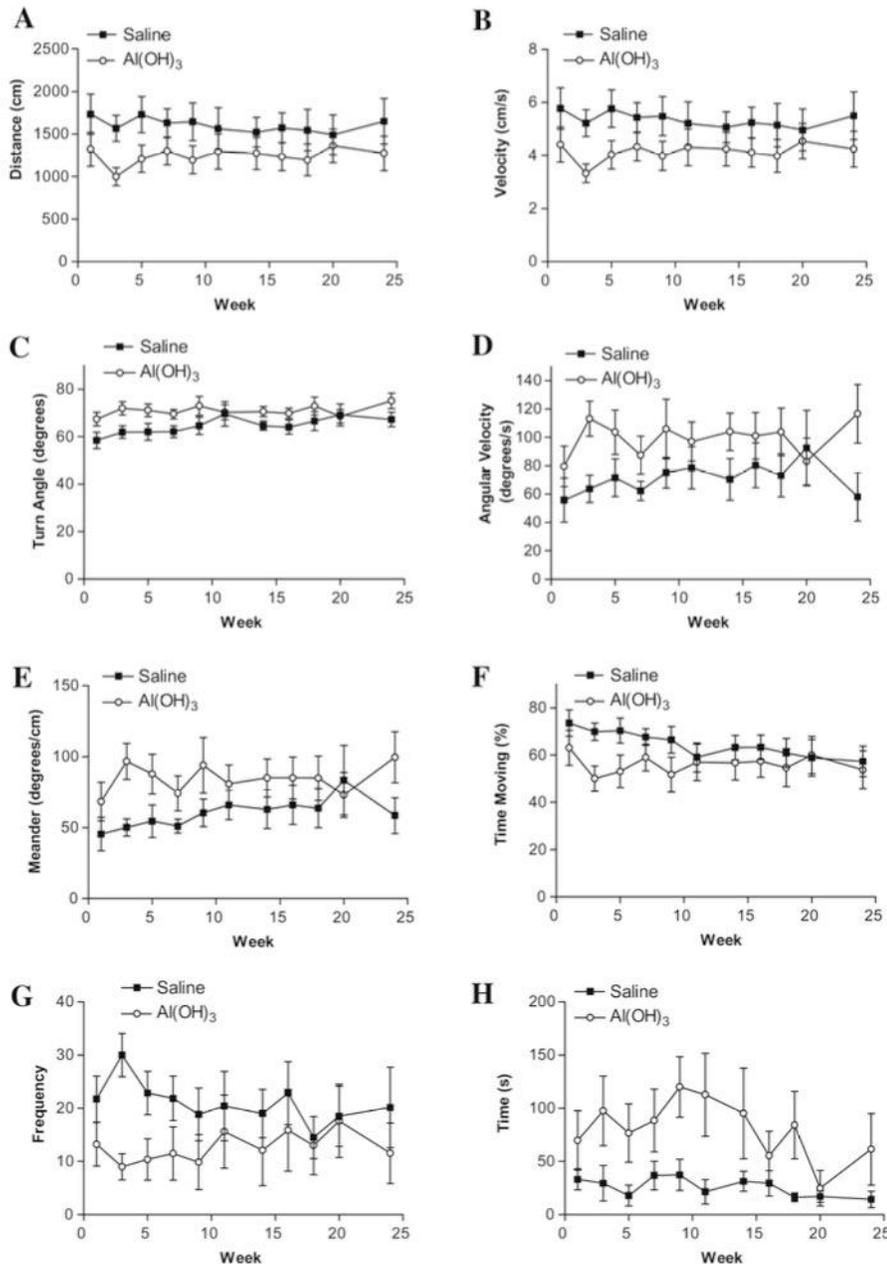
### **6 month:**

153 mcg/kg (1225 mcg for 8 kg infant)

These are maximum-possible dosages (because different vaccine products have different amounts) for average-weight infants.

Accumulating evidence shows that aluminum adjuvants have adverse neurological effects at dosages lower than or approximately equal to dosages infants receive from vaccines. These effects appear to depend on the particulate nature and biopersistence of the aluminum adjuvant. Injected Al adjuvant has adverse effects that are apparently mediated by the particles and independent of solubilized  $\text{Al}^{3+}$  ions released by the slowly dissolving particles (Crepeaux 2017).

Al adjuvant injections in mice cause adverse effects at vaccine-relevant dosages of 100, 200, 300 and 550 mcg/Kg body weight (Crepeaux 2017, Shaw 2009, Petrik 2007, Shaw 2013). These include deficits in learning and memory (Shaw 2009), deficits in neuromuscular strength/function (Petrik 2007), and changes in locomotor activity and/or gait (Shaw 2009, Shaw 2013). Autism is associated with gait and movement abnormalities (Kindregan 2015) and memory dysfunction (Williams 2006).



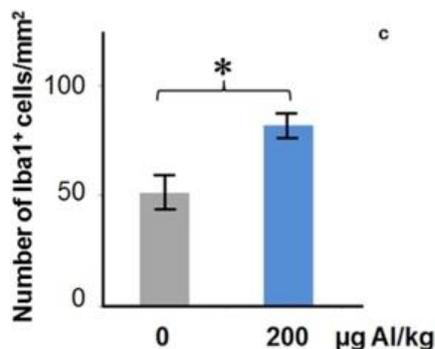
**Fig. 4.**

Open field movement analysis as an assessment of spontaneous activity and anxiety in control mice vs. mice injected six times with aluminum hydroxide. Aluminum hydroxide injected mice showed the following behavioural changes: (A) Shorter distances moved ( $***p < 0.0001$ ). (B) Slower movement ( $***p < 0.0001$ ). (C) Greater mean turn angle ( $***p < 0.0001$ ). (D) More rapid turning ( $***p < 0.0001$ ). (E) Greater meander ( $***p < 0.0001$ ). (F) Smaller percentage of time in overall movement ( $**p = 0.0030$ ). (G) Fewer entries into the centre of the open field ( $***p < 0.001$ ). Late entry into centre ( $***p < 0.0001$ ). (All measures, two-way ANOVA).

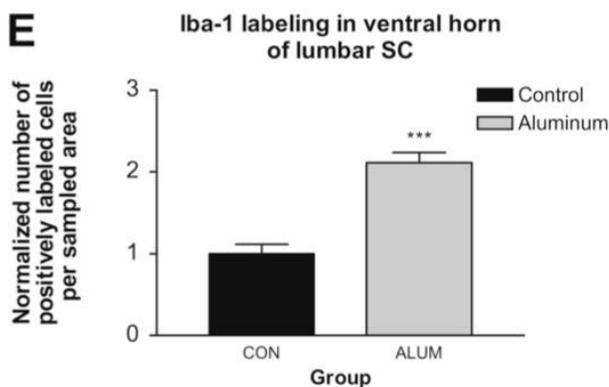
**Fig. 7: Dosage of 300mcg/Kg ALOH adjuvant caused large and persistent changes in exploratory behavior and movement in open field tests. This is an indicator of neurotoxicity. Human autistics also display abnormal movement and exploratory behavior. Adapted from Shaw and Petrik 2009.**

Al adjuvant dosages of 200mcg/Kg (as 3 x 66mcg/Kg) (Crepeaux 2017) and 300mcg/Kg (as 6 x 50mcg/Kg) (Shaw 2009) increased microglial activation in the ventral forebrain and lumbar spinal cord, respectively. The elevated microglial activation was measured about 6 months after Al adjuvant injection, which suggests that the

microglial activation is chronic. Activated microglia indicate an ongoing inflammatory process and suggest the presence of elevated cytokines. Human autistics have activated microglia and elevated cytokines throughout the brain (Vargas 2005, Suzuki 2013, Li 2009).



