Family First Additional Comments

Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005

Executive Summary

During the debate in 1996 on the *Therapeutic Goods Amendment Bill 1996 (No.2),* then Labor senator Belinda Neal said:

> These issues need to be addressed by the executive of this government and addressed with absolute and direct accountability.[1]

Then 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.[2]

The onus is on those who seek to repeal that Bill to show there has been sufficient change since 1996 to warrant such action. Not only have they failed to do so, but they have not even attempted to do so.

The issue before Senators back in 1996, and before us now, was made by a number of submissions and by Monique Baldwin, a regulatory associate with a pharmaceutical company and somebody who is very familiar with the role and operations of the Therapeutic Goods Administration (TGA). Writing in *The Australian* last month, Dr Baldwin said:

> 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 has serious ethical and social concerns that go far beyond scientific analysis.[3]

The TGA has told this Committee it is not competent to address these concerns. On December 15 last year the TGA said that it confines itself to technical questions of quality, safety and efficacy - it does not consider ethical issues.[4] The reason the TGA is not able to make these decisions is because it is our responsibility – the responsibility of elected leaders – not theirs.

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1 *Senate Hansard* May 9, 1996 p 624

2 *Senate Hansard,* May 21, 1996, p 821

3 Probe a prescription for social concern, The Australian, 31 January, 2006, p.12

4 Dr Graham and Ms Halton, Department of Health and Ageing, CA Hansard, 15 December 2005, pages 30-31.

In discharging this responsibility, elected leaders must consider community attitudes. For this reason the research of the Southern Cross Bioethics Institute, which is current and which was done professionally, is important. It found that 87 per cent of Australians thought the number of abortions performed in Australia was too high. While the community does not want laws changed, they do want governments to take initiatives to reduce the number.[5]

The Southern Cross Bioethics Institute is not alone in its view. On January 4, the *Sydney Morning Herald* editorialised:

> A substantial majority (sic) supports abortion on demand — but at the same time an even greater majority (sic) is uneasy with the number of procedures carried out and wants the abortion rate cut somehow.[6]

If the Senate passed this Bill, it would be doing the opposite of what the community wants. The Parliament would be sending a message that RU486 is just another drug and abortion is just another medical procedure. Elected leaders would be sending the message that they are not prepared to deal with the real issues that women face when deciding whether or not to proceed with their pregnancies.

In this context, it is worth noting an issue last year in the Victorian electorate of Murray, whose Member, Dr Sharman Stone, is a strong supporter of this Bill because of her concern for rural women. An agency which had provided practical help to pregnant women for almost 30 years, faced closure due to a lack of funds. Given the enormous help it has given to hundreds of rural women, Dr Stone did virtually nothing to help.[7]

During the committee hearings it has become clear there are other reasons why it would be wrong to give the TGA the power to approve this drug. The Committee has heard about the possible medical and psychological effects of RU486, both short term and long term.

We have been also learned that the TGA does not require medical practitioners and pharmacists to report adverse effects of a drug.[8] Consequently the TGA cannot properly monitor the effects of a drug. This is a serious issue given that RU486 has caused deaths and that we do not know what long-term psychological effects it will have.

A Minister, on the other hand, could make mandatory monitoring a condition of approval, by a body such as the Adverse Drug Reactions Assessment Committee

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5 Submission 1012, Southern Cross Bioethics Institute.

6 Editorial: No excuse for wilful ignorance. *The Sydney Morning Herald*, 4 January 2006.

7 Christie Peuker, We will fight for service: senator. *Shepparton News*, 3 November 2005.

8 Submission 920, Women's Forum Australia, page 21.

(ADRAC). Even if the TGA could impose such conditions, there is no guarantee they would maintain them or that they would be accountable if they removed them.

The submission of a rural pharmacist, Jenny Madden[9], highlighted the fact that the morning-after pill is now available over the counter at pharmacists. At the time of the original application, the manufacturer said:

> It is only to be used as an emergency contraceptive and one of the reasons it is available on prescription only is so doctors can regulate how patients use it.[10]

A TGA committee removed this restriction 12 months after the original approval and were not held accountable for this backflip. Had the Minister been responsible, there would have been much greater public accountability.

Women's Forum Australia has pointed out that the TGA is funded by the industry because it is required to recover its operating costs from application fees and charges.[11] A body responsible for approving contentious drugs, such as RU486, must not only be impartial but be seen to be impartial. If perceptions of bias, as distinct from actual bias, are an issue, the perception of bias of an ongoing, unelected body is of greater concern than the perception of bias of a Minister who happens to have a particular portfolio at a particular time.

