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TESTIMONY - STATE BIOSIMILAR SUBSTITUTION
Idaho Board of Pharmacy

CONSIDERATIONS REGARDING 27.01.01. - RULES OF THE IDAHO STATE BOARD OF PHARMACY

Speaker:
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As prepared for delivery

- Good afternoon. I would like to thank Mr. Johnston and each of the members of the Idaho Board of Pharmacy for allowing me to be here today to provide the patient perspective the proposed rule.

- I am here today on behalf of the Global Healthy Living Foundation, and the more than 70,000 members we represent nationwide, and the approximately 1,300 in Idaho, to express our concern regarding the proposed rule being discussed today.

- We represent patients nationwide who are living with chronic illnesses. Our President, Seth Ginsberg, was diagnosed with Spondyloarthropathy, which is an inflammatory rheumatic disease, at age 13.

- Many of the patients we represent, including those with diabetes and Rheumatoid Arthritis, take biologics to manage their conditions.

- At the Global Healthy Living Foundation, our focus is on improving the lives of patients with chronic illnesses through health care education and programs that stress the importance of diagnosis, early and innovative medical intervention, long-term lifestyle improvement and therapeutic compliance.

- We work to advance new and improved medical treatments, such as biologics and biosimilars, for patients. As promising as these innovative drugs are, we believe that assuring their safety should be of paramount concern.

- We appreciate that the proposed rule includes a provision that addresses record keeping for substitution involving these products. However, this alone does not satisfy the safety needs required for this class of medicine.

- In the rule, a passive notification system is proposed, whereby substitution would simply be noted in the patient's medication record but no direct communication with the prescriber would occur.

- In other words, a physician would have to contact the pharmacy to determine whether a substitution has occurred. For a prescription filed electronically or filled by a mail-order pharmacy, perhaps weeks in the past, it could prove extremely difficult and require extensive research for the physician to know even which pharmacy or pharmacies to contact. This is an impractical system that essentially removes the physician from medical decision-making.

- The relationship between a patient and their physician hinges on a high level of communication and trust. In many cases, a patient and their physician have worked together for years to find the most appropriate therapy to manage their condition. This has resulted in chronically debilitated individuals progressing from being bed-ridden to active and productive lifestyles

- Treatment for the diseases these products are indicated for require an incredible amount of clinical decision-making. In fact, personalized treatment is often necessary. The physician is in the best position to account for all of the needs of their individual patients. They have the ability to factor in treatment history and response, risk for adverse events, co-morbidities, disease duration, severity, and the potential to impact quality of life.

- Based on our research and the feedback from several thousand patients we serve, it is clear that patients overwhelmingly want their doctors notified directly if their medication has been substituted.

- Let me share an analogy one of our patient advocates used to sum up her feelings about the situation: "It's as if I am renovating a bathroom in my home. My architect develops a blue print and associated list of materials. As my bathroom gets constructed, I believe it is being built with storm grade material and a 5-year warrantee. Without me or my architect knowing, the contractors boss makes a decision to substitute the storm grade materials. Storm grade material are not necessarily higher quality than regular material. But they are better for certain people depending on where they live. Do I as a home owner have a right to know whether or not my architect's agreed upon materials have been substituted?"

- We say yes you do. The same way patients and physicians have a right to know when their complex biologic or interchangeable biosimilar has been substituted.

- As patient advocates, safety is our top priority in the health care process.

- We appreciate your thoughtful consideration of this topic and for taking the steps necessary to keep patients in Idaho safe.

- The Global Healthy Living Foundation, and the patients we represent, urge the Idaho Board of Pharmacy to reconsider the omission of active and direct physician communication requirements.

- We would be pleased to provide any further information that would be helpful to you as you move forward in finalizing this important rule.