**Fig. 8: Al adjuvant (200mcg/Kg) caused an increase in microglial activation in the brain of mice. The protein iba1 indicates activated microglia. Measurements were performed 6 months after Al adjuvant injection, indicating that the microglial activation is a chronic condition. \* P<0.05. From Crepeaux et al., 2017.**



**Fig. 9: Al adjuvant (300mcg/Kg) caused an increase in microglial activation in the lumbar spinal cord of mice. The protein iba1 indicates activated microglia. Measurements were performed 6 months after Al adjuvant injection, indicating that the microglial activation is a chronic condition. \*\*\*p < 0.001, one-way ANOVA. From Shaw and Petrik 2009.**

Activated microglia are implicated as a causal factor in autism, because microglia mediate inflammation in the brain. Microglia can produce IL-6 when in an activated state. A recent review on microglia and autism (Takano 2015) states:

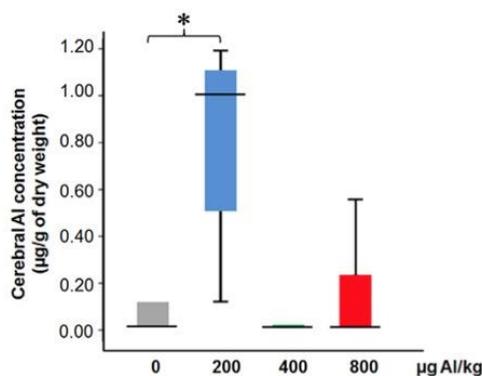
*“...any factors that alter the number or activation state of microglia either in utero or during the early postnatal period can profoundly affect neural development, thus resulting in neurodevelopmental disorders, including autism.” (Takano 2015)*

Microglia appear to play an important role in the causation of autism (Takano 2015, Kneusel 2014). Hence, the microglial activation caused by aluminum adjuvants suggests a role in autism.

Several studies show that Al adjuvants increase brain aluminum content (Crepeaux 2017, Flarend 1997, Shaw 2009, Khan 2013, Crepeaux 2015). A dosage of 200 mcg/Kg Al adjuvant caused a 50-fold increase in brain aluminum content in mice, from 0.02 ug/g to 1.00 ug/g dry weight of brain (Crepeaux 2017). These measurements were performed 6

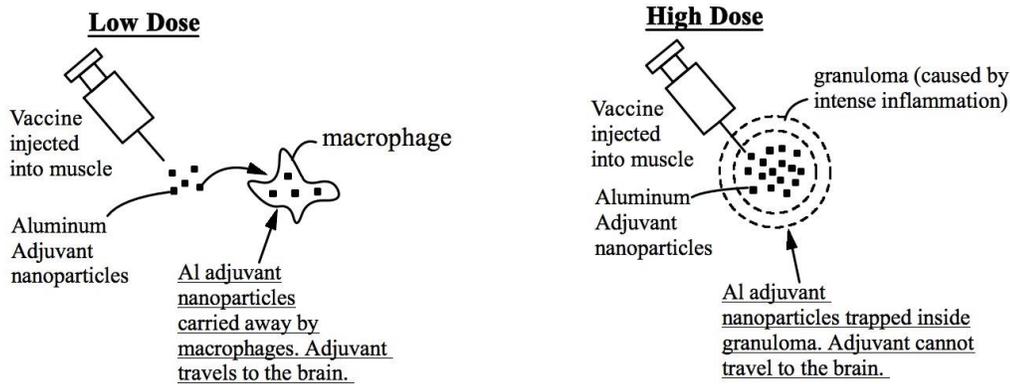
months after the final injection, indicating that the Al persists in the brain long-term (Crepeaux 2017). See Fig. 10. Al adjuvants have been found to accumulate in the brain of mice up to one year after injection (Khan 2013). Crepeaux 2015 demonstrated persistence and increasing accumulation of Al adjuvant particles up to 270 days in spleen and lymph nodes of mice. Increasing accumulation of Al in distant organs over time suggests that toxic effects may increase with time, and may be delayed by months or years after exposure.

The 400 and 800 mcg/Kg doses used in the Crepeaux 2017 study did not cause adverse effects or elevated brain aluminum. The authors attribute this surprising inverted dose-response relationship to granulomas induced by the higher dosages. Granulomas trap the Al adjuvant at the injection site, thereby preventing its transport into the brain and other sensitive tissues. Granulomas occur after about 1% of vaccinations (Bergfors 2014). This is cause for concern because it indicates that, for 99% of vaccinations, the Al adjuvant can be transported around the body. It is not confined to a granuloma. See Fig. 11.



**Fig. 10: Dosage of 200 mcg/Kg Al adjuvant caused a 50-fold increase in brain aluminum content, from 0.02 to 1.00 ug/g dry weight, in mice. Higher dosages (400 and 800 mcg/Kg) did not increase brain Al content, presumably because the higher dosages caused a granuloma at the injection site. A granuloma traps the Al adjuvant at the injection site, thereby preventing systemic dispersal and transport into the brain. These measurements were performed 6 months after the final injection, indicating that the Al persists in the brain long-term. \*P<0.05. From Crepeaux et al., 2017.**

## **Proposed Mechanism For Inverse Dose-Toxicity Relationship:**



**Fig. 11: High dose Al adjuvant injection into the muscle causes a granuloma, which traps the Al adjuvant and prevents it from traveling into the brain. Low dose does not form a granuloma. Hence, the lower dose is free to travel to the brain. Consequently, the lower dose is more toxic than the higher dose. This mechanism explains the surprising inverted dose-toxicity results of Crepeaux et al. 2017.**

## **Particle Transport and Macrophage Chemotactic Protein (MCP-1)**

Aluminum adjuvants travel into the brain (Khan 2013, Crepeaux 2015, Crepeaux 2017, Shaw 2009, Flarend 1997). Al adjuvant particles are carried through the blood-brain barrier and into the brain by macrophages (Khan 2013). Transport is promoted by macrophage chemotactic protein-1 (MCP-1) (Khan 2013). MCP-1 causes macrophages to travel around the body and into the brain. Particle transport into the brain by macrophages is well-established and has been investigated for therapeutic applications (Choi 2012, Pang 2016).