Supporters of this Bill have not made a case for change. Relying on unfounded conspiracies or untested allegations of bias is insufficient reason to change the law. RU486 is a unique drug which raises major social, ethical and policy issues. These issues must be addressed by us, as Australia's elected leaders, and not passed off to unelected expert committees.

For these reasons, Family First opposes this bill.

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9 Submission 635, Jenny Madden

10 Byden-Brown, Sarah, Morning-after pill on sale. *The Australian*, 1 July 2002.

11 Submission 920, Women's Forum Australia

Introduction

The *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005* would allow abortion-causing drugs like RU486 (Mifepristone) to be imported into Australia without the need for the Health Minister's approval.

The debate is complex and involves a wide range of issues, including:

- Principally, who should make such important policy decisions – the Health Minister as an elected community representative, or unelected bureaucrats in the Therapeutic Goods Administration;
- Whether abortion drugs like RU486 are suitable for women in rural areas, given the availability of abortion in rural areas was the initial impetus for the current debate ;
- Limitations of the Therapeutic Goods Administration in approving and monitoring abortion drugs; and,
- Concerns about the safety of the drug and the risks it would pose to women's health.

The explanatory memorandum says that the bill only deals with RU486, but in fact it would affect a whole range of abortion drugs including "Alprostadil, Carboprost, Dinoprost, Dinoprostone, Gemeprost and Misoprostol … [and] vaccines against human chorionic gonadotrophin."[12]

Another submission noted that passing the bill "… would mean there would also be no ministerial scrutiny over anti-fertility vaccines."[13]

Conduct of the inquiry

The Committee was only allowed time to hold hearings in Canberra, Melbourne and Sydney, which made it difficult to consult with people in rural areas. This was particularly disappointing given the initial impetus for the current debate over RU486 was to increase abortion access for women in rural areas. The policy of the Committee to select witnesses closer to these three cities, even if people who made submissions lived in the same state, meant that some rural people missed out on appearing as witnesses.

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12 Ms Mongan, Australian Federation of Right to Life Associations, CA Hansard, 3 February 2006, page 23.

13 Submission 920, Women's Forum Australia, page 16.

The Committee was only given one day after the last hearing day to finalise the report on this important issue. Hansard for the Sydney hearing was not to be made available until late on the same afternoon the report had to be finalised. This meant that evidence given at the Sydney hearing was less likely to be reflected in the final report.

Senators are expected to have less than one day to consider the report once it is tabled, before they debate and vote on the bill. This is why Family First has labelled the process a farce. Despite all the hard work of the Committee and those who provided submissions and appeared as witnesses, Senators cannot be expected to properly consider the report in less than one day. They need at least a week to be able to make an informed decision on the bill.

Ministerial accountability for RU486

The current legislation was passed in 1996 with bipartisan support for making the Health Minister responsible and accountable for an issue of great community concern.

> Former ALP Senator Belinda Neal, said: "We acknowledge that this issue raises large concerns within the community. It raises issues beyond purely health issues. These issues need to be addressed by the executive of this government and addressed with absolute and direct accountability." (*Senate Hansard* May 9, 1996 p624)
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> 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."(*Senate Hansard,* May 21, 1996, p821)

Research shows the community is concerned about the high number of abortions and wants it reduced.

The research, by the Southern Cross Bioethics Institute in Adelaide, found:

> While 62%-69% of Australians support abortion on demand as a general principle, 64%-73% think the abortion rate is too high (depending on whether the figure of 90,000 abortions or the ratio of 1 in 4 pregnancies aborted is used), and 87% think that it would be a good thing if it could be reduced without restricting access to legal abortion.
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> To legislate for the removal of the current special status of RU486 as a drug requiring ministerial approval sends the message that our federal representatives are intent on consolidating and strengthening abortion practices despite the views of the community.
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> Rather than basing a decision on the fact that surgical abortion is currently available, any decision should reflect the reality that abortion itself is of great moral concern to the Australian public. [14]

14 Submission 1012, Southern Cross Bioethics Institute, page 3.

The thousands of submissions to the committee inquiry reflect that concern.

