



“Whack-a-mole” student work and an update on TGA regulatory reform


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Skeptic Café , The Clyde Hotel, December 18, 2017



The Monash “Whack-a-mole” project



- **Aim:** To provide BMS students with practical experience of the role of regulators in protecting the public from false and misleading therapeutic claims by product sponsors and health practitioners
- **Methodology:** Evaluate the evidence for questionable claims made about therapeutic goods and services and, if appropriate, submit a complaint to the appropriate regulator.
- **Why the title:** “Whack-a-mole”?

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 Student presentations:
Eliza Li




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 Student presentations:
Michael Mackie


(Parent company of Healthy Care and VitAustralia)



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 **Student presentations:
Gabriel de Carheil**



- Breaks up congestion and stagnation of qi at the center, dispels wind-damp and wind resolves spleen damp, tonifies spleen qi.
- A valuable medicine for poor digestion due to deficiency of spleen with phlegm-damp or food accumulation causing nausea, vertigo, headache, pasty or loose stools, and flatulence.
- Valuable in motion sickness and morning sickness.
- Traditionally used in cholera.


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 **Update on TGA
Regulatory Reform**




 **Cutting Red Tape**
The Australian Government's online resource for regulation reform






Has the TGA been “captured” by industry?

- A recent article in the New England Journal of Medicine reviewed the history of using industry fees to boost staffing and improve the operation of the U.S. Food and Drug Administration (FDA).
- User fees emerged in 1992; inadequate public funding was slowing the approval of promising new treatments.
- By 2016, industry fees provided approximately 43% of the \$4.8 billion budget of the FDA in 2016.
- This has resulted in concern about unhealthy closeness between the FDA and industry (“corrosive capture”).




<http://www.nejm.org/doi/pdf/10.1056/NEJMhle1710706>

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Has the TGA been “captured” by industry?

- The policy of successive Australian governments has been that the TGA should provide its own funding from industry fees.
- In the late 1980’s, the original agreement was that the TGA would recover 50% of the cost of its activities from industry.
- By 1999, cost-recovery had risen to 100%, where it remains today.




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 **Has the TGA been “captured” by industry?**



- The recent Senate inquiry into women who have had transvaginal mesh implants heard that this “industry-funded model of regulation” raised questions about the regulator's independence.
- This, given the succession of TGA device scandals, including pelvic mesh, joint prostheses, breast and contraceptive implants, cardiac stents, etc.

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 **Has the TGA been “captured” by industry?**



Adjunct Prof John Skerritt
Deputy Secretary for
Health Products
Regulation
Department of Health


- In response, a TGA spokesperson said, “This system has been in place for more than 20 years and there has been no evidence of any sort of “regulatory capture”.
- Other medicines and device regulators internationally also are fully or significantly funded by industry fees. This takes the burden off the taxpayer...”.

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..takes the burden off taxpayers

- This statement is disingenuous. Regardless of whether the regulator is funded by industry fees or the government the consumer pays, either through higher prices of therapeutic goods, or increased taxation.




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So, has the TGA been “captured” by Industry?


- I will argue that the shenanigans around the Therapeutic Goods Amendment (2017 Measures No.1) Bill provide concrete evidence of TGA “regulatory capture”.
- The TGA and the Department of Health attempted to bypass the Senate Committee review of this Bill arguing that it was non-controversial!
- Which it was not!




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Update on TGA Regulatory Reform



- Fortunately, Senator Richard Di Natale responded to requests to get the Bill reviewed by the Senate Community Affairs Legislation Committee.
- A public hearing was requested, but rejected because of short time-frame encompassing Christmas & New Year.
- The closing date for submissions is 12 January, 2018.
- The reporting date is 2 February 2018. ¹³




Update on TGA Regulatory Reform

Review of Medicines and Medical Devices Regulation – Stage Two

Report on the regulatory frameworks for complementary medicines and advertising of therapeutic goods


Emeritus Professor
Mr Will Delaune
Professor John
July 2015



Current Federal Health Minister
Hon Greg Hunt MP

- The legislation under consideration implements the recommendations of the 2015 Expert Panel Review of Medicines and Medical Devices Regulation.
- While there are many positive aspects of the amendments proposed, the Bill fails to address four key concerns about the regulation of complementary medicine and the advertising of therapeutic goods to consumers.