MCP-1 is elevated in the brains of human autistics (Vargas 2005) and is elevated in the blood of neonates later diagnosed with autism (Zerbo 2014). This suggests that neonates with high MCP-1 will experience elevated Al adjuvant transport into the brain when injected with Al adjuvanted vaccines. This is consistent with Al adjuvants causing autism by inducing immune activation and elevated cytokines in the brain.

## **Aluminum Induces IL-6 Expression In The Brain**

Water-soluble aluminum salts (e.g.  $\text{AlCl}_3$ , Al lactate) induce elevated IL-6 in the brain and other tissues. In fact, aluminum appears to selectively induce IL-6 (Viezeliene 2013). Studies of aluminum exposure and IL-6 expression in the brain include:

Cao 2016: Ingestion of 30 or 90 mg/kg/day aluminum (as  $\text{AlCl}_3$ ) for 90 days significantly increased gene expression of IL-6 and other cytokines in the brain (hippocampus).

Alawdi 2016: Ingestion of 3.4 mg/kg/day aluminum (as  $\text{AlCl}_3$ ) for 6 weeks caused a 4-fold increase in IL-6 in the brain (hippocampus). This dosage is far lower than the outdated “no observed adverse effects level” (NOAEL) oral dosages (26 and 62 mg/kg/day) used as benchmarks for toxicity threshold (Mitkus 2011, Offit 2003).

In fact, other experiments show that oral dosages of 3.4, 4, 5.6, 6, and 20.2

mg/Kg/day aluminum cause numerous adverse effects in mice or rats and hence the NOAEL for orally ingested Al is currently unknown (Alawdi 2016, Dera 2016, Sethi 2008, Sethi 2009, Bilkei-Gorzo 1993).

The induction of IL-6 may occur because aluminum strongly induces oxidative stress (Exley 2003). Oxidative stress induces IL-6 expression (Viezeliene 2013).

## **CDC Website Cites Fatally Flawed Study Of Al Adjuvants (Mitkus 2011)**

---

Dosages of Al adjuvants received by infants increased dramatically as the vaccine schedule was expanded in the 1980s and 1990s. However, as the vaccine schedule expanded, the increasing dosages of Al adjuvants were not tested for safety. Government agencies (HHS, NIH, CDC, FDA) have not pursued any new experimental work on Al adjuvant toxicity.

To support the safety of Al adjuvants at today's higher dosages, the CDC cites a 2011 FDA study of aluminum exposure from vaccines (Mitkus 2011). This study is the only scientific evidence cited by the CDC and FDA websites to support the safety of Al adjuvants.

The Mitkus 2011 study is a theoretical modeling study of Al adjuvant kinetics; it contains no new data concerning Al adjuvant toxicity (from animal models or epidemiology). Mitkus 2011 calculates a body burden of aluminum resulting from the slow dissolution of Al adjuvant particles, and compares the dissolved-aluminum body burden to a "minimal risk level" (MRL). The MRL is derived from a study of ingested Al toxicity in mice (Golub 2001). The Golub 2001 study provides the NOAEL (26 mg/kg/day ingested), which is converted into the MRL for human infants (based on 1mg/kg/day ingested) by using a safety factor of about 30.

The Mitkus study is fatally flawed for these reasons:

### **1) MITKUS ASSUMES AL ADJUVANT PARTICLES ARE HARMLESS**

Mitkus makes an unstated assumption that Al adjuvants have zero toxicity while in particulate form. Mitkus only considers the potential toxicity of aluminum ions (Al<sup>3+</sup>) released by the slowly-dissolving Al adjuvant particles.

Al adjuvants comprise low-solubility and biologically-persistent microscopic particles. The Mitkus analysis assumes that the particles are absolutely nontoxic and perfectly harmless, even when present in the brain and other organs. Mitkus provides no justification for this unstated assumption. Further, the assumption is contradicted by recent findings on Al adjuvant toxicity (Crepeaux 2017) and particulate toxicity generally. Particles can have toxic effects mediated by surface chemistry (e.g. surface charge and surface catalytic activity) and particle shape, among other characteristics of solid particles (Sharifi 2012, Podila 2013).

Several studies show injected Al adjuvants cause behavioral abnormalities, abnormal weight gain, learning and memory impairment, motor neuron death/apoptosis, neuromuscular strength deficits, chronic microglial activation/brain inflammation, and large (e.g. 50X) increases in brain and spinal cord aluminum content (Petrik 2007, Shaw 2009, Shaw 2013, Crepeaux 2017). These adverse effects occur at dosages less than or approximately equal to dosages received by infants according to the CDC vaccine schedule.

### **2) NEW RESEARCH SHOWS INGESTED AL HARMFUL AT DOSAGES LOWER THAN 26 MG/KG/DAY**

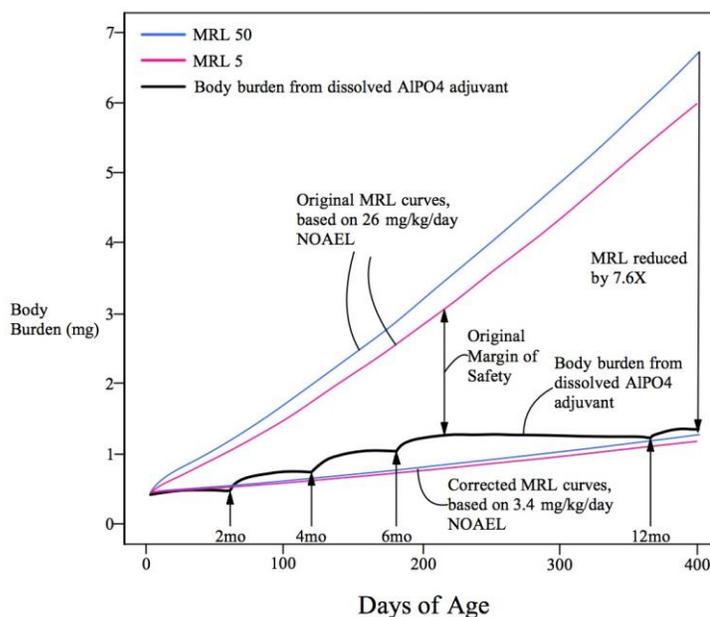
Mitkus assumes that Al adjuvant toxicity is mediated exclusively by solubilized Al (Al<sup>3+</sup> ions) released by the slowly-dissolving Al adjuvant particles. To establish a threshold toxicity level from the solubilized Al, Mitkus relies on a mouse feeding study (Golub 2001) reporting a "no-observed adverse effects level" (NOAEL) oral dosage of 26 mg/Kg/day ingested aluminum. Mitkus

used a 30X safety factor for applying this dosage to humans, which is reasonable.

