

**A Submission on Behalf of
The Australian Catholic Bishops Conference**

From

The Bishops Committee for the Family and for Life

To

**The Senate Community Affairs
Legislation Committee's**

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

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We thank the members of the Senate Community Affairs Legislation Committee for the opportunity to make a brief submission to your Inquiry regarding this important matter.

The Australian Catholic Bishops Conference (the Conference) is the peak body of the Catholic Bishops of Australia. The Bishops Committee for the Family and for Life (Bishops Committee) is a Committee of the Conference. One of the Committee's important responsibilities is the promotion of respect for human life. The subject matter of your Inquiry is very relevant to this responsibility.

The Current Situation

In 1996, when RU486 was first considered for use in Australia, it was recognised that it represented a new class of drug. Prior to, and since 1996, the safety and efficacy of medicines have been assessed by the Therapeutic Goods Administration (TGA). But RU486 is not a medicine. The Oxford Dictionary definition of medicine is "the science and art concerned with the cure, alleviation, and prevention of disease, and with the restoration and preservation of health". RU486 is concerned with none of these matters. RU486 is an abortifacient. Its sole purpose is to cause an abortion.

In 1996, legislators recognised that access to abortifacients, because they are different in their intended purpose to drugs used as medicine, raises social policy matters, the consideration of which is not within either the role or the professed expertise of the TGA. Accordingly, it was decided that consideration of the social policy issues regarding this new class of drug would be reserved to the relevant Minister. What has changed since 1996?

The Role of the Therapeutic Goods Administration

As noted, the role of the TGA is to assess therapeutic goods which are defined on the TGA's web site (and similarly in the legislation) as "a good which is represented in any way to be, or likely to be, for therapeutic use." The dictionary definition of therapeutic is "of or pertaining to the healing of

disease...curative medical treatment". RU486 is not a curative medical treatment. It is not a therapeutic good. It is an abortifacient with related social policy issues.

The TGA strives to perform its function of assessing therapeutic goods and has many technically competent staff. But it is unreasonable to expect such staff to adequately assess the social policy issues regarding a product such as RU486 which is not "concerned with the cure, alleviation, and prevention of disease, and with the restoration and preservation of health".

Abortion

As is well known, the Catholic Church seeks to protect human life in all situations. How a society protects and preserves the lives of the most vulnerable in society is a measure of the quality of that society. Catholics have a long and well established practice of assisting and protecting vulnerable people, as well as advocating for such protection and assistance.

It is acknowledged that there are people in our society who do not share our views regarding the need to protect the most vulnerable. Differing views about abortion is one such area in which people disagree about the need to protect the most vulnerable – the unborn child, dependent on its mother and society for protection.

Abortion is a sensitive and complex community issue. It is not appropriate for any consideration of abortion to be merely about the technicalities or the efficiency of different methods of abortion. It is for that reason that it is not appropriate for the TGA to be the sole body to consider an abortifacient such as RU-486. The social policy aspects of such a product must be taken into account.

Currently, consideration of the social policy implications of RU486 is undertaken by the relevant Minister. There is no reason for that arrangement to change.

The person most appropriate to assess the social policy implications of RU486

We elect our politicians and, from the political process, Ministers are appointed and given responsibility for making decisions about important issues. We hold politicians in general, and Ministers in particular, responsible for the decisions that they make.

As a society, we do not approve of Ministers hiding behind bureaucrats or technocrats when an important or difficult decision has to be made. Especially regarding social policy issues, Ministers are expected to seek advice from appropriate sources, including the bureaucracy, and to then make a decision and be held responsible for that decision. There is no reason for there to be a different process for assessing the social policy issues of

RU486. Like other such decisions, it is, and should be, the responsibility of the relevant Minister.

The safety and efficiency of RU486

We leave it to others to discuss the technical, safety and efficiency aspects of RU486. However, motivated by our concern for the health of Australian women, we note Professor John Horvath's Minute to the Minister re RU-486 (Mifepristone)-Medical Abortion. Professor Horvath is the Commonwealth's Chief Medical Officer.

In his Minute to the Minister, Professor Horvath says: "Mifepristone is administered orally. While its use avoids the small anaesthetic and surgical risk associated with surgical termination, it carries a significantly higher risk of later adverse events, such as incomplete termination and prolonged bleeding, and thus a higher proportion of women who undergo medical abortion require subsequent and at times, urgent intervention".

Professor Horvath goes on to say: "RU-486 or Mifepristone is a method for inducing an abortion that is associated with an increased risk of adverse outcomes over conventional surgical termination, and requires similar and in some cases even greater levels of backup.....Making Mifepristone available, as a prescription medicine, without appropriate frameworks to ensure its safe use, would increase the risks to women undergoing pregnancy termination in this country".

Conclusion

The current arrangements for assessing the important social policy issues regarding the abortifacient RU486 are consistent with arrangements for assessing comparable important social policy issues. There is no need to change the standard arrangements so that the social policy issues regarding RU486 would be assessed by a non-standard method.

If Senators wish to discuss these matters further, we would be happy to make ourselves available.

Bishops Committee for Family and for Life

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