

Submission regarding The Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for the approval of RU 486) Bill 2005

Dear committee,

I would submit that the Therapeutic Goods Administration (TGA) is an inappropriate body to determine the full range of issues surrounding the use of RU486 and as such, there should be an additional layer of public scrutiny. This bill seeks to remove that additional layer and as such should be rejected.

The above bill was passed in 1996 with the realisation that abortifacients are a special category of therapeutic goods. Abortifacients are poisons, with the sole purpose being to poison an unborn child. **The Australian community expects that such chemicals be thoroughly scrutinised both from a therapeutic and an ethical point of view.** The Australian community would also expect that they would have the ability to have input into such a decision. The above bill would place the approval process out of the hands of the Australian community onto an unelected, unrepresentative body.

I would submit also, that apart from ethical considerations, **there are medical considerations that the TGA would not be in an appropriate position to judge.** What would be the effect of making a drug like this available in rural areas where there is not the access to specialist medical help should complications arise? The shortage of medical specialists in rural areas may be used as an argument for using these substances, but, in fact, they will still need to be used under supervision. The sometimes desperate situations that people who will use this poison will find themselves in, means that they will, if it is approved, put pressure on already stretched resources, to allow unsupervised access. It is easy to see that the result of this will be an increase in maternal mortality.

I would expect **the TGA would be unable to adequately make appropriate ethical decisions** regarding abortifacients. The ethics committees already in place do not allow for any public input and as such do not necessarily reflect the opinion of the Australian community. The most important ethical decision will of course be to determine whether to poison an unborn child is ever appropriate. There are a lot of variations on this theme such as, if it is ever appropriate, in what situations it may be acceptable? One is reminded of Thalidomide which was used in pregnancy to reduce nausea but was appropriately withdrawn because of the debilitating effects on the unborn child. One could also plead that it be returned because of women's choice - why should they suffer nausea in pregnancy? In this case, the unborn child was recognised as having status. This brings to light the very complicated nature of the ethics of substance use in pregnancy.

Problems arising should this Bill be passed, giving the TGA responsibility for the approval of RU 486:

Lack of guidelines and accountability of TGA

If the TGA is to control the approval of RU486, where will its guidelines come from ? Will the members of the TGA have full responsibility for the approval process? IF RU 486 is approved, will the TGA be held accountable for the decision that is made and is there legal recourse for the Australian public should this decision prove to be disastrous?

Vulnerability to prosecution of doctors of conscience

Who will support doctors who do not use RU 486 after it is approved? What will stop courts deciding that doctors are negligent if they decide not to use RU 486 if it becomes accepted practice.

Possible Compensation issues

In the United States of America, where RU 486 is approved, the supplier is a company that is not resident in the USA and only markets RU 486. This gives the company relative immunity should there be a wish for members of that community to seek recompense. Will this situation be allowed in Australia or will there also be amendments to the Therapeutic Goods Act to make sure that appropriate and full responsibility for the production of RU 486 be taken by the manufacturers?

General Considerations

In talking to people about the proposed Bill I have found that they have some misconceptions of the issues involved. Here are some of the questions asked of me recently.

Will there actually be an increased number of abortions because of the availability of the drug?

I believe the Australian community would like the issue to go away. The abortion issue is vexed. What most people would like to see regardless of what they think of the use of abortifacients is that the amount of abortions and the cost to

the community be reduced. The proper question that should be asked is, "Will the approval of the drug result in less abortions?" I don't think anyone would agree that this is the expected scenario.

If women choose to have an abortion, the options are medical or surgical. Should we put women at more physical (and emotional) risk of the surgical option, for the sake of deterring them from abortion?

I don't agree that women should be put at risk, but I think we need to consider the choices that are already made. The choice to have sexual contact in a non-permanent relationship may result in emotional trauma, unwanted pregnancy and sexually transmitted diseases, with resultant consequences. Why is the debate occurring at the abortion end? It is so people can make sexual choices without having to bear the full consequences - Choice without responsibility. What we need to be encouraging is Choice with Responsibility. Men also have often taken no responsibility and accepted no consequences for their actions.

I am also mindful that the consequences of a medical option for abortion will be to make later abortions more accessible. I would argue that access to abortion in this state is already too accessible and that in making it more so we are inevitable reducing the status of the unborn child to nothing. The next consequence of this is to reduce the status of children. I see this as already happening. My wife and I have six children whom we love enough to invest significant time home schooling them. I get many comments at my work place about how many children I have - the implication being that I should know how to control the number of children I have. We are so pleased when we have families (mainly those from overseas from countries like Korea or Vietnam) affirm how fortunate we are having many beautiful children.

So I think the question should look at the broader implications and thus ask "Should we put women and children in the community at more physical (and emotional) risk for the sake of a few who wish abortions to be an easier option?"

I would ask that you consider my above points. I would again submit that the Therapeutic Goods Administration (TGA) is an inappropriate body to determine the full range of issues surrounding the use of RU486. This bill which seeks to give the TGA this inappropriate responsibility and remove that additional layer of community input, should be rejected.

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