

Submission to Senate Community Affairs Legislation Committee regarding the Therapeutic Goods Amendment (2017 Measures No.1) Bill

Attention: Additional Committee Support
Senate Community Affairs Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600

I am a private citizen, increasingly concerned about the power that industry, commerce, and multinationals are wielding over Governments and various regulatory bodies. I attended a recent Victorian Skeptics meeting which noted that the Therapeutic Goods Administration (TGA) is now 100% funded by industry and outlined the machinations of the Australian Government and the TGA with respect to the Therapeutic Goods Amendment (2017 Measures No.1) Bill. This reinforced my concern about “regulatory capture” and resulted in this submission.

The Bill before the Senate supports the implementation of recommendations of the 2015 Expert Panel Review of Medicines and Medical Devices Regulation (MMD Review). Regrettably, the Bill fails to address longstanding concerns by consumers and health professionals about the regulation of complementary medicine and the advertising of therapeutic goods to consumers.

First, the MMD Review recommended (No 47) that where a medicinal product is listed (self-assessed) in the Australian Register of Therapeutic Goods (ARTG) the sponsor should be required to include a prominent disclaimer on all promotional materials relating to the product, including product information on websites, to the effect that the efficacy claims for the product have not been independently assessed and/or are based on traditional use. Even though this recommendation was supported by consumer and health professional groups, it was rejected by the Government, presumably due to industry lobbying and TGA acquiescence.

Second, I understand that the TGA and the Department of Health attempted to bypass the Senate Committee review of this Bill arguing that it was non-controversial. This argument ignored numerous concerns documented in many submissions lodged in response to the TGA’s so-called, consultations.

Third, when Senator Richard Di Natale responded to requests to get the Bill reviewed by the Senate Community Affairs Legislation Committee, the short time-frame allocated for submissions (over Christmas & New Year) appeared to be a deliberate attempt to stifle debate, as was the decision to reject requests for a public hearing.

Regardless, I understand that concerned civil society organisations are planning to hold their own public hearing at the Australian National University on January 24, 2017 to which the media have been invited.

Now to my main concerns about specific provisions of the Bill.

1. The abandonment of advertising pre-approval (Part 2 of the Bill)

This should be postponed until the other provisions of the Bill, such as increased post-marketing surveillance and strengthened penalties and sanctions, have been shown to eliminate the need for pre-approval. I am concerned that eliminating pre-approval will produce an increase in the already unacceptable rate of misleading and deceptive advertisements for Listed products.

I ask the Senate to recommend that the abandonment of advertising pre-approval be postponed until the need for it has been shown to have disappeared.

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2. Failure of transparency with respect to TGA complaint handling (Division 6, section 42DK, 42DKB (1), 42DV, 42DY, of the Bill)

These provisions contain the words, 'The Secretary may give', 'The Secretary can give', etc. Unless the words 'may', 'can' (above) are changed to 'must', complainants will continue to be frustrated by lack of transparency from the TGA.

The Victorian Skeptics meeting I attended heard that since 2011, over 540 complaints had been submitted to the TGA for non-compliance with Panel determinations and other reasons. Over that time the TGA has only published information on about 78 (14%) complaints.

In short, the TGA has an unenviable reputation as a black hole with respect to advertising complaints.

I ask the Senate to change this Bill to prevent this appalling behaviour of the regulator from continuing.

3. TGA endorsement of pseudoscience by accepting an industry submitted list of "permitted" indications (Schedule 2, Part 1, section 26BF of the Bill - Permissible indications)

This states, 'The Minister may, by legislative instrument, make a determination in relation to either or both of the following: (a) indications; (b) requirements in relation to indications.'

Submission to the TGA's so-called' consultations had pointed out that including numerous TCM, Ayurveda, Homeopathy, Herbalism and other traditional indications on the TGA's draft permitted indication list were endorsing pseudoscience, would not be understood by the average consumers, and required a disclaimer pointing out that these traditions were not in accord with modern medical knowledge.

At the Victorian Skeptics meeting we heard that scientific investigation has not substantiated many aspects of these traditions, such as the homeopathic principles of "like cures like" and traditional Chinese medicine concepts of meridians through which the life-energy known as "qi" flows.

To stop consumers from being misled, I ask the Senate to recommend that products making traditional claims have a disclaimer, such as, "*this traditional indication is not in accordance with modern medical knowledge*"

4. The elimination of Stakeholder involvement in the TGA's new complaint system (Minister Hunt, Second reading of Bill 2.3 Advertising)

We heard that Stakeholder involvement is currently provided by the Therapeutic Goods Advertising Code Council and Complaint Resolution Panel. These bodies are to be abolished from 1 July 2018, even though the TGA has a track record of making bad decisions in isolation that favour industry.

I ask the Senate to recommend that stakeholder input be continued.

In conclusion, I believe that the TGA has developed a culture that favours industry assistance more strongly than consumer protection ("regulatory capture"). I request the Senate Community Affairs Legislation Committee to suggest specific amendments to the Bill to protect consumers.

Wendy Logan


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