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Coalition of State Rheumatology Organizations

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555 E. Wells Street, Suite 1100
Milwaukee, WI 53202-3823
Phone: 414-918-9825
Email: info@csro.info
Website: www.csro.info

May 1, 2023

House Insurance Committee
900 N. Third St.
Baton Rouge, Louisiana 70802

Re: Opposition to HB 403

The Coalition of State Rheumatology Organizations (CSRO) is a national organization composed of over 30 state and regional professional rheumatology societies, including our member organization in Louisiana. CSRO was formed by physicians to ensure excellence and access to the highest quality care for patients with rheumatologic, autoimmune, and musculoskeletal disease. It is with this in mind that we write to you regarding HB 403.

A step therapy protocol is a requirement that a patient try and fail a sequence of prescription drugs prior to being provided coverage for other non-preferred drugs that may be prescribed by their physician. Current law allows physicians to override the step therapy protocol under certain clinical circumstances. Current step therapy law enables a stable patient to stay on the treatment that has kept their disease under control unless there are being switched to an approved generic or interchangeable biosimilar. HB 403 adds a biosimilar not deemed to be interchangeable with its reference product to that list. Biosimilars that are not interchangeable have not met the evidentiary standard required by the FDA to earn the “interchangeable” designation.

Consequently, we are concerned that this will result in stable patients, who would otherwise be able to remain on their medication via a step therapy exception, being switched to a potentially inappropriate therapy. The distinction between an interchangeable biosimilar and non-interchangeable biosimilar is highly significant for the purposes of such a scenario. These switches can cause severe consequences for patients due to the complexity of autoimmune conditions and the potential immunogenicity of the drugs used to treat them. Louisiana’s step therapy law was passed, with the exception for stable patients, to prevent this scenario from happening.

These risks are contemplated by federal law, which defines interchangeability as a separate and higher standard.

"**(3)**

The term “interchangeable” or “interchangeability”, in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."

-42 U.S.C. § 262(i)(3)

Indeed, federal law further requires that a determination of interchangeability by the FDA must demonstrate:

"**(B)**

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for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch."

-42 U.S.C. § 262(k)(4)(B)

We find this distinction and additional evidentiary standard meaningful in terms of patient safety. Allowing for such substitutions would also be inconsistent with the American College of Rheumatology's position statement on the issue.

However, CSRO supports the use of biosimilar products and believes the legislation could be amended to ameliorate our concerns. We appreciate your consideration of our comments and are happy to answer any questions you may have.

Sincerely,

Gary Feldman, MD, FACR
President
Board of Directors

Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs