28 February 2005

Elton Humphrey
Secretary
Australian Senate Community Affairs Committee
Parliament House
Canberra ACT 2600

Dear Mr Humphrey and Members of the ASCA Committee:

Supplementary Submission to the Australian Senate Community Affairs Committee

We write to place on record corrections to the misleading and inappropriate conclusions drawn in the section entitled "Factually flawed claims", a subsection of the Committee's report (pages 9-11) on the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill, now law. Our purpose is to address misinterpretation.

Dr Michael F Greene

The Senate report correctly states that Dr Greene compares medical abortion with surgical abortion at eight weeks gestation in his 2005 New England Journal of Medicine article. However, the article is written to address the question of risk of RU486 and the Senate report is misleading. Dr Greene cautions that providers should be aware of potential complications, but that the very small risk should not be used as an argument against the use of medical termination. He has reiterated this many times in his media statements. He restated this claim in stronger terms in an interview on the *NEJM* website (http://content.nejm.org/cgi/content/full/353/22/2317/DC1) when he claimed that "So on the surface of it, it seems that one risk is 10X higher than the other. However, when you get to numbers that are that small, they are very difficult to measure with precision. And I don't think that I or anyone else on the basis of the available data at the moment would be willing to say that that is necessarily a statistically *significant* difference at the level of certainty that a scientist would want before making such a statement." He pointed out that despite long-term and widespread use in Western Europe and China, there has been no incidence of infection with Clostridium Sordelli associated with medical abortion using RU486 procedures
http://www.who.int/reproductivehealth/publications/safe_abortion/safe_abortion.pdf, p. 14)
Dr Greene himself concludes that patients should be informed of the risks before they consent to the procedure with which PHAA firmly agrees.

The FDA and Mifepristone

PHAA stated in its submission that the US FDA had recently affirmed the safety of medical abortion for American women and authorised its (RU486) continued use. Again we believe that the Senate report is misleading. This is not a factually flawed claim, but a difference in interpretation. After the four deaths of American women, the FDA did put up additional advice on its website and further updated it twice. However, the recommendations the FDA makes regarding the infection did not reflect changes in the Agency's view on appropriate policy or protocol concerning the drug. In its Public Health Advisory, the Agency reaffirms its recommendation against prophylactic antibiotics, and confirms its recommended protocol. It is accurate to characterise the FDA's behaviour as a *reaffirmation* of the agency's views

about the appropriateness of the protocols they had developed for use of the drug in the US, and the drug's suitability for marketing in that country.

We also take this opportunity to register our strong objections to the tone and conduct of some Committee members during the inquiry. We believe the questions outside the committee's terms of reference put to us by several of the Committee's members opposed to the Bill should have been disallowed.

We ask that the inquiry report be suitably amended to reflect the information contained in this letter.

Sincerely,

Dr Cathy Mead, President and Dr Angela Taft, National Co-convenor Women's Health Special Interest Group

Public Health Association