



EMILY's List Australia

Senate Inquiry **Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005**

Submission

About EMILY's List Australia

EMILY's List Australia is a financial, personal and political support network for Labor women candidates seeking public office in Australia. Since 1996, EMILY's List has helped to elect 102 new Labor women to Parliaments around the country. EMILY's List candidates support the principles of choice, diversity, equity, equal pay and access to quality affordable childcare for all women who need it.

EMILY's List has 2,500 members across the country who have donated over \$500,000 to the campaigns of progressive Labor women and who support a progressive policy agenda which includes the right of women to determine their own futures.

EMILY's List and reproductive choice

EMILY's List Australia is a pro-choice organisation which advocates for the rights of women to determine their reproductive health in consultation with their doctor.

EMILY's List and women's safety

EMILY's List Australia believes that women have a right to safe, effective health procedures which minimise harm and maximise positive health outcomes.

Ministerial Approval for Abortifacients

EMILY's List Australia believes that the Therapeutic Goods Administration is the best-placed organisation to determine the safety and effectiveness of medicinal treatments including mifepristone (RU 486).

The *Therapeutic Goods Act (1996)* states that “*Medicines...intended for use in women as abortifacients...must not be evaluated or registered or listed without the written approval of the Minister*”. This is the only category of medicines to be restricted in this way. The current legislation effectively prohibits the Therapeutic Goods Administration from exercising its vital role in evaluating the effectiveness and safety

of these products (progesterone antagonists and vaccines against human chorionic gonadotrophin) and the appropriateness of their use in Australian clinical settings.

EMILY's List is concerned that the current debate regarding the amendment to the *Therapeutic Goods Act (1996)* has not been focused on the key issue of ministerial responsibility for approval of this range of drugs. It is disappointing that Members of Parliament and anti-choice interest groups have been treating the Inquiry as a *de facto* referendum on the legality of abortion in Australia – an issue which is a matter for the individual state parliaments and in which the Federal Parliament has no jurisdiction.

The Therapeutic Goods Administration (TGA) has presented evidence to the Senate Inquiry which confirms its rigorous approach to the consideration of medications it is currently empowered to investigate and approve, including the ongoing screening of available medicines in Australia (Dr David Graham, National Manager, Therapeutic Goods Administration, CA 17 Hansard December 15, 2005).

Dr Andrew Pesce, Executive Councillor of the AMA, has presented evidence to the Senate Inquiry which outlines the designation of appropriate experts to examine the evidence “in terms of community need and data on safety and efficacy, make the relevant assessment and give a decision”.

“It is not a matter of the minister...it is a matter of the process and the reference to an independent umpire: the expert group” (Mukesh Haikerwal, AMA President p. CA7 Hansard December 15, 2005). Put simply, this legislation allows for the consistent practise of the TGA's responsibilities across the range of treatments considered for approval in Australia.

EMILY's List Australia is satisfied that the leading medical practitioner organisations in this country, the Australian Medical Association (AMA) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) have devoted significant research and review to inform their support of the introduction of mifepristone to Australia.

Similarly, EMILY's List notes the support of peak health organisations such as the World Health Organisation (WHO) and the Public Health Association of Australia (PHAA), which are rigorous not only in their consideration of the effects of treatments but also in their advocacy for health consumers.

In conclusion, EMILY's List is pleased to support the removal of Ministerial approval for RU-486 and like treatments and supports the co-sponsored legislation to allow the Therapeutic Goods Administration to determine the safety and efficacy of medications prior to their introduction into the Australian market.



Michelle O'Byrne
Co-Convenor
EMILY's List Australia

Emily Lee-Ack
National Coordinator
EMILY's List Australia

EMILY's List (Australia) Inc

Level 2, Queen Victoria Women's Centre, 210 Lonsdale Street Melbourne VIC 3000

Phone: 03 8668 8120

Email: emily@emilyslist.org.au

Web site: www.emilyslist.org.au