

January 18, 2018

Senate Health and Human Services Committee
South Dakota State Capitol
500 E Capitol Ave.
Pierre, SD 57501

Re: Support for Senate Bill 75

Dear Chair Soholt:

On behalf of the 1-in-10 people in South Dakota living with a rare disease, the National Organization for Rare Disorders (NORD) respectfully requests you to pass SB 75, an act to allow interchangeable biologic products (biosimilars) approved by the Food and Drug Administration (FDA). The bill has the potential to benefit many of our organization's members, and it will protect patients by including language calling for prescriber communication. With your support, you will be benefiting numerous patients suffering from rare disorders in South Dakota.

According to the legislation, pharmacists will be required to communicate – to a patient's prescribing physician – any and all dispensations of a substitute biological product for another biologic drug. NORD applauds the development of these innovative and valuable therapeutic treatments and supports the expanded access that biological products will offer for rare disease patients. Yet, due to the distinctions between biologics, any substitution of a biological product must include communication between the prescriber and pharmacist to keep patient safety a top priority.

NORD is the leading voice of the rare disease community dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. Any disease affecting fewer than 200,000 Americans is considered rare. With nearly 7,000 rare diseases identified and 30 million Americans affected, the population represented by NORD is extraordinarily heterogeneous. We believe strongly that every patient deserves the medical care that is best suited for their medical situation and that is most likely to give them the best results. Based on the reports we receive from member organizations, as well as individuals, it is increasingly difficult for rare disease patients to receive optimum care if any degree of customization to individual patients is required.

In light of this challenge, prescriber communication between the pharmacist and prescriber about which biological product is dispensed can help ensure all rare patients receive optimum care.

Biological products differ from generics in that they are not identical to their biologic counterpart. Due to the sensitive manufacturing process of biological products, even the slightest change can have a significant negative impact on a patient's therapeutic regimen. This is a

serious issue for a large segment of the rare disease community because not all drugs work the same for every patient, especially when dealing with unpredictable disease progression.

To ensure patient safety, health care providers need to know which medicine was dispensed to the patient, whether a substitution was made, and, if so, to what alternative product. These factors are critical, and need to be taken into consideration when supplying a patient with medication.

NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and service. Patients in the rare disease community experience many unforeseeable variables and outcomes. By securing effective biological product substitution laws, South Dakota can guarantee these patients prudence in prescriber communication that has the potential to dramatically alter the course of their treatment.

Once again, on behalf of NORD and the millions of Americans who face the struggles of a rare disease, we appreciate the opportunity to comment on this legislation. We strongly urge you to support SB 75, which includes prescriber communication and will ensure that increased access to this new age of medicines is done in a safe, reliable, and consistent way for patients and physicians.

If we can supply additional information, please do not hesitate to let us know. I can be reached at (202) 545-3830 or via email at tboyd@rarediseases.org.

Sincerely,



Tim Boyd, MPH

Director of State Policy

CC: Members of the South Dakota State Senate