

Extract from Senate Hansard 8 December 2005

**THERAPEUTIC GOODS AMENDMENT (REPEAL OF MINISTERIAL
RESPONSIBILITY FOR APPROVAL OF RU486) BILL 2005
Second Reading Speech**

Senator NASH (New South Wales) (9.41 a.m.) – I move:

That this bill be now read a second time.

I seek leave to have the second reading speech incorporated in *Hansard*.

Leave granted.

The speech read as follows –

This Bill removes responsibility for approval of RU486 from the Minister for Health and Ageing, and provides responsibility for approval of RU486 to the Therapeutic Goods Administration.

In 1996, this parliament allowed an amendment to the Therapeutic Goods Act 1989. That amendment made the Minister for Health and Ageing ultimately responsible for decisions in relation to the importation, trial, registration and listing of RU486 and other abortifacients, rather than the Therapeutic Goods Administration, which is the statutory body usually responsible for the approval of medicines in Australia. This was on the grounds that these drugs amounted to a special category of drug requiring an additional layer of public scrutiny.

That debate occurred some 10 years ago over concerns about the safety of the drug, in the context of what was known about RU486 at that time.

The Australian community expects that medicines and medical devices in the marketplace to be safe, of high quality and of a standard at least equal to that of comparable countries. Responsibility for that falls on the Therapeutic Goods Administration. The TGA provides a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines, and to ensure the quality, safety and performance of medical devices.

The Therapeutic Goods Administration has the knowledge and expertise to conduct the evaluation of RU486 for quality, safety and efficacy. That is why the TGA has been entrusted to evaluate more than 50,000 therapeutic goods that have already come before it.

On behalf of Senators Troeth, Allison, Moore and myself I commend the Bill to the Senate and present the explanatory memorandum.

I seek leave to table the explanatory memorandum.

Leave granted.

Senator NASH—I seek leave to continue my remarks later.

Leave granted; debate adjourned.