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1. It abandons advertising pre-approval

(Part 2 of the Bill)

- Of 46 published submissions to the TGA consultation on advertising reforms, only 13% supported removal of pre-approval in favour of self-regulation; all came from industry or media organisations.
- Many stakeholders argued that the current system of pre-approval of advertisements must not be terminated until the formal 3-year review of the reform package has been completed.
- This would enabling the data collected to be used as a performance indicator of the success of advertising reforms.
- ***To-date, this argument has been ignored.***


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The advantages of pre-approval

- The system reviews over 2000 advertisements per year with an average turnaround time of 7 days.
- The majority of new advertisements require changes to avoid Code breaches, sometimes wholesale revisions.
- Pre-approval is the only defence between a misleading advertisement on prime-time television and the unwitting consumer; complaints and post-marketing reviews take a long time to remove bad advertisements.
- Some of the worst offenders are not members of industry associations so self-regulation is unlikely to impact.
- Prevention is better than cure.

<http://www.doctorportal.com.au/mjainsight/2016/38/advertising-reform-watering-down-consumer-protection/>




2. The TGA takes over the advertising complaint system




- Since 2011, the CRP has submitted 541 complaints 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.
- The TGA has an unenviable reputation as a black hole with respect to advertising complaints.
- Division 6, section 42DV of the Bill states (1), (2), ‘the Secretary may, in writing, direct... complaints to be published..’






2. The TGA takes over the advertising complaint system



- 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.




3. The TGA’s pseudoscientific list of permitted indications

- The current TGA’s list (submitted by industry) contains around 1000 indications for "traditional medicines" such as Homeopathic products, Traditional Chinese Medicines, Ayurveda and others.
- 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.


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3. The TGA’s pseudoscientific list of permitted indications


- It includes such gems as:
 - Balance aggravated Vata (Traditional Ayurvedic medicine only),
 - Harmonise middle burner, Spleen and Stomach (Chinese medicine tradition of use),
 - Dispel/expel/extinguish/disperse/clear External Wind (Chinese medicine tradition of use) and
 - Helps enhance/promote uterine health (Tradition of use, unspecified)
 - and Galactagogue/lactagogue/ improve breast milk production (Tradition of use, unspecified)
- It appears that the TGA has been captured by industry and has endorsed pseudoscience.

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The TGA also does nothing about:

<p>Anxiostat</p> <p>May be supportive during anxiety</p>		<p>Anxiostat contains:</p> <ul style="list-style-type: none"> • Aconite 200x • Borax 200x • Kali phos 200x • Ergotine 200x • Alprazolam 12x • Diazepam 12x • Chlorpromazine 4c 	<p>Suggested dose:</p> <p>4-5 sprays directly under tongue 2-3 times a day or as directed by a healthcare practitioner.</p> <p>Frequency of dose can be increased during acute conditions.</p>
<p>Bactrol</p> <p>May be supportive for bacterial infections</p>		<p>Bactrol contains:</p> <ul style="list-style-type: none"> • Hepar sulph 30x • Myristica 30x • Anthraxinum 30x • Pyrogenium 30x • Silicea 30x • Streptococcin 30x • Pneumococcin 30x • Staphylococcin 30x • Penicillium LM9 • Streptomycin LM9 • Ciprofloxacin LM9 	<p>Suggested dose:</p> <p>4-5 sprays directly under tongue 2-3 times a day or as directed by a healthcare practitioner.</p> <p>Frequency of dose can be increased during acute conditions.</p>



Senate submission points

- The abandonment of advertising pre-approval (Part 2 of the Bill):
 - Delay implementation until 3-year review.
- The TGA black hole on reporting complaint outcomes:
 - Change Division 6, section 42DV of the Bill that states (1), (2), ‘the Secretary may, in writing, direct... to must direct complaint determination to be published.
- TGA elimination of the Complaint Panel and Code Council:
 - The Senate to ask the TGA how stakeholder input will be continued.
- TGA endorsement of pseudoscience by accepting an industry submitted list of over 1000 “traditional” permitted indications:
 - Demand a disclaimer: “*this traditional indication is not in accordance with modern medical knowledge, etc.*”

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 In conclusion:

- Active skepticism is needed!
- Please email a submission, no matter how brief, addressing one or more of the points highlighted on the last slide.
- To: committee.sen@aph.gov.au
- Re: Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 and related bill.

See also: <http://www.medreach.com.au/?p=2353>

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