Dear Senator,

I am writing on behalf of the Alliance for Safe Biologic Medicines, a group of physicians, patients, pharmacists, researchers, and manufacturers of both biologic and biosimilar medicines, working together to promote their safe use globally.

We understand that the Senate Economics Legislation will be receiving submissions on the National Health Amendment (Pharmaceutical Benefits) Bill 2015.

With regard to the provisions in this Bill related to the substitution of medicines, we would like to raise issues to the provisions in this Bill related to the pharmacy-level substitution of biosimilar medicines.

Attached is a letter sent to the Health Minister, the Hon Sussan Ley, on this matter which we would like this inquiry to consider.

Should you have any questions, please feel free to contact our executive director, Michael Reilly, who is cc'd here.

Yours faithfully,

Ray Patnaude

The Hon Sussan Ley MP
Minister for Health
Minister for Sport
Suite M1 41
Parliament House
CANBERRA ACT 2600

Email: Minister.Ley@health.gov.au

Dear Minister:

On behalf of the Alliance for Safe Biologic Medicines, an organization of physicians, pharmacists, patients and manufacturers of both biologics and biosimilar working together to promote their safe use, we are concerned with Australia's recent policy developments that appear to be intended to advance pharmacy-level substitution of biosimilar medicines. As health professionals with many decades of experience, we have personally seen our patients benefit from biologic medicines and recognize the promise of biosimilars expanding access to these treatments. However, we are also very aware of the potential risks our patients could face with pharmacy-level substitution. Further, both prescribers and pharmacists in many countries share our concerns with this practice.

In existence since 2010, ASBM has been surveying prescribers of biologics in 11 countries, including the United States, Europe, Canada and Latin America since 2012 to gather their perspectives and opinions on the use of biologics and biosimilars. We have shared these data with lawmakers and regulators in most of the countries surveyed to consider in the development of their policies regarding the naming, prescribing and substitution of biosimilars. Over the past two years we have also worked with the World Health Organization in their crafting of international standards for clear biosimilar naming.

Our surveys have shown that most prescribers of biologics (62% of participating European physicians, 71% of participating Canadian physicians and 85% of participating Latin America physicians) consider a pharmacy-level determination of which biologic to dispense to their patient to be "unacceptable".

ASBM joins these physicians in opposing pharmacy-level substitution of biosimilars until these medicines have been sufficiently evaluated for safety and efficacy, including repeated switching between products -- whether it be between the reference biologic and a biosimilar or between two biosimilars.

Unlike chemical medicines, the greater size, complexity and sensitivity of biologics means that they cannot be copied exactly. A reverse-engineered biosimilar medicine from a different cell line designed to mimic the therapeutic properties of its reference biologic medicine can only ever be "similar" to that product, never the same. Even seemingly minor production differences can produce unexpected effects, including unwanted immune responses that may harm rather than heal. We know that patient

responses can vary with chemical medications and expect the same to be true with biologic ones. However, given the chronicity and seriousness of the diseases these medications are designed to treat, we believe there is less margin for error and recommend a slower and more conservative approach to substitution until more is known about these medications.

The question of pharmacy-level substitution has been widely debated in highly regulated jurisdictions around the world and consistently rejected as inappropriate without sponsors demonstrating there is no loss of safety or efficacy as a result of repeated switching. The United States Congress even defined a category of biologic -- interchangeable —for which such evidence of safety and efficacy with repeated switching have been demonstrated. The U.S. Food and Drug Administration has yet to either approve a biologic as interchangeable or provide guidance on what would be necessary to satisfy these statutory criteria.

We fully understand that this is a difficult scientific and regulatory question and warrants thoughtful handling on the part of all governments. We also fully understand the potential fiscal impacts of these medications to healthcare payers and realize that these costs cannot be ignored. ASBM is fully committed to promoting the safe use and increased access of biologic medicines for patients throughout the world and would be happy to provide any technical or other assistance we can as you explore your policy options.

Kind regards,

Harry L. Gewanter, MD, FAAP, FACR
Pediatric Rheumatologist
Chairman, Alliance for Safe Biologic Medicines

Philip J. Schneider, M.S., F.A.S.H.P.
Professor, University of Arizona College of Pharmacy
Advisory Board Chair, Alliance for Safe Biologic Medicines

Cc: Senator the Hon Fiona Nash
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