Additional comments

Senator Gary Humphries

Senator Guy Barnett

Senator Steve Fielding

Senator Helen Polley

Senator Barnaby Joyce

1. The nature of the Chair's Report is to provide a description of "the approval processes in question and the pharmacological properties of RU486" along with "an outline of the issues and arguments raised in evidence by those groups and individuals supporting the Bill and those opposing the Bill."

2. These additional comments go further. As full or participating members of the Committee who have considered all the evidence in the 4788 submissions and correspondence received and given at the public hearings we would like to state our conclusions.

3. The central claim of the supporters of the Bill is that RU486 is simply another drug, not essentially different from any other drug, and that therefore there is no justification for the 'restricted goods' provisions in the existing legislation.

4. After considering all the evidence we conclude that this central claim is without foundation because it ignores the fundamental fact that RU486 is a drug intended to cause abortion.

5. It is used as the first drug in a two drug regimen administered during the first 9 weeks of pregnancy for the purpose of ending the life of the developing child and bringing about its expulsion from the mother's body. RU486 has also been used in abortions up to 20 weeks gestation. Even if the TGA approved it solely for abortions up to 9 weeks once it was registered there would be nothing to prevent its off-label use for mid-trimester abortions.

6. This use does not correspond to any of the meanings of "therapeutic use" given in Section 3 of the Therapeutic Goods Act 1989.

7. Opinions in the community on abortion are divided and conflicted. Recent opinion polls indicate that Australians think there are too many abortions and that they disapprove of abortion for financial and social reasons.

8. Supporters of the Bill argued that, given that the States and Territories are responsible for the legal status of abortion in their jurisdictions, the Federal

Parliament has no right to retain legislation that can be construed as limiting the methods of abortion available in Australia. We strongly reject this argument. The Federal Parliament has constitutional responsibility for imports and other matters reflected in the very existence of the Therapeutic Goods Act 1989. In voting on the provisions dealing with abortifacients as "restricted goods" Senators and Members are necessarily voting on the question of abortion. To vote to treat that class of drugs intended for use in abortion as simply equivalent to genuinely therapeutic drugs would be to state that these drugs do not raise any particular ethical or social issues connected with abortion itself.

9. The Therapeutic Goods Administration is empowered by the Act to consider the safety, quality and efficacy of a drug. It has no power or competence to consider the broader social and ethical impact that may follow if a drug is registered for import and use in Australia. Under the existing 'restricted goods' provisions the Minister can consider the social and ethical impact of an abortifacient drug. If this Bill is passed, and these provisions are removed, then the social and ethical implications of introducing RU486 to Australia cannot be taken into consideration. We hold that allowing the abortion drug RU486 into Australia is a major social policy change that therefore should only be able to be made by a Minister accountable to the Parliament and the people.

10. We believe that there is strong evidence of serious risk to women associated with the use of RU486 in abortions, evidence which could properly be assessed by the TGA in considering the safety and efficacy of the drug.

11. Given the requirements of close consultation with the administration of RU486 and the difficulties in many regional areas with an appropriate level of access to medical facilities and supervision we have grave concerns for the health and lives of women in regional areas and specific disadvantaged groups who would use the drug.

12. Supporters of the Bill were of one voice in claiming the safety of RU486. Many claimed that a medical abortion was as safe or safer than a surgical abortion. Several claimed that RU486 had a higher adverse event rate than the over the counter allergy drug Claratyne ® . These comparisons are demonstrably false. Medical abortion carries with it a ten fold higher mortality rate than surgical abortion. RU486 is certainly far more dangerous than Claratyne ® .

13. Many supporters of the Bill were also distressingly cavalier in their attitude to the eleven deaths of women officially acknowledged to have occurred in association with RU486 abortions. One witness stated that the difference between 10 women out of 100,000 dying from an RU486 abortion compared to 1 woman per 100,000 dying from surgical abortion at the same gestational stage was like the difference between 10 grains of sand and one grain of sand – imperceptible to the human eye. As Senators entrusted with making laws for the peace, order and good government of this Commonwealth of Australia we utterly reject this cavalier approach to the lives of Australia women. We cannot

support any diminution of the checks currently in place before a drug which may take the lives of healthy young Australian women is allowed into this country.

