AUSTRALIAN SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE

INQUIRY INTO

THERAPEUTIC GOODS AMENDMENT

(REPEAL OF MINISTERIAL RESPONSIBILITY FOR APPROVAL OF RU486) BILL 2005

Peter McCullagh, MD (Melb), D Phil (Oxon), MRCP (Lond).

I believe, on the basis of reports of the debate which has already ensued on this Bill and of the first Inquiry hearing, that a substantial conflation of scientific and social issues has occurred and that there is considerable risk that, when Parliamentary consideration of the Bill takes place, this may be similarly confused. This being so, I submit that the most valuable contribution that the Community Affairs Legislation Committee can make in its report to the Senate is to separate these issues clearly and explicitly and to indicate those aspects with which the Senate is not only entitled to deal, but has a responsibility to the electorate to address.

The Therapeutic Goods Amendment Bill 1996 (Number2) was passed without dissenting vote. The transcript of the debate makes it clear that its passage did not reflect a general agreement among Senators that the practice of abortion in Australia at that time, and the introduction of the agent RU 486, should be proscribed. What passage of the Bill ***did*** reflect was, in the first place, that Senators recognized a responsibility to be aware of issues likely to evoke concern and dissension within their electorate and, secondly, that the introduction of RU 486 into abortion practice was such an issue.

Speakers contributing to the 1996 debate differentiated well between their personal and party views specifically on abortion, and its technological aspects, and their belief in the generally applicable duty of any government to take account, not just of purely technical detail, but also of much broader social considerations in reaching policy decisions. This is, of course, the basis of political decision. If all issues coming before government are to be resolved solely on the basis of technical input, there will no longer exist a need for an elected parliament. Issues can then be decided entirely by an unelected and unaccountable bureaucracy or, in the future, by algorithms incorporated in software devised by unaccountable programmers.

Two essential goals, which can only be accomplished within the context of a parliamentary process, are to ensure that a fair representation of all views of the community are introduced into the consideration of an issue and to ensure that this is

done within as open and generally accessible a process as it is possible to achieve. To recognize that these goals are not necessarily achieved in some instances is not to concede that they should not remain a priority in every one. If the specific content of the 1996 Bill is used as an example, it is appropriate that, whereas the Therapeutic Goods Administration may have had adequate technical expertise to assess technical aspects relating to RU 486, it lacked both the competence and the authority to arbitrate on the associated social issues.

Senator Neal expressed the concepts identified in the preceding paragraph during the 1996 debate: *Whilst the Opposition does not agree with Senator Harradine's particular objective that these drugs should be removed entirely from circulation and that they should not be allowed in Australia, we acknowledge that this issue raises large concerns within the community. It raises concerns beyond purely health issues. These issues need to be addressed by the executive of this government and addressed with absolute and direct accountability and absolute and complete transparency.* Senator Chamarette provided the example that she would expect parliamentary consideration of any proposal to import plutonium and expressed the general proposition that: *I believe that the appropriate accountability mechanism for an issue which has political and social components needs to be open and transparent.*

It's not necessary to delve into distant history to find instances of the Australian Parliament asserting its responsibility to consider the wider social implications of intended specific uses of therapeutic agents which, if submitted to evaluation in pharmacological isolation, could pass muster. In 2004, the most vocal of Australian suicide advocates suggested that those seeking self-closure should seek to obtain a supply of a 10 x strength formulation of sodium pentobarbitone widely used in veterinary practice for euthanasia (and colloquially referred to around the traps as 'green dream' on account of the colouring incorporated in it as a safety measure). This preparation requires intravenous administration, hardly a constraint restricting its self-administration by 2004. Unlike abortion, suicide is legal in all Australian States and Territories. It could be (and was) argued that members of the community have a right, not only to use therapeutic agents to kill themselves in the privacy of their home, but to access information that would assist them. Yet, the Australian Parliament chose to involve itself in restricting promulgation of information about suicide (Criminal Code Amendment (Suicide Related Material Offences) Act 2005). The Parliament was not concerned with pharmacological issues, for instance whether any of the agents recommended for suicide use were likely to be legitimate, safe and effective when used, in other formulations and with other intent.

Parliament's involvement in suicide 'education campaigns', irrespective of the legality of suicide and of the legitimacy or otherwise of therapeutic agents to be used, was a clear example of a role it has conventionally accepted, namely that of examining the broad social picture. Technical inputs are important but only within that broader picture. For instance, a technical consideration which has emerged in relation to RU 486, namely the extent of, and basis for, the recently recognized susceptibility of users to *Clostridium sordellii* infection clearly requires clarification before an overall

pharmacological assessment of its use in abortion can be made with any confidence. However, the primary issue for consideration by the Inquiry is ***where*** responsibility for decision-making in relation to RU 486 should rest. In this instance, it is not in dispute that TGA input into decision-making is ***necessary.*** However, it is certainly not ***sufficient.***

Where, within our Parliamentary process, should decision-making lie. Conventionally, a minister is held responsible for decisions taken by his or her department. However, I submit that the type of decision-making with which this Inquiry is concerned is such that a wider input from elected representatives would be an improvement. Ideally, decisions of this type would best be made by the government of the day. In practice, this may equate with a cabinet decision, probably after consultation with other members. Any decision to approve use should be presented to Parliament as prescribed in 1996, in the interests of transparency. In view of the common, but inaccurate, perception that the 1996 Act prohibits use of RU 486 to procure abortion (as distinct from requiring ministerial permission of importation for this purpose), it would enhance transparency if notification of refusals of requests was also presented to Parliament.