March 10, 2018

Senator Jeb Bradley
Chair, Senate Health and Human Services Committee
New Hampshire State Capitol

Mr. Chairman and Committee Members,

As the chair and advisory board chair of the Alliance for Safe Biologic Medicines (ASBM), we are writing to urge you to **support Senate Bill 350 (SB 350) relative to biological products dispensed by pharmacists**. ASBM is an organization of patients, physicians, pharmacists, manufacturers of both innovative and biosimilar medicines, researchers and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.

As a practicing rheumatologist and a past president of the American Society of Health-system Pharmacists, we are keenly aware of the benefits of biologics in treating serious conditions like cancer, rheumatoid arthritis, diabetes, and MS. "Copies" of these medicines, called "biosimilars" have the potential to provide these therapies at reduced cost. Yet unlike generic versions of chemical drugs biosimilars are not exact duplicates of their reference products. Indeed, the complexity of biologics and their proprietary manufacturing processes mean that these "copies" can only ever be similar, never the same. Even the smallest structural difference between a biologic and its attempted copy can have a significant impact on a patient, including reduced efficacy or unwanted immune responses.

We believe that when interchangeable biosimilar products are substituted, communication between patients, pharmacists, and health care providers is essential to patient care. We fully support and are concerned that patient safety will be compromised if this legislation is not enacted.

Since 2012, ASBM has conducted surveys of physicians in 12 countries, to gather their perspectives on biosimilars. The results of these surveys have since been shared with policymakers in the U.S., Australia, Canada, Europe, Latin America, and the World Health Organization in Geneva, Switzerland.

- **Our survey of 376 U.S. physicians revealed that 80% of those surveyed called communication in the event of a biosimilar substitution "very important" or "critical".**

- **Further, 82% of U.S. physicians called the authority to block a substitution by indicating "do not substitute" or "dispense as written" on a prescription "very important" or "critical".**

These results are consistent with those of physicians around the world. All ASBM surveys are available on our website at www.safebiologics.org/surveys.

SB 350 empowers pharmacists to offer lower-cost biosimilars to patients, while reflecting the importance of pharmacist-physician communication. It allows treatment decisions to remain between physician and patient, without posing undue or onerous burdens upon the pharmacist:

- It provides that only "interchangeable" biosimilars (those determined by the FDA to produce the same effects in a patient as the reference product without additional risks) may ever be substituted.

- It allows a physician to prevent a substitution they consider inappropriate for their patient by writing on the prescription "medically necessary" or words of similar meaning.

- It ensures the patient is aware of the substitution of an interchangeable biosimilar.

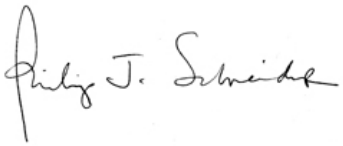
- Finally, SB 350 requires that the pharmacist communicate to the physician within a reasonable time frame (5 days) which product the patient ultimately received – the biologic prescribed by the physician, or a substituted biosimilar- so that an accurate patient record can be kept by all parties.

SB 350 will extend these valuable protections to New Hampshire's patients while increasing their access to biologic therapies. For these reasons, lawmakers in **38 states and Puerto Rico have passed similar bills** in the past few years.

Thank you in advance for taking the necessary steps to keep patient safety a priority in New Hampshire by supporting Senate Bill 350.

Sincerely,

Madelaine Feldman, MD, FACR
Chairman, The Alliance for Safe Biologic Medicines



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