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Committee Secretary
Community Affairs Committee
Department of the Senate
Parliament House
Canberra ACT 2600

29 January 2006

Dear Members of the Community Affairs Committee,

Submission to the Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005

As a professional Drug Regulatory Affairs Associate working for a multi-national pharmaceutical company, I work with the Therapeutic Goods Administration (TGA) every day. It is my job to negotiate with the TGA to gain approval to market new drugs in Australia. As such, I have been watching this debate with particular interest.

I have no doubt the Committee will hear a lot about important issues such as women's health, reproductive freedom and the social and ethical implications of abortion.

But the question before the Senate is primarily about who decides. Who should take ultimate responsibility for allowing abortion drugs like RU486 to be evaluated, registered, listed or imported in to Australia?

The proposed amendments to the *Therapeutic Goods Act* would pass this responsibility from the Health Minister to the Therapeutic Goods Administration, the body which ensures that drugs approved for use in Australia are safe and of high quality.

Supporters of the amendments say that we should treat RU486 like any other drug. But in my professional experience, RU486 is not like any other drug. It is not designed to prevent, treat or diagnose an illness, defect or injury. It is not therapeutic. It is designed to cause an abortion that will end a developing human life. RU486 raises serious ethical and social concerns that go far beyond scientific analysis.

When it comes to a question of such public interest and controversy, with deep distrust and cynicism on both sides of the divide, it is very important that the approval process surrounding RU486 is not merely independent and unbiased. It must be *seen* to be so. In this case, open debate amongst our elected representatives is essential.

The TGA is an unelected body. Individual Health Ministers come and go. Whoever he or she is, what matters is that he or she is accountable to the electorate for any decision to approve or not approve RU486. The Health Minister is also directly accountable to Parliament. The Health Minister is currently required to present written approval of RU486 to each House of the Parliament within 5 sitting days of it being given. The current system ensures accountability, transparency and public confidence in the process.

This was widely recognised in the original parliamentary debates back in 1996. Former Greens Senator Christabel Chamarette said: “We deserve to have parliamentary scrutiny of decisions. We deserve to have a voice on issues and not simply leave them to boards of experts.”[1]

And from the then ALP Senator Belinda Neal: ‘These issues need to be addressed by the executive of this government and addressed with absolute and direct accountability and absolute and complete transparency”.[2]

So what has changed? Do we need accountability and transparency any less than we did 10 years ago?

The TGA was never designed to negotiate the myriad of public policy complexities that accompany debate about such a drug. This task lies with our elected – and accountable - representatives. And they should not wash their hands of this responsibility.

In conclusion, I recommend that the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 should be rejected.

Yours faithfully,

Dr Monique Baldwin
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[1] *Senate Hansard* May 21, 1996, p821
[2] *Senate Hansard* May 9, 1996, p624