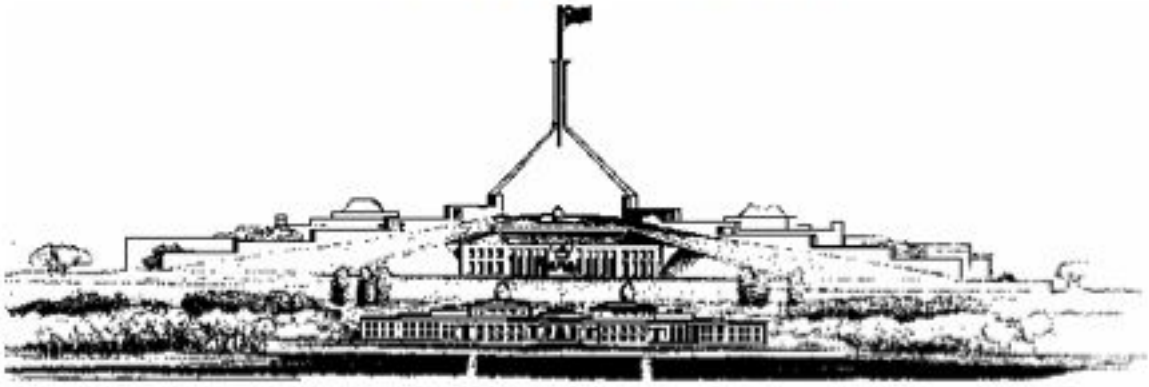
COMMONWEALTH OF AUSTRALIA

PARLIAMENTARY DEBATES



HOUSE OF REPRESENTATIVES

Main Committee

THERAPEUTIC GOODS AMENDMENT (MEDICAL DEVICES AND OTHER MEASURES) BILL 2008

Second Reading

SPEECH

Tuesday, 26 May 2009

BY AUTHORITY OF THE HOUSE OF REPRESENTATIVES

SPEECH

Date	Tuesday, 26 May 2009	**Source**	House
Page	4399	**Proof**	No
Questioner		**Responder**	
Speaker	Dutton, Peter, MP	**Question No.**	

Mr DUTTON (Dickson) (7.01 pm)—The Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008 provides for a number of amendments to the Therapeutic Goods Act and in part implements some of the reforms proposed originally for the establishment of the Australia-New Zealand therapeutic products authority. The process to establish the Australia-New Zealand therapeutic products authority commenced with the signing of a memorandum of understanding between Australia and New Zealand in December 2003. However, the process stalled in July 2007 under the pressure of domestic political conditions in New Zealand at that time. As my colleagues have noted in the Senate, with a different political landscape in New Zealand today there is an opportunity now for the government to continue with the trans-Tasman reform process initiated by the coalition government.

This bill will amend the operations of the Therapeutic Goods Administration. The TGA has an important role in regulating therapeutic goods, such as medicines and medical devices, according to quality, safety and efficacy. However, it is important that any regulation is also efficient and efficacious. This is particularly the case for the TGA, which operates on a cost recovery basis for the listing of relevant products on the Australian Register of Therapeutic Goods. It is imperative that under any cost recovery process compliance requirements and costs do not jeopardise the listing of potentially beneficial products for the Australian community.

Specifically, the proposed changes in the bill provide for the exemption of medical devices under the act to allow for stockpiling and timely supply in emergency situations, the removal of the requirement that instruments allowing stockpiling of therapeutic goods be disallowable, a narrower 'fit and proper' test in the granting of manufacturing licences and conformity assessment certificates, inclusion of the United States and European Pharmacopoeia as default standards for therapeutic goods in addition to the existing British Pharmacopoeia default, improved information disclosure by the TGA and the clarification of regulation applying to advertising.

The coalition broadly supports the amendments contained within the bill, as does industry, according to available stakeholder feedback. The inclusion of the United States and European Pharmacopoeia in addition to the existing British default for therapeutic goods standards is a commonsense reform, providing a degree of flexibility for organisations bringing beneficial products to market in Australia.

The reforms to the fit and proper test provide workability to what is currently too broad a test. The amendments provide practical and measurable guidance as to persons who did not meet the requirements of a fit and proper person. The provisions to improve access to information held by the TGA is important in the interests of transparency, and this will provide interested stakeholders with relevant information pertaining to the details on that Australian Register of Therapeutic Goods: summaries of evaluations of applications to register new therapeutic goods and the records of the advisory committees established under the act.

