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COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

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February 26, 2015

Oregon House of Representatives
900 Court St. NE
Salem, Oregon 97301

RE: Oppose HB 2026 – Relating to biological products; declaring an emergency

Dear Members of the Oregon State House of Representatives:

The Coalition of State Rheumatology Organizations (CSRO) is a national organization composed of 30 state and regional professional rheumatology societies formed in order to advocate and ensure excellence and access to the highest quality care for patients with rheumatologic and musculoskeletal disease.

Rheumatologists are especially aware of the dramatic long-term, life-changing clinical improvements that biological products have on some of the most disabling conditions that affect Americans. Biological products available for the treatment of rheumatoid arthritis and other autoimmune diseases have had a significant impact on improving our patients' quality of life, preventing disability, and lowering mortality.

As the Oregon State House of Representatives considers **HB 2026 - CSRO wishes to convey its opposition to the serious deficiencies in the proposed legislation**.

As currently written, HB 2026 lacks the necessary patient protections for the dispensing of biological products. Most notably, this bill contains no provision for physician notification and lacks safeguards to properly define what products can be substituted and how physicians should be involved in that process.

In testimony before the U.S. Food and Drug Administration (FDA) regarding the approval pathway for biosimilars, Dr. Greg Schimizzi, past president of CSRO, recommended that after a biosimilar is approved, physicians should always be involved in decisions regarding their patient's use of a biosimilar. Allowing health systems to impose an automatic substitution for biologics is isn't safe for patients, without having a full understanding of their health history.

Furthermore, prompt notification to a physician from a pharmacist about a biologic substitution should be a requirement in any legislation regarding biologic products. Delayed information about biosimilar medication in the event of an adverse reaction or medication failure can be detrimental to patient safety.

CSRO recognizes that follow-on biologics and biosimilars are a natural evolution of medications and as the FDA is expected to approve the first biosimilar drugs this year, we welcome the consideration of biosimilars legislation. At the same time, we must insist that patient safety remain the most important concern.

Sincerely,

Michael Schweitz, M.D.
President, CSRO