RU486 is different to other drugs because it is an abortion drug which could see 'do-it-yourself' abortions in the home. For example, in New Zealand "… a woman might be given the drug to take at home …"[15] and the Rural Doctors Association of Australia said some women "… may well safely be able to administer at home."[16]

Even if administered in a surgery or hospital, RU486 would cause many women to abort at home.[17] One submission noted that "the process is less predictable & gives women less control, anonymity & privacy, as the abortion can occur anywhere & at any time."[18]

It is clear this social policy issue is not settled.

This is a serious social policy issue, as well as a major moral and ethical issue. That is why elected members have been given a conscience vote.

The question is: should policy decisions be made by elected leaders or unelected bureaucrats?

One witness commented that:

> … politicians are unavoidably concerned about medical issues because they are concerned about the common good. The good of our community requires that we have a good health system. If politicians wash their hands of concern of medical issues, we would not have Medicare, for instance, we would not have public hospitals, we would not have universities to train our health professionals and so on …
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> … all of our political leaders [need] … a certain courage, a willingness to lead at the moment, because the temptation would be very strong to pass this to somebody else – to some bureaucrat or to some group such as the TGA – to worry about.[19]

The TGA admits that it confines itself to only technical questions of quality, safety and efficacy. The TGA does not consider ethical issues.[20] Questions of ethics and values in major social policy issues are for elected leaders to decide. That is their job; what the community elects, and expects, them to do. When politicians make

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15 Dr Tippett, CA Hansard, 15 December 2005, page 39.

16 Dr Page, CA Hansard, 15 December 2005, page 28.

17 See discussion with the AMA, the Rural Doctors Association and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists about how a woman aborting at home could dispose of her foetus. CA Hansard, 15 December 2005.

18 Submission 240, Dr Elvis Seman, page 2.

19 Bishop Anthony Fisher, CA Hansard, 6 February 2006, page 11, 13.

20 Dr Graham and Ms Halton, Department of Health and Ageing, CA Hansard, 15 December 2005, pages 30-31.

decisions, they must consider community attitudes and they are accountable to the people at elections. Unelected bureaucrats do not represent the community and are not accountable to the community.

The great advantage of the current system is that it is clear the Health Minister is responsible and he or she must report to Parliament if they approve importing an abortion drug into Australia. I agree with Professor Charles Franks' statement that "responsibility must be allocated to identifiable persons before they can be held accountable."[21]

Family First believes the Federal Parliament would be setting a dangerous precedent if we were to give unelected bureaucrats the power to make policy decisions.

Women in rural areas

The current debate over RU486 was initiated when Professor Caroline De Costa published an article in the *Medical Journal of Australia* calling for RU486 to be made available, saying it "… is critical for many women in rural areas and women in some ethnic groups whose access to surgical abortion is limited."[22]

Member for Murray, Dr Sharman Stone, has also lobbied for the introduction of RU486 in Australia, specifically for rural women.[23] Family First is disappointed that Dr Stone did not take a much stronger stand last year when a pregnancy support service in her electorate faced closure due to a lack of funds. Family First lobbied the Federal Government to provide funding to keep open the Goulburn Valley Pregnancy Support Service which, for almost 30 years, has been providing practical help to women to continue with their pregnancies.[24] Fortunately, on the day the centre was due to close its doors, November 18 last year, the Government announced a one-off $40,000 grant, ensuring it can remain open until June 2006. Given the organisation has made such an enormous difference to the lives of so many women in her electorate, it is disappointing Dr Stone failed to take a much stronger stand.

In response to calls to introduce RU486, the Health Minister sought advice from his Department. On the issue of whether the drug was suitable for women in rural areas, the Department advised "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 greater levels of backup.

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21 Franks, CES (2004), Putting accountability and responsibility back into the system of government. *Policy Options*, October. Page 64.

22 De Costa, CM (2005) Medical abortion for Australian women: it's time. *Medical Journal of Australia*, Vol 183(7), pages 378-380.

23 Submission 901, Dr Sharman Stone.

Melissa Polimeni, Chance of abortion backdown. *Herald Sun*, 14 October 2005

24 Christie Peuker, We will fight for service: senator. *Shepparton News*, 3 November 2005.

[It is]… unsuitable for women in rural and remote areas who may have limited access to obstetric facilities."[25]

Abortion supporters share these concerns. The Women's Abortion Action Campaign has said:

> Ensuring, if you are not set up to perform a suction curettage, that you have a back up system of where to refer women to, if the possibility of retained products after administration of RU486 eventuates – these are huge practical problems which are not easily overcome, particularly if one is working in a rural or remote area.[26]

A number of other submissions highlighted the difficulty of accessing health services in rural areas to reduce the risk to women of using RU486.

