Dr. Kathleen Dermody
Committee Secretary
Senate Economics Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600

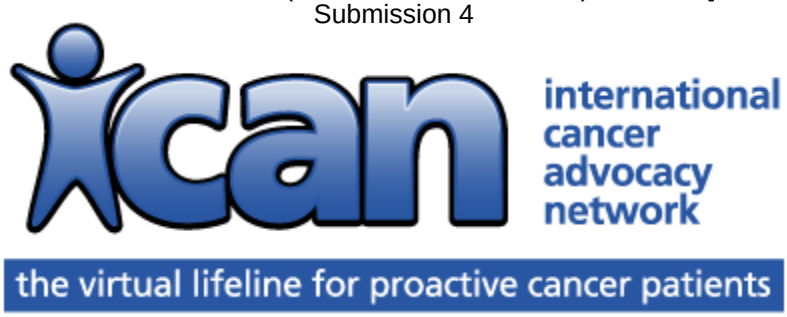
Dear Senator Dermody,

As you consider the National Health Amendment Bill 2015 (Pharmaceutical Benefits) in the Senate Economics Legislation Committee, we would like to bring your attention to the very important patient safety issues regarding pharmacist substitution of biosimilar medicines. We recently wrote to Health Minister Sussan Ley on this issue. It goes into more detail regarding these very important issues which we hope your inquiry will consider.

Our letter to Minister Ley is attached as a Word document and is below as email text for your convenience.

Thank you for your consideration,

Marcia Horn
CEO, ICAN--International Cancer Advocacy Network



June 12, 2015

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

Dear Minister Ley,

ICAN, the International Cancer Advocacy Network, is a strong supporter of using biologics and biosimilars in the fight against cancer and other diseases. However, we put a premium on patient safety and want to ensure, when biologics and biosimilars are taken by a patient, that their administration meets the highest standards of safety and efficacy, as well as cost.

ICAN is a five-star rated American-based non-profit cancer patient advocacy organization. We work with the direct navigation of Stage IV cancer patients in 53 countries (including Australia, New Zealand, and the rest of the Pacific Rim). We have a global network of over 1100 volunteers (again, including Australia).

We deal daily with biologic therapies for our patients. Biologic therapies, and thus biosimilars, will become a growing area for metastatic cancer patients and hold great promise for treatment, reduction of health care costs and, most importantly, for long-term patient survival.

There are currently two fundamental issues facing governments and the medical community regarding biologics and biosimilars:

1) Substitution of biosimilars by pharmacists for the biologic (or another biosimilar) prescribed by the physician and,

2) Notification of physicians by pharmacists when a substitution has been made.

ICAN joins virtually all patient and physician groups in strongly supporting the right of physicians and patients working together to determine which drug patients take. Any substitution by a pharmacist for a physician-prescribed biologic (or another biosimilar) must only take place after the appropriate national or regional regulatory authority has determined that the switching is safe.

This is not the same issue as generics—where another company can produce an identical drug to the original. In the case of biologic drugs, a "copy" (the "biosimilar") can be different in manufacture from the original biologic (or another biosimilar)—and even as a result of processing and handling. Thus, the effects on a patient can be different leading to significant, and legitimate, concerns for patient safety.

And, even after it is determined that such switching (in the U.S., the term adopted is "interchangeability") is safe, it is still essential that any such switching be done only if the physician has not insisted otherwise ("dispense as written" in the prescription). It is also critical, if the physician has either allowed substitution or not prohibited it, that the physician (and thus the patient), be notified by the pharmacist that a substitution has been made.

Because biosimilars are not identical to the original biologic drugs (or to each other) dispensing them to a patient without the knowledge of the prescribing physician could lead to adverse reactions, or even a tragedy. Given how simple notification is, there is just no reason to risk patient safety.

Substitution without informing the physician could also add an unnecessary layer to health care costs. For all patients who do not respond to the originally intended treatment, and especially those patients who suffer adverse reactions, physicians would be in the dark as to the cause. This will require precious physician time, additional diagnostic tests, and in the cases of significant reactions, hospitalization. These additional unintended costs can simply be avoided with the requirement for prescriber communication by the pharmacist.

Your support for ensuring pharmacist substitution only after interchangeability has been determined, and then only with physician (and thus patient) notification, will ensure safety for ICAN's Australian patients, and for all Australian patients.

Thank you for your consideration.

Respectfully submitted,

Marcia Horn

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Minister for Industry and Science
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The Hon Karen Andrews MP
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