Committee Secretary
Senate Community Affairs Legislation Committee
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 **(Cth)**

This document responds to the Committee's call for submissions regarding the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017* (Cth).

In essence, the Bill fails to address substantive problems with the overall regime regarding pharmaceuticals, medical devices and products that are incorrectly perceived as having therapeutic attributes. In terms of consumer protection the Bill as it stands is inadequate; amendment is desirable. A review of the statutory framework for the Therapeutic Goods Administration, its resourcing and its engagement with stakeholders is recommended.

Basis

The submission is made by Assistant Professor Bruce Baer Arnold and Associate Professor Wendy Bonython, both of the School of Law & Justice at the University of Canberra. It reflects teaching in trade practices, intellectual property, health and tort law. It also reflects the authors' research into effective regulation regarding the development, evaluation and marketing of pharmaceuticals, medical devices and empirically-unsubstantiated practices such as homeopathy.

The submission does not represent what would be reasonably construed as a conflict of interest.

Background

The Therapeutic Goods Administration (TGA) is an arm of the Department of Health. It enjoys a statutory immunity from negligence, in contrast to other regulatory bodies. The Objects – the statement of its *raison d'etre* – in the *Therapeutic Goods Act 1989* (Cth) – are substantially weaker than those in other consumer protection legislation, for example the *Competition & Consumer Act 2010* (Cth). The organisation is primarily funded by the commercial entities that it is meant to regulate. It has undergone a series of internal and external inquiries, all of which have expressed concern about its performance and which regrettably do not appear to have resulted in appropriate cultural change.

The TGA has been reluctant to meaningfully engage with stakeholders outside industry, fostering perceptions that it has experienced regulatory capture (ie incorrectly considers that the interests of the businesses that it regulates are the same as the interests of the organisation and of the community at large). It is regarded with disquiet by health practitioners, academics and others over its failure to anticipate and/or prevent harms. That failure contrasts with responses overseas that are both more timely and more effective. A salient example of failure is its December 2017 decision regarding urogynaecological mesh, which followed months of media

reporting, high-profile litigation and the Senate Community References Committee Inquiry into the number of women in Australia who have had transvaginal mesh implants. Put simply, the TGA should act to minimise injury to individuals and an avoidable burden on taxpayers rather than having to be prompted by the Sydney Morning Herald and the Senate Committee.

Assurances from the Department that lessons have been learnt, that there are no significant problems and that only minor fine-tuning of the legislation is required should therefore be regarded with caution.

In providing this submission we are concerned not to disrespect the Committee. It is appropriate, however, to note that the cost of underperformance by the TGA dwarfs the organisation's budget, with for example a direct burden on the taxpayer through medical treatment (including surgery, recovery and rehabilitation) avoidable if the TGA was more effective and an indirect burden through lost productivity (eg patients and carers off work because they were injured).

That cost is relevant in assessing the Government's commitment of $20.4 million over four years (thereafter through cost-recovery) for improved TGA activity alongside a greater emphasis on industry self-regulation. The overall regulatory framework was demonstrably ineffective in relation to the PIP implants and urogynaecological mesh. The limits of the self-regulation are evident in judgments such as *Australian Competition and Consumer Commission v Reckitt Benckiser (Australia) Pty Ltd* [2016] FCAFC 181, where the initiative was taken by the Australian Competition & Consumer Commission – an example unheeded by the TGA.

The Bill

We endorse the adoption of consumer-oriented recommendations by the Expert Panel Review of Medicines and Medical Devices Regulation. Overall we consider that

- although the Bill has some value there remains a need for substantive reform beyond changes to the description and promotion of prescription medications and products that are described as complementary
- the effectiveness of the amended Act will require administrative action, notably a sustained effort by the TGA to engage with non-industry stakeholders on a timely and sustained basis.

Data for evaluation of deregulation

Best practice in de- or re-regulation of health products and services requires a consideration of data rather than advocacy statements by entities with vested interests.

On that basis it is premature to end the current advertising pre-approval mechanism until completion of the formal three year review of the reform package. The review provides the basis for an assessment of the regime on the basis of empirical data. There has been no demonstration that ending the current arrangements will result in a tangible benefit to consumers (and more broadly the national economy) through for example enhanced competition, industry investment and reduction in Health Department costs. In contrast it is clear that some enterprises have both a commercial incentive and a willingness to behave in ways that are misleading or deceptive. The history of consumer protection litigation over the past decade

demonstrates that self-regulation is inadequate and must be bounded by a vigilant regulator operating consistently within a coherent framework. We note inconsistency in decisions by the industry associations responsible for pre-approval, and inappropriate exclusions under the current regime.

Given the comments above regarding the broader dimensions of regulation we suggest that changes should not precede the evidence.

Greater transparency is essential

Concerns regarding a lack of transparency are of long standing and are substantive. We accordingly endorse the suggestion that section 42DV of the Bill be amended through replacement of 'may' with 'must'. The rationale for discretion is unclear and the current wording will, we consider, result in confusion.

As a corollary we suggest that the TGA clearly and publicly advise stakeholders, through the Committee, with information about measures for involving stakeholders in the new advertising regime.

That advice will offset the trust deficit attributable to the TGA's unwillingness to meaningfully engage with consumers. It will also enable informed critique of the organisation's proposals. It is wholly consistent with both the Government's recurrently stated commitment to 'open government' (endorsed by Opposition parties) and the principles articulated by the Australian National Audit Office regarding efficient, effective, accountable policy implementation.