> I am a rural pharmacist, who works in larger rural centres such as Wagga Wagga and Albury. I also work in smaller communities, and my most recent placement was at Condobolin, a town of about 3,500 people, with one pharmacy and a small hospital. Although there are currently 4 doctors in Condobolin, there are no facilities for women to have their babies there. So they must go at least an hour away to Parkes or Forbes, where there is not always an obstetrics specialist available, or to Orange, Dubbo or Wagga Wagga, which are a minimum of 2 hours away.[27]

Dr David Gawler expressed concern that:

> the manufacturer's protocol for the "safe" use of RU486 stipulates that a woman having such an abortion must see a medical practitioner on day 1, 3 and 14. In many areas of Northern Australia, serviced by itinerant doctors, this would not be possible. In addition, continuous medical cover is often not available.[28]

Dr Elvis Seman discussed the practical problems of administering RU486 in a rural setting:

> I am from Broken Hill originally. I have practised as an obstetrician in Woomera, Lameroo and lots of country places, so I am quite familiar with the system and the patient assisted transport scheme. I know this is expensive. It is very inconvenient for those women to travel to the city, but mark my words: this is money well spent if fewer women are going to die from it. So that is where I would like to see my money spent: sticking to the safer, albeit at times less convenient, option.

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25 RU-486 (Mifepristone) – Medical Abortion. Minute to the Minister. Department of Health and Ageing, November 2005.

26 Women's Abortion Action Campaign, submission 905, page 10.

27 Submission 635, Ms Jenny Madden, page 1.

28 Submission 1, Dr David Gawler, page 1.

> Consider this as well, because of all the adverse things that can occur: women will come back haemorrhaging severely—not a lot, but they will. This is a real panicky sort of situation for doctors in the country. They have got to summon a colleague who can give the anaesthetic, then urgently deal with the haemorrhage. Worse still, there is ectopic pregnancy. It is terrifying to see a young woman come in hematonic shock from a ruptured tubular ectopic pregnancy. This is an emergency. They may or may not be able to deal with it up there. They will have to evacuate these particular women to Perth; they may die along the way. And this is an important point: with surgical termination you can confirm you have terminated a pregnancy from inside the womb at the time. You have got an early warning system of an ectopic pregnancy.
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> This does not exist with chemical abortion, because the tissue that is passed by the woman is never analysed—but that is the nature of it—and, furthermore, the drugs induce symptoms that can mimic an ectopic pregnancy.
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> This is why in the adverse event report 11 out of 17 of the ectopics that were reported had ruptured. So you are going to have a delay in diagnosis of ectopic pregnancy. This is uncommon, but we are talking about uncommon things, because our safety is so good at the moment we must not compromise it. To reiterate, I would rather see my money spent more expensively sending some of these isolated women to the city to have a safer procedure.[29]

Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) admits that it confines itself to only technical questions of quality, safety and efficacy. It does not consider ethical criteria.[30]

The TGA, which is currently part of the Department of Health and Ageing, will become part of a new statutory authority being established on 1 July 2006 to regulate therapeutic products in Australia and New Zealand, making it even more arms length from the Government. [31]

Dr Monique Baldwin, a regulatory associate with a pharmaceutical company who is very familiar with the role and operations of the TGA, wrote last month in *The Australian*:

> … 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

29 Dr Seman, CA Hansard, 3 February 2006, page 51-52.

30 Dr Graham and Ms Halton, Department of Health and Ageing, CA Hansard, 15 December 2005, pages 30-31.

31 See: http://www.tga.gov.au/docs/html/recruit/empcond.htm

> human life. RU486 has serious ethical and social concerns that go far beyond scientific analysis.[32]

A number of submissions also raised concerns over the TGA being fully funded by the industry it is supposed to regulate:

> The fact that the TGA is dependent on the industry it is charged with regulating for its operating costs raises the issue of whether or not the TGA must not only be independent but be seen to be independent. The TGA risks the perception that it may exhibit a bias towards the drug industry, rather than serving the Australian community which contributes little to its budget. Given the controversial nature of RU486, Women's Forum Australia believes that the risk of this perception is a further reason why it would be inappropriate for the TGA to be responsible for approving this drug.[33]

The person or group responsible for RU486 must be independent and seen to be independent. This cannot be said of the TGA, which is in the financial clutches of the industry and depends on money from pharmaceutical companies.