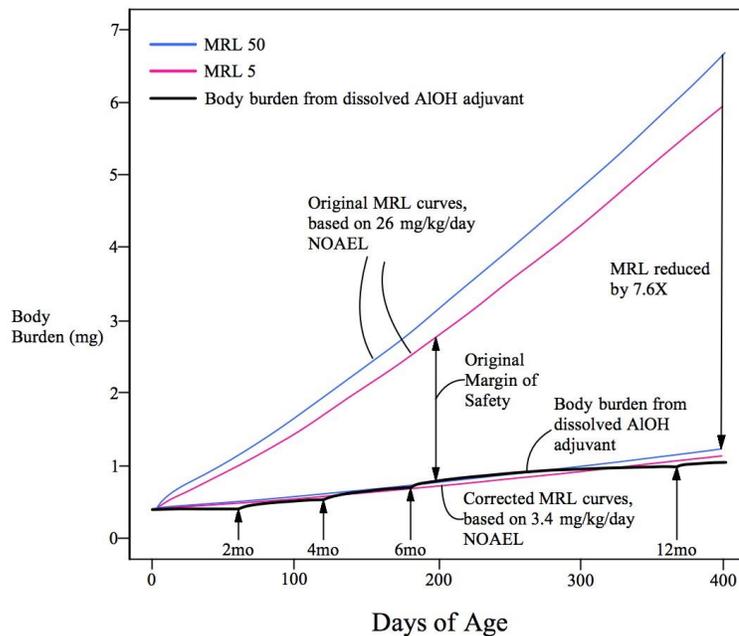
However, other experiments show that much lower oral dosages of 3.4, 4, 5.6, 6, and 20.2 mg/Kg/day aluminum cause adverse effects in mice or rats (Alawdi 2016, Dera 2016, Sethi 2008, Sethi 2009, Bilkei-Gorzo 1993). The adverse effects include chronic brain inflammation, learning and memory impairment, and kidney inflammation. So, the Mitkus analysis is wrong because 26 mg/kg/day is not a NOAEL. The “minimal risk level” (MRL) determined by Mitkus is too high by a factor of at least  $26/3.4 = 7.6$ . Using

a corrected NOAEL of 3.4 mg/Kg/day (based on Alawdi 2016) results in vaccine aluminum exposure exceeding the MRL for AlPO<sub>4</sub> adjuvant, and approximately matching the MRL for AlOH adjuvant. The new, corrected MRL lines indicate that Al phosphate adjuvant (Fig. 12) and Al hydroxide adjuvant (Fig. 13) from the CDC vaccine schedule may cause toxicity from the solubilized Al per se.

Since 3.4mg/Kg/day is not a NOAEL (adverse effects were observed at this dosage) the true NOAEL is less than 3.4/mg/Kg/day. See Figs. 12-13.



**Fig. 12: Body burden vs. MRL comparison chart for Al phosphate adjuvant (AlPO<sub>4</sub>) corrected in accordance with the new discovery (Alawdi 2016) that ingestion of 3.4 mg/kg/day Al causes adverse effects. The body burden exceeds the corrected MRL curve for almost the entire first year of life, indicating toxicity. The toxicity of Al adjuvant particles is a separate, additional issue. MRL 50 and MRL 5 refer to two different infant growth rates. Adapted from Mitkus et al., 2011.**



**Fig. 13: Body burden vs. MRL comparison chart for Al hydroxide adjuvant (AlOH), corrected in accordance with the new discovery (Alawdi 2016) that ingestion of 3.4 mg/kg/day Al causes adverse effects. The body burden overlaps the new, corrected MRL, indicating borderline toxicity. The margin of safety is gone. MRL 50 and MRL 5 refer to two different infant growth rates. The toxicity of Al adjuvant particles is a separate, additional issue. Adapted from Mitkus et al., 2011.**

### 3) NO AL ADJUVANT TOXICITY DATA CITED, DESPITE AVAILABILITY

Mitkus does not cite any toxicity data for injected Al adjuvants. Mitkus instead uses toxicity data for ingested, non-particulate, water-soluble Al (Golub 2001, which used Al lactate) to derive the MRL. This data comes from a single study (Golub 2001).

So, remarkably, Mitkus claims a safe level of injected Al adjuvant exposure, without citing any Al adjuvant toxicity data. The error is unnecessary and neglectful because at least two animal studies of injected Al adjuvant toxicity were available prior to the Mitkus publication in 2011 (Petrik 2007, Shaw 2009). These papers were not cited or mentioned by Mitkus 2011.

Each of these three flaws is fatal for the validity of the Mitkus study in establishing the safety of aluminum adjuvants. Hence, the CDC is completely lacking valid evidence for the

safety of Al adjuvants. This is especially true for safety regarding neurological and long-term outcomes, because other available studies of Al adjuvant safety (e.g., Jefferson 2004) do not consider (or are incapable of detecting) these outcomes.

## CDC Fails To Investigate Toxicity of Al Adjuvants

The CDC has conducted no epidemiological studies on long term safety (e.g. considering neurological outcomes) of Al adjuvants. There is one ecological study of country-level data, which reported an association between Al adjuvant exposure and autism (Tomljenovic 2011). However, being an ecological study, it is highly susceptible to confounding and biases.

Dr Frank DeStefano of the CDC's Immunization Safety Office is co-author of a

feasibility study (Glanz 2015) on using the Vaccine Safety Datalink (VSD) to investigate the safety of individual vaccine ingredients. The paper focuses on Al adjuvants. It acknowledges that thimerosal is the only vaccine ingredient studied for autism or neurological safety, and that a possible association between Al adjuvants and autism has not been explored in epidemiological studies. Glanz 2015 states:

*“To date, there have been no population-based studies specifically designed to evaluate associations between clinically meaningful outcomes and non-antigen ingredients, other than thimerosal.”*

The CDC has not investigated Al adjuvant safety concerns, despite the accumulating scientific evidence of harm and evidence linking Al adjuvants to immune activation mechanisms of brain injury.<sup>1</sup>

## Conclusion

---

The science reviewed here tells a consistent and compelling story: that vaccines may cause autism by stimulating immune activation and elevated cytokines in the brain. Al adjuvants are implicated as a cause of autism because they can be transported into the brain, because they cause microglial activation at vaccine-relevant dosages, and because aluminum induces IL-6 in the brain.

In statements asserting no vaccine-autism link, the CDC cites scientific evidence that is not relevant to Al adjuvant safety or is incapable of disproving an Al adjuvant-autism link (Taylor 2014, DeStefano 2013, Mitkus 2011). In support of claims for Al adjuvant safety, the CDC relies on a profoundly flawed theoretical modelling study (Mitkus 2011). There is little scientific evidence supporting the safety of Al adjuvants, especially in relation to autism and other long term neurological outcomes.

---

<sup>1</sup> However, the Glanz paper notes that studies of aluminum adjuvants are problematic because of expected small differences in exposures in the low and high exposure groups. Glanz 2015 concludes: “...children below the 10th percentile would be exposed to between 0 mg and 3.1mg, while children above the 90th percentile would be exposed to between 4.8 mg and 5.3 mg of aluminum from vaccines. It is unclear if such differences in aluminum exposure would be biologically meaningful.” (Glanz 2015). So, epidemiological studies may not provide reliable evidence for safety or harm. Controlled, prospective human trials of aluminum adjuvant exposure from vaccines will likely be prohibited for ethical reasons. Also, Al adjuvants are essential ingredients for Al adjuvanted vaccines. Consequently, it will be

challenging to design studies of long term adverse effects of Al adjuvants in humans. Experiments in animal models can provide valuable information. Al adjuvants should be tested for effects on: 1) excitatory/inhibitory imbalance; 2) core symptoms of autism (social, communicative and repetitive/stereotyped behaviors); 3) IL-6, IL-17, and other cytokine levels in the brain; 4) other physiological abnormalities associated with autism (e.g. mitochondrial dysfunction, microbiome dysbiosis, Purkinje cell loss, cerebellum abnormalities etc); and 5) microglial activation and immune activity in the brain. Investigating these outcomes can provide valuable information concerning the safety of Al adjuvants.

## References

---

Akintunde et al., 2015 Increased production of IL-17 in children with autism spectrum disorders and co-morbid asthma, *Journal of Neuroimmunology* 286 (2015) 33-41.

Al-Ayadhi et al., 2012 Elevated serum levels of interleukin-17A in children with autism, *Journal of Neuroinflammation* 2012, 9:158.

Alawdi et al., Neuroprotective Effect of Nanodiamond in Alzheimer's Disease Rat Model: a Pivotal Role for Modulating NF- $\kappa$ B and STAT3 Signaling, *Molecular Neurobiology*, 54 (3):1906-1918.

Atladdottir et al., Maternal infection requiring hospitalization during pregnancy and autism spectrum disorders, *Journal of Autism and Developmental Disorders*, 2010 Dec;40(12):1423-1430.

Bauman et al., 2014 Activation of the Maternal Immune System During Pregnancy Alters Behavioral Development of Rhesus Monkey Offspring, *Biological Psychiatry*, 2014;75: 332-341

Bergfors et al., 2014 How common are long-lasting, intensely itching vaccination granulomas and contact allergy to aluminium induced by currently used pediatric vaccines? A prospective cohort study, *European Journal of Pediatrics*, 173:1297-1307.

Bilkei-Gorzo, 1993, Neurotoxic effect of enteral aluminum, *Food and Chemical Toxicology*, 31(5):357-361.

Brown et al., 2014 Metabolic consequences of interleukin-6 challenge in developing neurons and astroglia, *Journal of Neuroinflammation*, 11:183.

Brown et al., Epidemiologic studies of exposure to prenatal infection and risk of schizophrenia and autism, *Developmental Neurobiology*, 2012 October ; 72(10): 1272-1276.

Bruce et al., 2011 Converging pathways lead to overproduction of IL-17 in the absence of vitamin D signaling, 2011 Aug; 23(8): 519-528.

Careaga et al 2017 Maternal Immune Activation and Autism Spectrum Disorder: From Rodents to Nonhuman and Human Primates, *Biological Psychiatry*, March 1, 2017; 81:391-401.

Chen et al., Postnatal systemic inflammation exacerbates impairment of hippocampal synaptic plasticity in an animal seizure model, *Neuroimmunomodulation*, 2013;20(4):223-32.

Choi et al., 2012, Delivery of nanoparticles to brain metastases of breast cancer using a cellular Trojan horse, *Cancer Nanotechnology*, 3:47-54.

Choi et al., 2016 The maternal interleukin-17a pathway in mice promotes autismlike phenotypes in offspring, *Science*, 2016 Feb 26; 351(6276): 933-939.

Ciaranello et al The Neurobiology of Infantile Autism, *The Neuroscientist*, 1:361-367

Coiro et al., Impaired synaptic development in a maternal immune activation mouse model of neurodevelopmental disorders, *Brain, Behavior, and Immunity*, Nov;50:249-258.

Crepeaux et al., 2015 Highly delayed systemic translocation of aluminum-based adjuvant in CD1 mice following intramuscular injections, *Journal of Inorganic Biochemistry*, 152:199-205.

Crepeaux et al., 2017 Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective low dose neurotoxicity, *Toxicology*, 375 (2017) 48-57.

DeLong et al., 1981 Acquired reversible autistic syndrome in acute encephalopathic illness in children, *Archives of Neurology*, 36:191-194.

Dera 2016, Protective effect of resveratrol against aluminum chloride induced nephrotoxicity in rats, *Saudi Medical Journal*, 37 (4).

DeStefano et al., 2013 Increasing Exposure to Antibody-Stimulating Proteins and Polysaccharides in Vaccines Is Not Associated with Risk of Autism, *The Journal of Pediatrics*, 163 (2).

Deverman and Patterson, 2009 Cytokines and CNS Development, *Neuron* 64:61-78.

Drozdenko et al., 2014 Oral vitamin D increases the frequencies of CD38+ human B cells and ameliorates IL-17-producing T cells, *Experimental Dermatology*, 23: 107-112.

Estes and McAllister, 2016 Maternal immune activation: implications for neuropsychiatric disorders, *Science*, 353 (6301) 772-777.

Exley, 2003 The Pro-Oxidant Activity of Aluminum, *Free Radical Biology and Medicine*, 36(3): 380-387.

Flarend et al., 1997 In vivo absorption of aluminum-containing vaccine adjuvants using 26 Al, *Vaccine*, 15(12/13):1314-1318.

Freyberg et al., 2015 Reduced perceptual exclusivity during object and grating rivalry in autism, *Journal of Vision*, 15(13):11, 1-12.

Galic et al., 2008 Postnatal Inflammation Increases Seizure Susceptibility in Adult Rats, *The Journal of Neuroscience*, 2008, 28 (27) 6904-6913.

Garay et al., 2013 Maternal immune activation causes age- and region-specific changes in brain cytokines in offspring throughout development, *Brain, Behavior, and Immunity*, 31: 54-68.

Ghaziuddin et al., 2002 Autistic symptoms following herpes encephalitis, *European Child and Adolescent Psychiatry*, Vol. 11, No. 3:142-146.

Gherardi et al., 2001 Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminium hydroxide in muscle, *Brain*, 124:1821-1831.

Ghiani et al., 2011 Early effects of lipopolysaccharide induced inflammation on foetal brain development in rat, *ASN Neuro*, 3 (4): 233-245.

Gillberg 1986 Brief Report: Onset at Age 14 of a Typical Autistic Syndrome. A Case Report of a Girl with Herpes Simplex Encephalitis, *Journal of Autism and Developmental Disorders*, Vol 16, No. 3:369-375.

Giulivi et al 2013 Gestational Exposure to a Viral Mimetic Poly(I:C) Results in Long-Lasting Changes in Mitochondrial Function by Leucocytes in the Adult Offspring, *Mediators of Inflammation*, Vol 2013:609602.

Glanz et al., 2015, Cumulative and episodic vaccine aluminum exposure in a population-based cohort of young children, *Vaccine* 33:6736-6744.

Golub et al., 2001 Long-term consequences of developmental exposure to aluminum in a suboptimal diet for growth and behavior of Swiss Webster mice, *Neurotoxicology and Teratology* 23 (2001) 365-372.

Gupta et al., 1998 Th1- and Th2-like cytokines in CD4+ and CD8+ T cells in autism, *Journal of Neuroimmunology*, 85:106-109.

