

21 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 register our objections to the tone and conduct of some Committee members during the inquiry. At times, the questioning was inappropriate, unprofessional and hostile as well as clearly outside the Inquiry's terms of reference.

We also write to address a number of factually incorrect claims made in the Committee's report on the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill, now law. In relation to the "Factually flawed claims" subsection of the report found on pages 9-11, we note the following:

#### **Adverse Drug Rates**

The inquiry report notes that 4 submissions made reference to what it claims was a factually flawed claim regarding the absolute and relative safety of Mifepristone as evidenced by adverse drug event rates. These were the Public Health Association; the National Union of Students, Women's Health NSW and the Bankstown Women's Health Centre.

In fact, the number of submitters referring to it was 5, and includes the submission made by Children by Choice (Sub 917).

The Committee claims that the "figures given for the adverse drug event rates improperly compare serious adverse vents requiring hospital treatment for RU486 with all reported adverse events for Claratyne, including minor side-effects such as dry mouth and headache."

In so doing, the report argues, the figures provide a “misleading and totally inappropriate comparison” which was “factually incorrect”.

The Committee’s argument is factually flawed in two key ways. Firstly, it claims that submissions making this claim misquote their source. The figure given in the submissions is .137%, which is sourced to NARAL 2004, but the Committee claims that “the bibliography” refers to a 2005 NARAL Fact Sheet entitled “Mifepristone is a Safe Choice, Fact Sheet 20 December 2005”.

We are mystified as to what “bibliography” the Committee is referring to. Four of the five submissions provide no source for the .137% claim, and the Children by Choice submission properly sources this information to the 2004 version of the NARAL Mifepristone Is a Safe Choice fact sheet.

The 2004 fact sheet give the adverse drug event rate for Mifepristone as .137%, and explicitly notes that this figure does not refer to what the Committee calls “serious adverse events” but includes “relatively minor events such as headache and nausea”. The extended analysis the Committee provides of the 2005 NARAL facts sheets use of the Henderson data is therefore irrelevant to discussions of factual flaws in evidence put before the Committee as this evidence was not put before the Committee for consideration.

## **Dr Michael F Greene**

The Greene article (which the Inquiry report incorrectly attributes to “Robert” Greene) was cited in the spirit in which it was intended: to demonstrate that RU486 is safe and effective in absolute and relative terms. As Greene himself writes: “As tragic as the deaths of these young, healthy women are, they remain a small number of rare events without a clear pathophysiologic link to the method of termination.” As Dr Cannold from Reproductive Choice Australia explained to the committee, Dr Greene, in an interview on the ABC’s *Health Report*, stated that he believed there was a negligible - or no significant - difference between the mortality risks posed by medical and surgical abortion at comparable gestational

ages. This is because the differences he estimated in mortality risks were so tiny or, as Dr Greene himself put it: “Ten times a very small number is still in fact a very small number”.

<http://www.abc.net.au/rn/talks/8.30/helthrpt/stories/s1521375.htm>

Dr Greene 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/PG.

Those who argued in their submissions that there is “no difference to the risk posed by medical and surgical abortion” did understand what Dr Greene was saying, and reflected that understanding in their submissions. It is the Committee’s majority whose understanding of these figures is “factually flawed”.

A good faith effort was made to explain the concept of statistical significance in general, and the meaning of Dr Greene’s numbers in particular, by Dr Cannold at the Melbourne hearing. Despite this, no mention of this testimony was made in the “factually flawed claims” section. Indeed, this testimony appears to have been completely ignored by the Committee’s majority bar their later mischaracterization of it as evidence of a “distressingly cavalier” attitude to the deaths of 10 women.

The radical mischaracterization of Dr Cannold’s testimony on this point reveals, in our view, an unprofessional abuse of trust of those who came before the Committee in good faith to offer their views and expertise. Regrettably, the Committee majority’s misuse of the Greene figures also encouraged those in the wider committee to keep citing the “10 times” claim in order to mislead women into believing that there RU486 was unsafe in absolute terms, and significantly less safe in relative terms to surgical abortion despite both claims being “factually flawed”.

These factual flaws would exist even if the Greene data were the only data set that existed, but are made more glaring by the fact that it is not, and other data sets have similarly concluded that the mortality risk for induced abortion regardless of method are comparable at around 1:100,000. The World Health Organization states, for instance:

When performed by trained health care providers with proper equipment, correct technique and sanitary standards, abortion is one of the safest medical procedures. In countries where women have access to safe services, their likelihood of dying as a result of an abortion performed with modern methods is no more than one per 100,000 procedures ([http://www.who.int/reproductivehealth/publications/safe\\_abortion/safe\\_abortion.pdf](http://www.who.int/reproductivehealth/publications/safe_abortion/safe_abortion.pdf), p. 14)

## **The FDA and Mifepristone**

This is not a factually flawed claim, but a difference in interpretation of the word “reaffirmed”. After the four deaths of American women, the FDA did put up additional advice on its website. On July 19, the organisation noted the deaths and their lack of ability at that time to connect them with the two drugs used to procure medical abortion, as well as the fact that “sepsis is a known risk related to any type of abortion. On November 4<sup>th</sup>, this information was updated to advise that the identical bacteria (*clostridium sordelli*) was responsible for the deaths of all four women, but that the FDA had not found any contamination in any batches of either of the drugs used to procure their abortions. Patient information sheets were updated to include the information above, and to advise both patients and doctors to be alert to early signs of the infection.

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 for oral, rather than vaginal, administration of Misoprostone. Proof that the agency’s advice remained unchanged was its noting in the public advisory that all four of its recommendations in the wake of the four sepsis deaths are “consistent with warnings in the Prescribing Information and information

for the patient in the Medication Guide.”

<http://www.fda.gov/cder/drug/advisory/mifeprex.htm>

In other words, despite intense and sustained pressure from the anti-choice movement in the US, the FDA’s response to the 4 sepsis deaths in the US did not see the agency chance its recommend protocols surrounding the use of RU486 to induce a medical abortion, nor seek to restrict access to the drug .

It is our view, this makes it entirely 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. It would seem, therefore, that it is the Committee’s conclusion that this claim is inaccurate that is “factually flawed”.

## **Conclusion**

In the 6<sup>th</sup> February hearing, Senator Barnett requested that Reproductive Choice Australia provide an amended submission to the Committee correcting what was then asserted to be factually flawed claims on which 5 submissions to the inquiry had relied. Though Reproductive Choice did not use the material in question in its own submission, and is not accountable to the Committee for the contents of its website, it has joined with those organizations unjustly accused in the report to refute claims made about the substance of their submissions to the Committee.

This supplementary submission shows that all 3 of the Committee’s claims about factual flaws are themselves “factually flawed”,

We trust that this submission will be prominently posted on the inquiry’s website, and that the inquiry report will be suitably amended to reflect the information contained herein.

Yours truly,

Ms Denele Crozier,  
Women's Health NSW

Ms Sarah Wickham  
National Women's Officer  
National Union of Students

Dr Leslie Cannold  
Reproductive Choice Australia