There was also concern that doctors and pharmacists are not obliged to report problems with RU486 and that reporting is voluntary:

> Further, while manufacturers and distributors of registered medicines must report evidence of adverse events, medical professionals and pharmacists are not required to do so. Yet, in the case of RU486, it is the medical professionals and pharmacists who are likely to be made aware of adverse effects. Experience in the USA demonstrates that it is essential that reporting of adverse effects of RU486, a drug which has caused deaths, must be mandatory and that whoever approves the use of RU486 must able to require such reporting regardless of whom becomes aware of adverse events. Since the imposition of such a requirement is beyond the scope of the TGA, it is more appropriate that the Minister approve this drug. [34]

Availability of RU486 over the counter at pharmacies

One rural pharmacist raised a concern about dispensing RU486 as a pharmacist, linking it to a concern about dispensing the morning-after pill Postinor-2.[35]

The morning-after pill was first made available in Australia in July 2002, on prescription after consulting a GP. There was concern reported in the media at the time that the company would move to make Postinor-2 available over the counter at

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32 Probe a prescription for social concern, The Australian, 31st January, 2006, p.12

33 Submission 920, Women's Forum Australia, page 21.

See also submission 930.

34 Submission 920, Women's Forum Australia, page 21.

35 Submission 635, Jenny Madden, page 2.

pharmacies. This was denied in an article in *The Australian* on 1 July 2002, which said:

> A Schering spokesperson said it had no intention of applying to Australia's Therapeutic Goods Administration to sell Postinor-2 without a prescription. "It is only to be used as an emergency contraceptive and one of the reasons it is available on prescription only is so doctors can regulate how patients use it."[36]

Schering's Product Information documents recommended that women consult their doctor to rule out a list of conditions that may be aggravated by taking the drug and endangering their health.

However, in June 2003, not even 12 months after the pill was made available by prescription-only, the National Drugs and Poisons Schedule Committee (a committee of the TGA) announced that Postinor-2 should be made available over the counter at pharmacies.[37], without prescription. This happened from 1 January 2004.

Furthermore, despite assurances that pharmacists would follow a voluntary protocol, there have been reports of pharmacies routinely flouting the protocols, the drug being handed over by a beauty consultant and girls as young as 15 buying it.[38]

Proponents of RU486 say it will be used under medical supervision, but if it is allowed into Australia, how long will such a restriction last? Experience with Postinor-2 suggests any dispensing restrictions will not last or be ineffective.

A system of voluntary reporting of adverse drug events is inadequate. It is likely, given the experience with Postinor-2 that, if RU486 is allowed into Australia, conditions would change.

Risk to women

There has been a significant amount of information presented to the committee about the dangers of RU486 for women. While this information is not central to the issue of who should decide on this important policy issue, it is relevant given the general view that RU486 would more likely be allowed into Australia if the decision is left to the TGA.

The physical risk of using methods of chemical rather than surgical abortion is greater for women. An editorial in *The New England Journal of Medicine* from late last year "… noted that while the death rate in the USA for surgical abortion in the first 8

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36 Byden-Brown, Sarah, Morning-after pill on sale. *The Australian*, 1 July 2002.

37 National Drugs and Poisons Schedule Committee (Therapeutic Goods Administration), Record of reasons 38th Meeting 17-19 June 2003 - http://www.tga.gov.au/ndpsc/record/rr200306.htm.

38 Price, Sarah, Morning-after pill sold by a beauty consultant. *Sun-Herald*, 30 May 2004. Spagnolo, Joe, Morning after pill. *The Sunday Times* (Perth), 8 January 2006.

weeks is around 0.1 in 100,000, the death rate from infection associated with RU486 for similar early abortions is close to 1 in 100,000."[39]

Feminist academic Dr Renate Klein, who supports abortion but is strongly opposed to RU486 because of the health risks to women, notes that

> … instead of terminating a pregnancy in 10 minutes [by surgical abortion] with a minimum recovery time of only hours, especially if a local anaesthetic is used, an RU 486/PG abortion is a drawn out multi-step procedure that can last for weeks.[40]

Head of the Urogynaecology Clinic at the Flinders Medical Centre, Dr Elvis Seman, agrees that chemical abortion is much more difficult than surgical abortion

> A woman having a surgical abortion is usually in hospital for a few hours, she experiences variable cramping & vaginal loss for a few days, & usually returns to work & normal activities after 2 days. In contrast chemical abortion takes an average of 9-16 days, with 9% of women bleeding over 30 days. Thus with chemical abortion women are sicker for longer & will need more help at home, & more time off work. The process is less predictable & gives women less control, anonymity & privacy, as the abortion can occur anywhere & at any time.[41]

An RU486 abortion also involves the use of a prostaglandin drug called Misoprostol to complete the abortion. This is despite the drug not being approved for that purpose and despite the fact that the manufacturer has advised against its use for abortion.

