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House Bill No 1033 – Prescribing of Biosimilar Drugs

Senate Human Services Committee – Sakakawea Room
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Madam Chair Lee, Members of the Senate Human Services Committee for the record I am Mark Hardy, PharmD, Executive Director of the North Dakota State Board of Pharmacy and I thank you for providing me the opportunity to offer testimony on HB 1033 relative to the prescribing of biosimilar drugs.

The Board of Pharmacy considers this legislation a positive step to better allow for and remove barriers in the dispensing of biological products and their interchangeable biosimilars. The topic of biological products, their corresponding biosimilars, and the concept of interchangeability have been very widely discussed topics over the past decade.

The growth of biological products now available to patients has exponentially expanded just as many thought when the legislature last discussed this topic in passing this portion of the law back in 2013. Biological products are highly complex and specialized medications used to treat medical conditions and disease states. Most of these medications are extremely expensive, many are well over $1,000 per month of treatment. The concept of biosimilars and the reference biologic drug is not simply a "*Brand*" verses "*Generic*" model. In reality, biological products are extremely complex molecules, the certainty of being able to create "*copies*" of biosimilar products exhibiting the same intended patient outcome is a difficult parameter to meet. Thus, the FDA came up with the term "*interchangeability*" to have a rigorous process to ensure that two biological products would be able to be interchanged, to ensure that the same patient outcome is achieved by either product. This process involves complex studies as well as reviews to ensure consistency. It is important to note that to our knowledge there has not been an interchangeable product approved by the FDA to date. However, many biosimilars have come to market.

Of course, the intention of having interchangeable biosimilars is to provide competition in products resulting in cost savings to the patient and the health care system.

Regarding the changes set forth in the legislative bill by the Interim Health Care Committee, the Board of Pharmacy supports these to allow for a more seamless process in transitioning patients from the biological to an interchangeable biosimilar product.

For those who may not have been involved or aware of the legislative history, SB2190 in 2013 enacted the original legislation. Much of the controversy revolved around the notification that the pharmacist may need to provide to the prescribing practitioner. Many indicated that this notification would prove so burdensome that it would prevent biosimilars from being dispensed, as well as creating regulatory patchwork of laws between states that could limit interchangeable biosimilars from being approved.

The way we interpret the new language in Section 2 (d) as written includes more provider notification options, including a simple notification by the pharmacist placing a record of dispensing in their software system, which seemingly applies to both hospital and retail pharmacy locations. The Board of Pharmacy is unsure of how the Pharmacy record, once entered, would translate back to be viewable by the prescribing practitioner. Regarding Section 4, we are currently making available an internet link to the US FDA approved biosimilar / biological interchangeable products, which is now termed to be the "Purple Book".

The Board of Pharmacy does support the changes made in this bill and would appreciate any opportunity to be involved in any dialogue that would bring clarity to the notification requirements. It has been our view since 2013 that if a biosimilar meets the high standard of being interchangeable a notification is not necessary.

I would be happy to answer any questions you may have on this complex topic and hope to be a resource to you in any way you deem appropriate.