Advertising provisions in this bill clarify the existing regulations regarding advertising of therapeutic goods. It is appropriate that current regulations requiring pre-approval of advertisements in mainstream media be extended to other media. These amendments are straightforward reforms designed to enhance the operation of the TGA and are largely uncontentious. However, I bring attention to the concerns outlined by my colleagues in the Senate regarding the amendments to the current exemption provisions. These amendments remove the requirement that instruments allowing the stockpiling of therapeutic goods be disallowable. The provision is said to be based on advice that the contents of the stockpile should have a classification of confidential in the interests of national security and therefore should not be tabled in the parliament and not be subject to public scrutiny. Whilst the coalition considers national security of paramount importance, I do bring attention to the caution by which such exemptions to parliamentary scrutiny of ministerial decisions should be made. Nevertheless, notwithstanding these concerns, the coalition is satisfied that this bill will enhance the operations of the TGA as a fundamental institution in our healthcare system.

Whilst I am on this debate in relation to our healthcare system, I want to again return to the very important issue surrounding a patient in New South Wales by the name of Pauline Talty. I want to bring to the House's

attention today the situation of this courageous young woman, Pauline Talty. As we have spoken about in the press before and also in this House, Pauline needs a lifesaving bowel transplant operation. Seven months ago —and I repeat, seven months ago—Pauline sought funding under the Medical Treatment Overseas Program to travel to Pittsburgh for this transplant. At the time, her doctors warned that she may only have around 12 months to live. Through the very long and agonising months since, she has had to repeatedly argue her case to the federal health department, which twice denied her treatment under MTOP, dismissing the advice of numerous health experts. On 13 May—two weeks ago tomorrow—the decision was reversed. Her battle with bureaucracy ended, or so she thought. The secretary of the health department wrote to Pauline to inform her that her lifesaving surgery overseas had been approved. On that afternoon, I stood in the House and praised the government for this change of heart. I had committed to do that. It was a very long, public campaign but, nonetheless, the government in the end changed the decision and I said at the time that if they did that I would praise them, and I did. This is very important, Madam Deputy Speaker.

The DEPUTY SPEAKER (Ms JA Saffin)—I call the honourable member's attention to the fact that whilst I am happy to give a lot of leeway, as we do in this place, you have strayed a long way from the bill, so please finish that remark.

Mr DUTTON—Sure, Madam Deputy Speaker, I am just finishing on this note and I thank the government for their accommodation made to Pauline's treatment. Two weeks might not seem a long time to any of us but consider someone in Pauline's position; two weeks is a long time. She still feels that the red tape is trapping her and that she is being asked to be the middle person between the federal department and the hospital in Pittsburgh, from her hospital bed in Sydney. It is not good enough.

The DEPUTY SPEAKER—Would the honourable member come back to the bill right now, please.

Mr DUTTON—Indeed I will. That is why I call tonight on the health minister to intervene in this particular case, because it is unacceptable that the bureaucratic process is still bogging down this particular issue. This government has this bill, which is an important bill, before the House tonight, and the government has the support of the coalition in relation to this bill. We have a health system in this country which is in crisis. The point that I make, by way of example through Pauline's case, in relation to this very important debate, is that this government gave a commitment to this dying young woman that they would cut the bureaucratic process, but they have not. So the call, again, for this government is to make sure that they put aside the bureaucratic nonsense and provide a better outcome for Pauline Talty.

The DEPUTY SPEAKER—Would the honourable member for Dickson please return to the bill, and if the honourable member has forgotten the title I will help him. It is the Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008. Thank you.

Mr DUTTON—We can all read, Madam Deputy Speaker, and we can all see the travesty that has taken place in relation to Pauline Talty. I have made my point in relation to Pauline Talty—

The DEPUTY SPEAKER—You have indeed!

Mr DUTTON—and I will be making it on many occasions subsequent to this if the government does not act promptly so that this debate can be had and this woman can get on with her life. That is the call we make to the government tonight.

In relation to the bill, there are some areas of concern. Those areas have been flagged in the Senate, and we have made the government aware of them tonight. In terms of the general thrust of this bill and the way in which it has been presented by the government, the coalition support the bill. As the alternative government of this country, we will continue to hold this government to account to make sure we have better patient outcomes in this country and to make sure that the government does not continue to put extra pressure on the public hospital system, which is already at—and in some cases beyond—breaking point. We renew that commitment to the Australian people tonight.