> The use of misoprostol in gynaecology is "off label" .In other word it is not licensed by its manufacturer to be used gynaecologically, not even for dealing with miscarriages. Thus whilst the use of misoprostol in chemical abortion is legal, it is unethical, & the TGA would be asked to approve a drug for an indication for which it is unlicensed.[42]

> … a spokesman for Pfizer Australia, said the company did not think it should be used after RU486. 'We would not recommend use outside TGA-endorsed indication and at this stage that just involves stomach ulcers," the spokesman said.'[43]

One submission noted major problems with the use of RU486 (Mifepristone) and Misoprostol:

> An investigator for the National Research Institute for Family Planning in Beijing wrote in a 2000 issue of the *Journal of the American Medical*

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39 Submission 628, Life Office, Catholic Archdiocese of Sydney, page 5.

40 Submission 930, Dr Renate Klein, page 7.

41 Submission 240, Dr Elvis Seman, page 2.

42 Submission 240, Dr Elvis Seman, page 3.

43 Patricia Karvelas, Abortion warning by drug's producer. *The Australian*, 31 January 2006.

> *Women's Association*: "The common complications ... are profuse bleeding and allergy ... Allergic reactions to Mifepristone and misoprostol were not uncommon, manifesting in facial edema, skin rash and itching, numbness of feet and hands, and even a serious case of allergic shock." The investigator wrote that mifepristone/misoprostol abortions are falling into disfavor among staff at larger hospitals in China: "The staffs were too busy to handle the procedure (more counseling, more visits and observation), and they also have to manage the referred cases with serious side effects and complications."[44]

The psychological risks of an RU486 abortion were discussed in a number of submissions:

> A medical abortion, marketed as an easy option, would have the effect of making it harder for women to ask for help when they are in crisis about their pregnancy. It is a natural reaction when in a crisis for people to seek a perceived quick and easy option. It takes time and dialogue to work out what will be best for all parties for the long term.
>
> …the consequences of delivering a dead foetus at home, or of pain and bleeding for … weeks would further increase psychological trauma to women and their families.[45]

Another quoted studies which reveal chemical abortions are more stressful and painful:

> Two recent UK studies have compared women having surgical abortions with women having chemical abortions. The researchers found that women having chemical abortions rated the procedure as more stressful & painful, & they experienced more post-termination physical problems & disruption to their lives. Women may not expect, or are not told, that they may see the foetus, & this was associated with more intrusive events – nightmares, flashbacks & unwanted thoughts related to the procedure. [46]

Such concerns were contrasted in one of the hearings with this bland and removed comment, apparently not recognising the reality of abortion for women:

> "… women are used to dealing with menstrual loss all the time. She can make a choice of what she wants to do. She needs to know that she may pass a foetus."[47]

Another quoted the head of the company that created RU486:

> Even Edouard Sakiz, the former chairman of Roussel-Uclaf, the French company that developed RU486, has said: "As abortifacient procedures go,

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44 Submission 920, Women's Forum Australia, page 13.

45 Submission 623, Drs Dianne and Stephen Grocott, pages 1 and 2.

46 Submission 240, Dr Elvis Seman, page 2.

47 Dr Andrew Pesce, Australian Medical Association, CA Hansard, 15 December 2005, page 9.

> RU486 is not at all easy to use ... a woman who wants to end her pregnancy has to live with her abortion for at least a week using this technique. It's an appalling psychological ordeal."[48]

Conclusion

Supporters of this Bill have not made a case for change. RU486 and other abortion drugs are part of a unique class of drugs and their distribution raises complex social, ethical and policy issues. They are different to other drugs in that they could see 'do-it-yourself' home abortions and women aborting at home. Questions of ethics and values in major social policy issues are for elected politicians to decide. Family First believes the Federal Parliament would be setting a dangerous precedent if we were to give unelected bureaucrats the power to make policy decisions.

Senator Steve Fielding

Leader of the Family First Party

Family First Senator for Victoria

48 Submission 920, Women's Forum Australia, page 15.