December 1, 2017

Tim Boyd, MPH
Director of State Policy
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Arkansas State Capitol
500 Woodlane St.
Little Rock, AR 72201-1090

*Transmitted via email*

**RE: Arkansas Board of Pharmacy proposed rule permitting the substitution of biologics without prescriber communication – Opposition**

To the Members of the House and Senate Public Health, Welfare and Labor Committee and the Legislative Council:

The National Organization for Rare Disorders (NORD) respectfully requests you reconsider the proposed changes to Regulation 7, which governs the substitution of biosimilar medications. We are concerned that, as written, this rule does not properly reflect the differences between generic and biosimilar medications. Additionally, this language does not call for communication between the physician and pharmacist if a biosimilar is substituted. We have serious concerns that this could have unintended impacts on patient care and safety.

NORD applauds the development of biosimilars, which are innovative and valuable therapeutic treatments, and supports the expanded access that biological products will offer for rare disease patients. Yet given the distinctions between biologics and biosimilars, this regulation 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 of access to optimum care, prescriber communication between the pharmacist and doctor about which biological product has been dispensed can help address this important concern of the rare disease community.

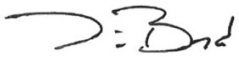
Biological products differ from generics in that they are not identical to their biologic counterpart. Due to the sensitive manufacturing process of biological products, even the slightest change can have a significant negative impact on a patient's therapeutic regimen. This is a serious issue for a large segment of the rare disease community as 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 biosimilar was dispensed to the patient, whether a substitution was made, and, if so, to what alternative product. These factors are all critical pieces of information that need to be taken into consideration when supplying a patient with medication.

On behalf of NORD and the millions of Americans who face the struggles of a rare disease, we hope that you take our concerns seriously and work to improve the language of this regulation to include prescriber communication for the substitution of biological products.

If we can supply additional information, please do not hesitate to let us know. Please feel free to contact me at tboyd@rarediseases.org. Furthermore, Andrea Taylor, NORD'S Arkansas Volunteer State Ambassador, can be reached at andrea.taylor@rareaction.org.

Sincerely,



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