Harre et al., 2008 Neonatal inflammation produces selective behavioural deficits and alters *N*-methyl-D-aspartate receptor subunit mRNA in the adult rat brain, *European Journal of Neuroscience*, 2008 Feb; 27(3): 644-653.

Harris et al., 2012 Alhydrogel® adjuvant, ultrasonic dispersion and protein binding: A TEM and analytical study, *Micron*, 43:192-200.

Hsiao et al., 2013 The microbiota modulates gut physiology and behavioral abnormalities associated with autism, *Cell*, 155(7): 1451-1463.

Huttenlocher and Dabholkar, 1997 Regional Differences in Synaptogenesis in Human Cerebral Cortex, *Journal of Comparative Neurology*, 387:167-178 (1997).

Jefferson 2004 Adverse events after immunisation with aluminium-containing DTP vaccines: systematic review of the evidence, *The Lancet* 4:84-90.

Jones et al., 2016 Autism with Intellectual Disability is Associated with Increased Levels of Maternal Cytokines and Chemokines During Gestation, *Molecular Psychiatry*, 22(2):273-279.

Khan et al., 2013 Slow CCL2-dependent translocation of biopersistent particles from muscle to brain, *BMC Medicine*, 11:99.

Kindregan et al., 2015 Gait Deviations in Children with Autism Spectrum Disorders: A Review, *Autism Research and Treatment*, ID:741480.

Knuesel et al., 2014, Maternal immune activation and abnormal brain development across CNS disorders, *Nature Reviews* 10:643-660.

Labouesse et al., 2015, Long-term pathological consequences of prenatal infection: beyond brain disorders, *American Journal of Physiology*, 309:1.

Li et al. 2009 Elevated Immune Response in the Brain of Autistic Patients, *Journal of Neuroimmunology*, 207(1-2): 111–116.

Li et al., 2015 Neonatal vaccination with bacillus Calmette–Guérin and hepatitis B vaccines modulates hippocampal synaptic plasticity in rats, *Journal of Neuroimmunology*, 288 (2015) 1-12.

Machado et al., 2015 Maternal Immune Activation in Nonhuman Primates Alters Social Attention in Juvenile Offspring, *Biological Psychiatry*, 2015 May 1;77(9):823-32.

Malkova et al., 2012 Maternal immune activation yields offspring displaying mouse versions of the three core symptoms of autism, *Brain Behavior and Immunity*, 2012 May ; 26(4): 607–616.

Marques et al., 2014 Autism Spectrum Disorder Secondary to Enterovirus Encephalitis, *Journal of Child Neurology*, 2014, Vol. 29(5) 708-714.

Mestas et al., 2004 Of Mice and Not Men: Differences between Mouse and Human Immunology, *Journal of Immunology*, 0022-1767:2731-2738.

Meyer et al., 2006 The Time of Prenatal Immune Challenge Determines the Specificity of Inflammation-Mediated Brain and Behavioral Pathology, *The Journal of Neuroscience*, 26(18):4752– 4762.

Meyer et al., 2007 The neurodevelopmental impact of prenatal infections at different times of pregnancy: the earlier the worse?, *Neuroscientist*, Jun;13(3):241-56.

Meyer et al., 2009 In-vivo rodent models for the experimental investigation of prenatal immune activation effects in neurodevelopmental brain disorders, *Neuroscience and Biobehavioral Reviews*, 33 (2009) 1061–1079.

Meyer 2014, Prenatal Poly(I:C) Exposure and Other Developmental Immune Activation Models in Rodent Systems, *Biological Psychiatry*, 75:307-315.

Mitkus et al., 2011 Updated aluminum pharmacokinetics following infant exposures through diet and vaccination, *Vaccine* 29 (2011) 9538–9543.

Offit et al., 2003 Addressing Parents' Concerns: Do Vaccines Contain Harmful Preservatives, Adjuvants, Additives, or Residuals? *Pediatrics*, 112(6): 1394-1401.

Oskvig et al., 2012 Maternal immune activation by LPS selectively alters specific gene expression profiles of interneuron migration and oxidative stress in the fetus without triggering a fetal immune response, *Brain Behavior and Immunity*, 2012 May ; 26(4): 623–634.

Pang et al., 2016 Exploiting macrophages as targeted carrier to guide nanoparticles into glioma, *Oncotarget* 7(24):37081.

Parker-Athill and Tan, 2010 Maternal Immune Activation and Autism Spectrum Disorder: Interleukin-6 Signaling as a Key Mechanistic Pathway, *NeuroSignals*, 2010;18:113–128.

Petrik et al., 2007 Aluminum Adjuvant Linked to Gulf War Illness Induces Motor Neuron Death in Mice, *NeuroMolecular Medicine*, Vol. 9, 83-100.

Pineda et al., 2013 Maternal immune activation promotes hippocampal kindling epileptogenesis in mice, *Annals of Neurology*, 2013 July ; 74(1): 11–19.

Podila et al., 2013 Toxicity of Engineered Nanomaterials: A Physicochemical Perspective, *Journal of Biochemical and Molecular Toxicology*, 2013 January ; 27(1): 50–55.

Robertson et al., 2016 Reduced GABAergic Action in the Autistic Brain, *Current Biology*, 26, 1-6.

Saad et al., 2016 Vitamin D status in autism spectrum disorders and the efficacy of vitamin D supplementation in autistic children, *Nutritional Neuroscience*, 19 (8) 346-351.

Semple et al., 2013 Brain development in rodents and humans: Identifying benchmarks of maturation and vulnerability to injury across species, *Progress in Neurobiology*, Jul-Aug;106-107:1-16.

Sethi et al., 2008 Aluminium-induced electrophysiological, biochemical and cognitive modifications in the hippocampus of aging rats, *Neurotoxicology* 29, 1069-1079.

Sethi et al., 2009 Curcumin attenuates aluminium-induced functional neurotoxicity in rats, *Pharmacology, Biochemisatry, and Behavior* 93:31-39.

Shen et al., 2016 Postnatal activation of TLR4 in astrocytes promotes excitatory synaptogenesis in hippocampal neurons, *Journal of Cell Biology*, 215(5):719-734.

Sharifi et al., 2012 Toxicity of Nanomaterials, *Chemical Society Reviews*, 2012 Mar 21; 41(6): 2323–2343.

Shaw and Petrik, 2009 Aluminum hydroxide injections lead to motor deficits and motor neuron degeneration, *Journal of Inorganic Biochemistry* 103 (11).

Shaw and Tomljenovic, 2013 Administration of aluminium to neonatal mice in vaccine-relevant amounts is associated with adverse long term neurological outcomes, *Journal of Inorganic Biochemistry*, 128 (2013) 237–244.

Shi et al., 2009 Activation of the Maternal Immune System Alters Cerebellar Development in the Offspring, *Brain, Behavior, and Immunity*, January, 23(1): 116–123.

Smith et al., 2007 Maternal Immune Activation Alters Fetal Brain Development through Interleukin-6, *Journal of Neuroscience*, 2007 October 3; 27(40).

Smith et al., 2012, Maternal Immune Activation Increases Neonatal Mouse Cortex Thickness and Cell Density, *Journal of Neuroimmune Pharmacology*, 7(3):529-532.

Stiles et al., 2010 The Basics of Brain Development, *Neuropsychology Reviews* (2010) 20:327–348.

Suzuki et al., 2011 Plasma Cytokine Profiles in Subjects with High-Functioning Autism Spectrum Disorders, *PloS ONE* 6(5).

Suzuki et al., 2013 Microglial Activation in Young Adults With Autism Spectrum Disorder, *JAMA Psychiatry* 70(1): 49-58.

Takano 2015 Role of Microglia in Autism: Recent Advances, *Developmental Neuroscience*, 37:195-202.

Tau and Peterson, 2010 Normal Development of Brain Circuits, *Neuropsychopharmacology*, (2010) 35:147–168.

Taylor et al., 2014 Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies, *Vaccine*, 32:3623-3629.

Tomljenovic and Shaw, 2011 Do aluminum vaccine adjuvants contribute to the rising prevalence of autism? *Journal of Inorganic Biochemistry* 105.

Tsilioni et al., 2015 Children with autism spectrum disorders, who improved with a luteolin-containing dietary formulation, show reduced serum levels of TNF and IL-6, *Translational Psychiatry*, 5, 647.

Vargas et al., 2005 Neuroglial Activation and Neuroinflammation in the Brain of Patients with Autism, *Annals of Neurology*, 2005;57:67–81.

Viezeliene et al., 2013 Selective induction of IL-6 by aluminum-induced oxidative stress can be prevented by selenium, *Journal of Trace Elements in Medicine and Biology*, 27:226-229.

Wei et al., 2011 IL-6 is increased in the cerebellum of autistic brain and alters neural cell adhesion, migration and synaptic formation, *Journal of Neuroinflammation* 2011, 8:52.

Wei et al., 2012 (a) Brain IL-6 elevation causes neuronal circuitry imbalances and mediates autism-like behaviors, *Biochimica et Biophysica Acta*, 1822 (2012) 831–842.

Wei et al. 2012 (b) Alteration of brain volume in IL-6 overexpressing mice related to autism, *International Journal of Developmental Neuroscience*, 30:554-559.

Wei et al., 2013 Brain IL-6 and autism, *Neuroscience* 252 (2013): 320–325.

Wei et al., 2016 Inhibition of IL-6 trans-signaling in the brain increases sociability in the BTBR mouse model of autism, *Biochimica et Biophysica Acta*, 1862(10):1918-1925.

Weir et al., 2015 Preliminary evidence of neuropathology in nonhuman primates prenatally exposed to maternal immune activation, *Brain, Behavior, and Immunity*, 48,139–146.

Williams et al., 2006 The Profile of Memory Function in Children With Autism, *Neuropsychology*, 20(1): 21-29.

Wobke et al., 2014 Vitamin D in inflammatory diseases, *Frontiers in Physiology*, 5: 244.

Zerbo et al., 2014 Neonatal cytokines and chemokines and risk of Autism Spectrum Disorder: the Early Markers for Autism (EMA) study: a case-control study, *Journal of Neuroinflammation*, 11:113.

Zerbo et al., 2017 Association Between Influenza Infection and Vaccination During Pregnancy and Risk of Autism Spectrum Disorder, JAMA Pediatrics, 171(1).

In regards to HB 1307 and HB 1320

As an individual who suffered a severe allergic reaction to a tetanus shot at age 2, and never had another vaccination until the age of 45, I urge you to consider the negative impact of vaccinations on a wide variety of individuals.

Simply labeling us, anti-vaccination is not only ineffective, it is untrue. But if it is legal and paramount for a woman to have the choice (her body – her choice) in terms of pregnancy, why should a vaccine be any different?

I did try to take a flu vaccine twice in my later years, both with drastically negative results, including the development of pneumonia and the advice to NEVER get another vaccine.

At 65 I have no problem telling my healthcare professionals NO to their constant pushing (offers?) of the multitude of vaccines available all FREE with my insurance and/or Medicare. What I may not have in the future, is the ability to fly, stay in a motel, see a grandchild's school play all because I don't have my required vaccination card.

Please allow parents the simple ability to choose what they wish to have for medical care for their children. These are the simple rights we seem to be willing to throw away all under the guise of a 'safety' that is rarely even 40% effective (flu vaccinations each year rarely have a success rate of even 50%). Especially since people are unable to sue a manufacturer for any damages their product might cause!

Representative Karen M. Rohr, Chair Senator Judy Lee, Vice Chair House Human Services Committee

Emily Meissner 701-430-7179

Tuesday, January 19th, 2021

Support for HB1307, Relating to Service without Vaccinations

Two weeks ago I took our son to see the allergist at Sanford Health Clinic because our son is suffering from asthma symptoms and needed a check up. We were refused service because I would not allow my son to wear a mask. His temperature was fine and he was not experiencing any symptoms of illness. We left the clinic that day without seeing the doctor and have made other arrangements for an appointment at another clinic.

Many seem to feel that the CDC is an authority on medical information so I have taken this from their website concerning masks.

## Who should not wear a mask

Masks should not be worn by

- Children younger than 2 years old
- Anyone who has trouble breathing
- Anyone who is unconscious, incapacitated or otherwise unable to remove the mask without assistance
- Wearing masks may be difficult for some people with sensory, cognitive, or behavioral issues. If they are unable to wear a mask properly or cannot tolerate a mask, they should not wear one, and [adaptations and alternatives](#) should be considered

[COVID-19: Considerations for Wearing Masks | CDC](#)

The reason that I want to tell you this experience our son and I had at a medical facility is to show you that even at a medical business our son was refused service from people who should have known better. The requirements of mask wearing in nearly every business in our area has greatly affected our lives in a negative way.

The covid-19 vaccine is an even more invasive requirement for service and for those of us that are unwilling to donate our bodies to medical research and become guinea pigs in this global

vaccine experiment, this requirement for service will pose an extreme burden on us. It is unconstitutional to discriminate against people when a business is a public accommodation. However, it has been shown to be the case that many businesses are unaware of this fact or simply ignore it because they know that the average person will not have the financial means to hire a lawyer and take them to court. I think it is a good idea to protect the citizens of North Dakota from being denied service because they have not taken the Covid-19 vaccine. The vaccine is not able to stop the spread of Covid-19 but is only given to reduce the symptoms of the illness if one contracts it.

Thank you for considering my written testimony. Please pass HB 1307.

Dear House Human Services Committee Members,

Thank you for your important service and dedication to the state of North Dakota.

I am a mother of nine children whom I homeschooled kindergarten thru high school for 32years.

I graduated from UND with a BS in Education, hold a ND teaching certificate, have my Masters in Public Health from the University of Michigan, and recently became a Certified Nursing Assistant.

After extensive careful study of vaccines, I stand in full support of the following three Bills...HB1307, HB1320, HB1306.