14. There have been a total of 11 known deaths associated with RU486 abortions. Three British women have died, five women have died in the United States, one in Canada, one in Sweden and one in France. In August 2001 a 26 year old, previously healthy woman was admitted to Sherbrooke University Hospital in Quebec, Canada with abdominal pain, vomiting and foul-smelling vaginal discharge. Seven days earlier she had had abortion medically induced by RU-486 and misoprostol. Despite treatment in the intensive care unit the woman died within 3 days of admission. Her uterus was found to be infected with a bacteria *Clostridium sordellii* and she was found to have died of toxic shock. As a result of this tragic death the trial of RU486 in which the woman had participated was halted and RU496 has never been approved in Canada.

15. Four American women, all otherwise healthy before submitting to an RU486/misoprostol abortion, have also died from toxic shock syndrome caused by *Clostridium sordellii* infection. These women were Holly Patterson (18), who died September 17, 2003; Hoa Thuy Tran (21), who died 29 December 2003; Chanelle Bryant (22), who died 14 January 2004 and Oriane Shevin (34), mother of two, who died 14 June 2005. According to Professor Ralph Miech, MD, Ph.D., the abortion drug **triggers a bacterial infection in a woman's cervical canal that doesn't normally occur**. **The bacteria thrive on the decaying tissue from the dying unborn child and impairs the woman's ability to fight off the infection.** Officials from the Food and Drug Administration and the Centers for Disease Control and Prevention have decided to convene a scientific meeting early 2006 to discuss this medical mystery, according to two drug agency officials who spoke on the condition of anonymity because of the sensitivity of the topic.

16. The death of 16 year old Swedish girl Rebecca Tell Berg on 3 June 2003 after an RU486 abortion resulted from blood loss six days after taking misoprostol to complete the abortion process. She was found by her boyfriend having bled to death in her shower.

17. An analysis of adverse events following RU486 abortions demonstrates that for every woman who dies in association with an RU486 abortion there are seventy women who suffer life-threatening complications, including severe haemorrhage, sepsis and ruptured ectopic pregnancy. Sixty eight American women have required blood transfusions after RU486 abortions with 42 of these cases classified as life threatening. Up to 8% of women who are undergo an RU486 abortion fail to abort. They may undergo a second surgical abortion further increasing the overall health risks. If the woman chooses not to have this second abortion and carries the pregnancy to term the risk of fetal malformation is 23%.

18. Governments and legislators in several other jurisdictions have taken steps to prevent or cease the use of RU486 for abortion. The Italian Government has just announced a ban on any general import of RU486 into Italy. This follows the suspension of a trial of RU486 in Turin last September after serious health concerns. The United States Congress has before it the RU486 Suspension and Review Act (also known as Holly's Law after Holly Patterson, an 18 year old woman who died after an RU486 abortion). This Act would suspend all sales of RU486 while the comptroller general investigates the Food and Drug Administration's handling of the approval process for RU486. A Congressional Subcommittee is also investigating the handling of the approval process for RU486 by the FDA, as well as its response to the five deaths and other adverse events related to RU486 abortions.RU486 remains unlicensed in Canada after the suspension of a trial following the death from toxic shock syndrome of a 26 year old woman on 1 September 2001.

19. Given these moves in other jurisdictions, the serious health risks to Australian women, and above all the necessity to consider the social and ethical implications of a drug intended to produce abortion, we conclude that the 'restricted goods' provisions for abortifacient drugs should remain in place and the Bill be rejected.

Senator Gary Humphries
LP, Australian Capital Territory

Senator Guy Barnett
LP, Tasmania

Senator Steve Fielding
FFP, Victoria

Senator Helen Polley
ALP, Tasmania

Senator Barnaby Joyce
NATS, Queensland