Sixty-third Legislative Assembly of North Dakota
In Regular Session Commencing Tuesday, January 8, 2013

SENATE BILL NO. 2190
(Senators Dever, Berry, J. Lee)
(Representatives Damschen, Devlin, Rohr)

AN ACT to create and enact a new section to chapter 19-02.1 of the North Dakota Century Code, relating to biosimilar biological products.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 19-02.1 of the North Dakota Century Code is created and enacted as follows:

Biosimilar biological products.

1. In this section:

   a. "Biological product", "biosimilar", "interchangeable", "interchangeable biological product", "license", and "reference product" mean the same as these terms mean under section 351 of the Public Health Service Act [42 U.S.C. 262].

   b. "Prescription" means a product that is subject to section 503(b) of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].

2. A pharmacy may substitute a prescription biosimilar product for a prescribed product only if:

   a. The biosimilar product has been determined by the United States food and drug administration to be interchangeable with the prescribed product;

   b. The prescribing practitioner does not specifically indicate in the practitioner's own handwriting "brand medically necessary" on a written prescription, does not expressly indicate that an oral prescription is to be dispensed as communicated, or has not taken a specific overt action to include the "brand medically necessary" language with an electronically transmitted prescription;

   c. The pharmacist informs the individual receiving the biological product that the biological product may be substituted with a biosimilar product and that the individual has a right to refuse the biosimilar product selected by the pharmacist and the individual chooses not to refuse;

   d. The pharmacist notifies the prescribing practitioner orally, in writing, or by electronic transmission within twenty-four hours of the substitution; and

   e. The pharmacy and the prescribing practitioner retain a record of the interchangeable biosimilar substitution for a period of no less than five years.

3. The board of pharmacy shall maintain on its public website a current list, or an internet link to a United States food and drug administration-approved list, of biosimilar biological products determined to be interchangeable under subdivision a of subsection 2.

President of the Senate

Speaker of the House

Secretary of the Senate

Chief Clerk of the House

This certifies that the within bill originated in the Senate of the Sixty-third Legislative Assembly of North Dakota and is known on the records of that body as Senate Bill No. 2190.

Senate Vote:	Yeas 26	Nays 20	Absent 1
House Vote:	Yeas 76	Nays 17	Absent 1

Secretary of the Senate

Received by the Governor at _____M. on _____, 2013.

Approved at _____M. on _____, 2013.

Governor

Filed in this office this _____day of _____, 2013,

at _____ o'clock _____M.

Secretary of State