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April 19, 2023

Senate Committee on Health
Sacramento, California 95814

Senate Committee on Health,

Re: SB 621 - Oppose unless Amended

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 California. 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 SB 621.

CSRO has taken a position of Oppose unless Amended on SB 621, and would like to echo the comments of the California Rheumatology Alliance, as well as their suggested changes to SB 621.

Although we believe this legislation could be amended to accommodate our concerns, we do not believe this legislation is necessary. 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 defined clinical circumstances found in Health and Safety Code 1367.206 (b)(1-5) where the preceding drugs in the step therapy protocol would be inappropriate for the patient.

Health and Safety Code Section 1367.206 (e) allows plans and insurers to require trial and failure of an interchangeable biosimilar product or AB-rated generic equivalent product regardless of the exceptions criteria found in Health and Safety Code 1367.206 (b)(1-5). It does not follow that absent section (e), a plan or insurer would be disallowed from using a step therapy protocol or from requiring trial and failure of either an AB-rated generic equivalent product or interchangeable biosimilar product where the criteria for an exception were not met. Step therapy protocols under existing law can mandate the use of all drugs such as brand, generic, and all biologics including reference products and biosimilars, whether they are interchangeable or not. Accordingly, a requirement to try and fail a non-interchangeable biosimilar product is indeed allowable under current law whether or not the word "biosimilar" is inserted into section (e) as proposed by SB 621. It also does not follow that the omission of the word biosimilar constitutes a prohibition.

Any argument that the law currently inhibits uptake of biosimilar products ignores three key facts. **First**, that garnering an exception to a step therapy protocol is contingent on a patient's medical situation meeting any of the clinical circumstances defined in section (b). If the drug is appropriate and none of the exception scenarios are met, then a plan can require trial and failure of a non- interchangeable biosimilar. If any of the circumstances are met it would mean that the drug is not clinically appropriate and the patient should not in fact be forced to try the drug. SB 621 seems to suggest that the patient should be forced to try the biosimilar drug independent of these questions of medical necessity. **Second,** Health and Safety Code Section 1367.206 (e)(2) further clarifies that the law in no way prohibits "a health care provider from prescribing a prescription drug that is clinically

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appropriate." As such, current law does not in any way prevent a prescriber from prescribing a biosimilar if they so choose. **Third,** the main barrier to use of biosimilars is not whether an exception to a step therapy protocol can be garnered, but whether insurance companies prefer biosimilar products on their prescription drug formulary.[1] Formulary construction, which is not impacted by existing law, is the predominant constraint on biosimilar prescribing and access.

While we believe that this legislation is unnecessary and will not have the intended effect of meaningfully improving clinically appropriate uptake of biosimilars, we do believe that it changes the relationship between Health and Safety Code 1367.206 (b)(1-5) and Health and Safety Code Section 1367.206 (e) in a manner that could endanger patients and lead to adverse events. Patient and provider groups generally agree that an allowance for the trial and failure of an AB-rated generic equivalent or interchangeable biological product is appropriate, because those drugs are substitutable with their branded equivalents under almost all circumstances. This is not the case for a non-interchangeable biosimilar product. Because Health and Safety Code Section 1367.206 (e) supersedes the exception scenarios found in Health and Safety Code 1367.206 (b)(1-5), SB 621 would serve to undermine the availability of the exceptions when otherwise available with respect to a biosimilar product.

For example, while CSRO supports the use of biosimilar products, a non-interchangeable biosimilar product has, by definition, not been demonstrated to the FDA to be "switchable."

"(B)

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)

For the purposes of whether a stable patient can be switched from their therapy to a non-interchangeable biosimilar pursuant to the exception provided for stable patients under Health and Safety Code 1367.206 (b)(5), we find this distinction and additional evidentiary standard meaningful. 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. Allowing for such substitutions would also be inconsistent with the American College of Rheumatology's position statement on the issue.

We appreciate your consideration of our comments.

Respectfully,

[1] https://healthpolicy.duke.edu/publications/realizing-benefits-biosimilars-overcoming-rebate-walls

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