2020 was wrought by many albeit good intended but heavy-handed broad sweeping Public Health regulations that cancelled out so much additional effective scientific information, procedures, and practices in hasty political and financial overriding of the Truth and to personal freedom. Our Government, you, must allow us the right to choose whether to vaccinate or not without fear of losing our right to education and work! And, to continue to study the effects of vaccines is very important also.

Thank you for your consideration on this matter.

Please Vote in support of HB1307, HB1320, HB1306

Sincerely,

Julie Liffbrig

District 33

# 2021 HOUSE STANDING COMMITTEE MINUTES

**Human Services Committee**  
Pioneer Room, State Capitol

HB 1307  
1/27/2021

To prohibit public accommodations from refusing services to an individual because the individual has not been vaccinated; and to provide a penalty
--

**Chairman Weisz** opened the hearing at 3:15 p.m.

<b>Representatives</b>	<b>Attendance</b>
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

## **Discussion Topics:**

- Vaccination something you cannot ask someone about
- Soften language
- Limited access to vaccination status and records

**Rep. Matthew Ruby (3:17)** presented amendment (Christmas Tree Version of HB 1307 21.0681.02001) - #5692.

**Rep. Matthew Ruby** moved to adopt amendment (Christmas Tree Version of HB 1307 21.0681.02001).

**Rep. Gretchen Dobervich** seconded the motion.

**Voice vote** – Motion Failed.

**Rep. Gretchen Dobervich (3:30)** made a motion for a Do Not Pass.

**Rep. Todd Porter** seconded the motion.

<b>Representatives</b>	<b>Vote</b>
Representative Robin Weisz	Y
Representative Karen M. Rohr	N
Representative Mike Beltz	Y
Representative Chuck Damschen	Y
Representative Bill Devlin	Y
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	Y
Representative Dwight Kiefert	Y
Representative Todd Porter	Y
Representative Matthew Ruby	Y
Representative Mary Schneider	Y
Representative Kathy Skroch	N
Representative Bill Tveit	N
Representative Greg Westlind	Y

Motion Carried Do Not Pass: 11-3-0

**Bill Carrier:** Rep. Todd Porter

**Chairman Weisz** adjourned at 3:32 p.m.

*Tamara Krause, Committee Clerk*

Introduced by

Representatives B. Koppelman, Christensen, Kading, Meier, Rohr, Schauer

Senators Clemens, Kannianen, O. Larsen

1 A BILL ~~for an Act to prohibit public accommodations from refusing services to an individual~~  
2 ~~because the individual has not been vaccinated; and to provide a penalty~~ for an Act to provide  
3 for limits on access to vaccination status and records.

4 BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

5 ~~SECTION 1.~~

6 ~~Public accommodation may not refuse service for failure to vaccinate - Penalty.~~

7 ~~1. For purposes of this section, "public accommodation" means every place,~~  
8 ~~establishment, or facility of whatever kind, nature, or class that caters or offers~~  
9 ~~services, facilities, or goods to the general public for a fee, charge, or gratuity.~~

10 ~~2. Except as provided in section 23-07-17.1, a person engaged in the provision of public~~  
11 ~~accommodations may not refuse services, goods, or access to facilities to an~~  
12 ~~individual because of the individual's failure to receive a vaccination or immunization~~  
13 ~~for a communicable disease.~~

14 ~~3. If a person engaged in the provision of public accommodation violates this section,~~  
15 ~~that person is subject to a civil penalty not to exceed two hundred fifty dollars for a first~~  
16 ~~offense and a civil penalty not to exceed five hundred dollars for a second and~~  
17 ~~subsequent offense.~~

18 SECTION 1.

19 Vaccination status or records.

20 1. A person may not inquire about an individual's vaccination status or request access to  
21 an individual's vaccination records.

22 2. This section does not apply to a health care facility, health care provider, or to an entity  
23 required to comply with section 23-07-17.1. For purposes of this section, "health care  
24 facility" means any facility in which health care services are provided and includes a

Sixty-seventh  
Legislative Assembly

1            hospital, special care unit, skilled nursing facility, intermediate care facility, basic care  
2            facility, assisted living facility, ambulatory surgical center, freestanding emergency  
3            department, rural primary care hospital, critical access hospital, inpatient hospice  
4            facility, including a clinic not located on a hospital's primary campus, health  
5            maintenance organization, home health agency, any field hospital, modular  
6            field-treatment facility, and a diagnostic, examination, treatment, imaging, or  
7            rehabilitation center.

**REPORT OF STANDING COMMITTEE**

**HB 1307: Human Services Committee (Rep. Weisz, Chairman)** recommends **DO NOT PASS** (11 YEAS, 3 NAYS, 0 ABSENT AND NOT VOTING). HB 1307 was placed on the Eleventh order on the calendar.

21.0681.02001

Sixty-seventh  
Legislative Assembly  
of North Dakota

HOUSE BILL NO. 1307

Introduced by

Representatives B. Koppelman, Christensen, Kading, Meier, Rohr, Schauer

Senators Clemens, Kannianen, O. Larsen

1 A BILL ~~for an Act to prohibit public accommodations from refusing services to an individual~~  
2 ~~because the individual has not been vaccinated; and to provide a penalty.~~ for an Act to provide  
3 for limits on access to vaccination status and records.

4 BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

5 ~~SECTION 1.~~

6 ~~Public accommodation may not refuse service for failure to vaccinate - Penalty.~~

7 ~~1. For purposes of this section, "public accommodation" means every place,~~  
8 ~~establishment, or facility of whatever kind, nature, or class that caters or offers~~  
9 ~~services, facilities, or goods to the general public for a fee, charge, or gratuity.~~

10 ~~2. Except as provided in section 23-07-17.1, a person engaged in the provision of public~~  
11 ~~accommodations may not refuse services, goods, or access to facilities to an~~  
12 ~~individual because of the individual's failure to receive a vaccination or immunization~~  
13 ~~for a communicable disease.~~

14 ~~3. If a person engaged in the provision of public accommodation violates this section,~~  
15 ~~that person is subject to a civil penalty not to exceed two hundred fifty dollars for a first~~  
16 ~~offense and a civil penalty not to exceed five hundred dollars for a second and~~  
17 ~~subsequent offense.~~

18 SECTION 1.

19 Vaccination status or records.

20 1. A person may not inquire about an individual's vaccination status or request access to  
21 an individual's vaccination records.

22 2. This section does not apply to a health care facility, health care provider, or to an entity  
23 required to comply with section 23-07-17.1. For purposes of this section, "health care  
24 facility" means any facility in which health care services are provided and includes a

Sixty-seventh  
Legislative Assembly

1           hospital, special care unit, skilled nursing facility, intermediate care facility, basic care  
2           facility, assisted living facility, ambulatory surgical center, freestanding emergency  
3           department, rural primary care hospital, critical access hospital, inpatient hospice  
4           facility, including a clinic not located on a hospital's primary campus, health  
5           maintenance organization, home health agency, any field hospital, modular  
6           field-treatment facility, and a diagnostic, examination, treatment, imaging, or  
7           rehabilitation center.