Committee Secretary
Senate Economics Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Dr Kathleen Dermody

I understand that, earlier this week, the *National Health Amendment (Pharmaceutical Benefits) Bill 2015* was referred to the Senate Economics Legislation Committee. The Inquiry appears to have a very short time line. I am informed that the hearing will be held this Thursday, June 18, with a reporting date of Tuesday, June 23. It appears that the reason for the referral to the Committee is "to allow stakeholders to respond to the proposed changes".

In view of the above, I would like to raise issues in relation to the provisions relating to "Schedule equivalence" which concerns substitution of medicines at the pharmacy level. I particularly would like to raise issues in relation to the substitution of biosimilar medicines. I have written to the Health Minister, The Hon. Sussan Ley, on this matter and would now like the inquiry to consider the issues I have raised.

First, however, allow me to introduce myself. My name is Stephen Murby and, inter alia, I am: a biosimilars spokesperson for the International Alliance of Patients' Organizations (IAPO) headquartered in London; a member of the International Advisory Board of the Alliance for Safe Biologic Medicines (ASBM) headquartered in Virginia, USA; a Consumer Health Forum of Australia (CHF) Board Special Representative; a CHF Honorary Life Member; and a former CHF Director, Treasurer and Chair.

I have a special interest in Biosimilars from the patient perspective and have been working with IAPO and others in developing and disseminating biosimilars information and resources to patient organisations over the past few years. Most recently, I spoke in September at the Biosimilars Global Congress 2014 Europe on Latest Development Revolutionizing the World of Biosimilars.

Recently Medicines Australia contacted me and invited me to address a Health Consumer Organisation Workshop on Understanding Biological and Biosimilar Medicines – The New Frontier on Wednesday 24 June 2015 at Rydges Sydney Airport, which I have accepted. A number of meetings with public health peak organisations have also been arranged, including with PSA and PGA.

During my presentation, I will be addressing a number of topics directly related to the impact and implications of regulatory frameworks for biosimilars in the context of: the recent TGA Review of Medicines and Medical Devices; the TGA interim advice on the naming of biosimilars (21 January 2015); and the, even more recent, advice issued by PBAC in respect of automatic substitution of biosimilars at the pharmacy level ('a' flagging).

My concerns with the PBAC decision include that it may effectively, albeit unintentionally, provide a backdoor route for unproven bioequivalence for biosimilars in the context of the Australian genome. Not just in the context of one biosimilar being available in addition to the approved biologic but even more so when two or more biosimilars are available (all of which would be 'a' flagged under the PBAC position) and the pharmacist has even greater substitution choice over the biologic.

My letter to Minister Ley is enclosed herewith for consideration by your Committee.

Yours sincerely

Stephen Murby