



Women's Electoral Lobby Australia Inc.

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WOMEN'S ELECTORAL LOBBY
AUSTRALIA

SUBMISSION TO

THE SENATE COMMUNITY
AFFAIRS COMMITTEE

INQUIRY INTO THERAPEUTIC GOODS
AMENDMENT (REPEAL OF MINISTERIAL
RESPONSIBILITY FOR APPROVAL OF RU486)
BILL 2005

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

Dear Senator Humphries,

The Women's Electoral Lobby Australia thanks the Senate Community Affairs Committee for its invitation to appear before it and give evidence to this inquiry.

We particularly thank the Committee and its chair for considering us an appropriate group to give evidence to this inquiry in spite of opposition from some Senators.

Having reviewed the evidence given by Ms Dundas at the Committee hearing we believe that the best ideas of WEL were represented in that evidence. We are proud that Ms Dundas stood firm in the face of sometimes hostile and occasionally obscure question.

We have expanded only slightly on the evidence that Ms Dundas gave and wish to focus on the question that is in front of the committee as proposed in the *Therapeutic Goods Administration (Repeal of Ministerial responsibility for approval of RU486) Bill 2005* whether the Therapeutic Goods Administration or the Minister for Health is the most appropriate body/person to assess the safety and appropriateness for the Australian community of pharmaceuticals.

Yours sincerely,

Eva Cox
Chair
National Co-ordinating Committee
Women's Electoral Lobby Australia

ABOUT WEL

WEL is a national independent political organisation dedicated to creating a society where women's participation and potential are unrestricted, acknowledged and respected and where women and men share equally in society's responsibilities and rewards.

WEL was formed in 1972 and since then has played a recognised role in the political and social history of Australia.

WEL has since its establishment been at the forefront of the struggle for equal employment opportunities, access to quality child care, sex discrimination legislation and many other issues of importance to Australian women and the Australian community.

WEL POLICY

WEL's policy is based on a number of principles of particular relevance to this inquiry is:

- Governments should not use laws or policies to intervene in the choices women make concerning their health, reproductive processes, marital status, sexual identity and activities unless they harm another living person. Government responsibility in relation to these matters extends only to education, regulation of the quality of services and products, and protection against coercion, to ensure that choices are fully informed and freely made.

FOCUS OF THE INQUIRY

This inquiry should not be a divisive debate about a women's right to choose.

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- WEL believes a woman has the right to choose whether to continue a pregnancy or not and decisions on the mode and timing of any termination should be between the woman and her medical practitioner.
- The 2003 Australian Survey of Social Attitudes conducted by the Australian National University found that 81% of Australians support a woman's right to choose and only 9% are against.
- The Parliaments of the Australian Capital Territory, Western Australia, South Australia and Tasmania have all passed legislation that allows for abortion under specified circumstances in the period that RU486 is generally recommended for use.
- The courts in Victoria and New South Wales have acknowledged that abortion is legal within particular conditions within the period that RU 486 is recommended for use.

This inquiry should be about good government and transparent administrative processes. Clinical decisions must be made by those most qualified to do so, after rigorous assessment and based on evidence. It is inappropriate to use the political system to make decisions on the appropriateness of a medical process for performing a legal procedure.

ASSESSING PHARMECUETICALS

The Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005 is a simple bill that would repeal the anomaly that currently exists in the *Therapeutic Goods Act 1989 as amended in 1996*. This specifically requires that the medications such as RU 486, labelled as restricted goods cannot be evaluated, registered, listed or imported without written approval by the Minister for Health.. This category covers only abortifacients and the requirement for ministerial approval puts inappropriate controls in the hands of an individual politician in an area where personal views are very divided. .

WEL believes that RU486 should be assessed like any other drug. RU486 is the only medicine that is subjected to the restricted goods condition. In fact, the restricted goods definition exists just for drugs like RU486. Medicines used for other purposes besides abortion are evaluated and regulated by the Therapeutic Goods Administration and do not require an additional tick of approval from the Minister for Health and Ageing.

The TGA is specifically charged with identifying, assessing and evaluating the risks posed by therapeutic goods that come into Australia, applying any measures necessary for treating the risks posed and monitoring and reviewing those risks over time. The TGA is regarded by this government—and by previous governments—as being the qualified body to manage the risks associated with any therapeutic good that is used or proposed for use in Australia. It is therefore reasonable to assume that it is also qualified to assess the risks associated with medications such as RU486.

Removal of the restricted goods definition and provisions in the act would mean that RU486 could be evaluated within the same framework as applies to all other drugs that are used in this country. It is reasonable to assume that this may provide potential importers the opportunity to bring this drug into Australia, but the process would be an evidence based evaluation by the TGA as it is with any drug.

RU486 is currently used in countries such as the United States, the United Kingdom, France and New Zealand. It is a safe and effective early alternative to surgical abortion. It is also important to note that it is not a drug with just one sole purpose; rather it is a drug that has many purposes, and we are denying those therapeutic purposes being explored in Australia because of the current legislation. We see that the safest way to progress the scientific debate is through the TGA and the TGA alone.

The TGA process would allow conditions to be set as they are with other drugs and their inquiries would be able to look at issues of the appropriate use and any necessity for medical follow up that may be needed. These are questions that need to be determined by evidence and expertise not by those opposing abortion raising the issues in ways designed to promote their anti choice views. The tone of the public debate reinforces the problems of shifting the issue from its basic administrative and medical concerns. .