Basis of Indications

Section 26BF of the Bill deals with permitted indications. The substantive basis of many of the indications sought by sponsors is unclear and may indeed by unavailable. If there is a benefit to consumers, the public health system and the national economy it is reasonable to expect that product sponsors who seek a commercial advantage from the marketing of goods should substantiate the basis of that benefit. That expectation is consistent with practice overseas.

Consistent with expectations about consumer autonomy and the salience of public awareness we endorse the suggestion that all indications citing traditional evidence as part of the permitted indications regime must clearly identify the basis of that evidence.

Complementary Products

It is disquieting that the Government in putting forward the Bill has disregarded recommendation 44 of the Expert Panel Review of Medicines and Medical Devices Regulation. The Panel called for a prominent disclaimer in all advertising relating to Listed complementary products (alerting consumers that efficacy claims for these products have not been independently assessed). That disclaimer is relevant given practice by some vendors and perception by consumers that listing means that the product has a certification by the TGA as therapeutically efficacious.

A salient example is the marketing of homeopathic products. A succession of authoritative independent scientific studies and inquiries by both regulatory bodies and parliamentary committees over the past three decades has failed to discover pharmacologically active compounds in products sufficient to substantiate claims by adherents of homeopathy that those products are therapeutically efficacious. Put

simply, for example, if no test is able to discern a compound in an 'extreme dilution' dispassionate observers may be forgiven for concluding that the compound is not present and therefore has no effect. Australia's National Health & Medical Research Council in 2014 stated

> There were no health conditions for which there was reliable evidence that homeopathy was effective. **No** good-quality, well-designed studies with enough participants for a meaningful result reported either that homeopathy caused greater health improvements than a substance with no effect on the health condition (placebo), or that homeopathy caused health improvements equal to those of another treatment.

The 2015 Review of the Australian Government Rebate on Private Health Insurance for Natural Therapies stated

> "The available evidence failed to demonstrate that homeopathy is an effective treatment for any of the clinical conditions for which it has been examined".

In 2010 the United Kingdom House of Commons Science & Technology Committee report on homeopathy stated that the Medicines and Healthcare products Regulatory Agency (MHRA), counterpart of the TGA, should

> not allow homeopathic product labels to make medical claims without evidence of efficacy. As they are **not** medicines, homeopathic products should **no** longer be licensed by the MHRA.

The United States Food & Drug Administration (FDA), counterpart of the TGA, has recently strengthened restrictions on the marketing of homeopathic products.

It is accordingly disquieting that the TGA's proposed list features homeopathic products among some 1,000 indications for 'traditional medicines'. The national pharmaceuticals and medical devices regulator should not be providing legitimacy to products that are inherently non-efficacious. As noted above we suggest a clearly legible disclaimer that underpins both public education and informed consumer choice, modelled for example on the United States Federal Trade Commission (counterpart of the Australian Competition and Consumer Commission) and stating

> This product's claims are based on practices that are not accepted by most modern medical experts. There is **no** recognised scientific evidence that this product works.

We do not propose a ban on homeopathic and other products that are characterised as 'traditional'. We do however suggest that if vendors of those products seek a commercial benefit by placing them in the market it is reasonable for those products to bear such a disclaimer.

Nutraceuticals and other products

The current Australian regime idiosyncratically differentiates between types of therapeutic claims, resulting in uncertainty among business (and associated administrative burdens), potential for regulatory arbitrage and confusion on the part of consumers. We endorse the suggestion that the new Code and complaint system not be restricted to what are formally categorised as therapeutic goods, instead addressing therapeutic claims regarding food and other products.

A principles-based advertising regime that centres on claims of therapeutic **efficacy** rather than on the specific delivery mechanism ('drug versus food') is conceptually

coherent, administratively achievable and desirable in an environment where there is growing investment in – and misunderstanding of – 'nutraceuticals' and other products.

Avoiding capture and addressing complaints

The TGA's raison d'etre is fostering public health through a principles-based consumer protection regime. Consumer protection is not antithetical to timely access to novel therapeutic goods and in making this submission we emphasise, as teachers of health law, that we are not seeking unconsidered restrictions on new pharmaceuticals or medical devices. It is fundamentally important to recognise however that the TGA as regulator must focus on public health and must not, through its close contact with product sponsors, fail to distinguish between industry and community priorities.

It must be prepared to deal with complaints about the advertising of therapeutic products – and what are perceived as therapeutic products. Importantly it must be equipped through legislation, resources and a sense of mission to deal with those products.

On that basis we endorse the call for sustained improvement of the TGA's provision of information about the processes for regulation of advertising of therapeutic goods. Statements by the TGA about its responses to past recommendations regarding improvement have been formalistic, whether because of bureaucratic indifference or under-resourcing.

We note with concern the data provided in the independent submission by Harvey and Braithwaite regarding the TGA's handling of complaints from the Therapeutic Goods Advertising Complaint Resolution Panel since 2011. That concern is shared by many clinicians, public health regulators and consumers. In any consumer protection regime it is important that action be seen to be done, and be done on a timely basis, in the interests of both consumers and business. Greater transparency is imperative and is achievable. (As noted above, we accordingly suggest amendment of section 42DV of the Bill, alongside the necessary resourcing.)

Overall, better and more timely communication will do much to boost confidence in the TGA's capacity and commitment to monitor and respond to concerns regarding pharmaceuticals, medical devices and other products.

Bruce Baer Arnold
Asst Professor
University of Canberra

Wendy Bonython
Assoc Professor
University of Canberra

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