

Independent Review of the Australian Therapeutic Goods Advertising Framework: Panel Session



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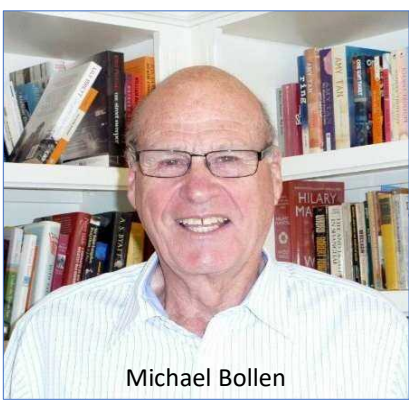
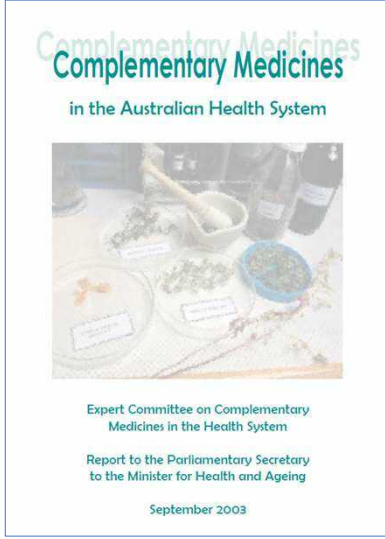


Michael Marshall



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Background to the Review



Michael Bollen

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Background to the Review

Review of Medicinal Medicinal Regulatory Stage

Therapeutic Goods Amendment Bill 2017

Report on the frameworks for complementary and advertising goods

Emeritus Professor Mr Will Delaat AM Professor John Harvey July 2015

Therapeutic Goods (Permissible Indications) Determination No.1 of 2018

TGA
efficacy assessed

Fifteen years later, after yet another review, significant changes were finally made to the regulation of complementary medicines and advertising:

- The TGA took over the advertising system; the previous Complaint Resolution Panel (CRP) was abolished,
- A limited list of permissible indications was introduced,
- A new Aust L(A) listing was created,
- The Therapeutic Goods Advertising Code was revised and made legally enforceable,
- The TGA received enhanced compliance and enforcement powers.³

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Federal Health Minister Greg Hunt said:



- The measures proposed, ‘will enable potential harms from inappropriate advertising to be comprehensively prevented...’
- ‘I can confirm that TGA will be adequately resourced and staffed to manage complaints from 1 July 2018’.
- He also promised an independent review of the effect of the new advertising measures within two years of implementation.⁴

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Concerns about the TGA takeover

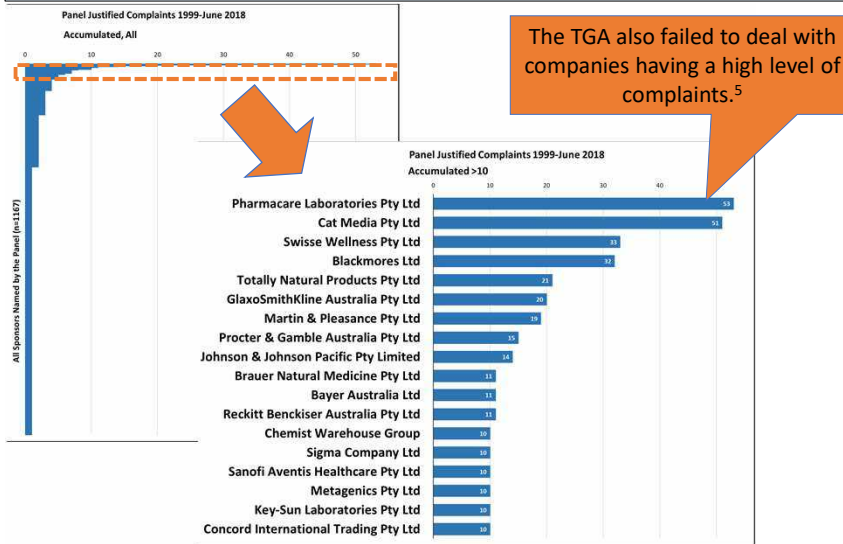


- Because the previous CRP had no power to enforce its determinations it referred many complaints to the TGA.
- This was because advertisers failed to comply with the Panel’s determination, or because repeated complaints about the same issue required regulatory action.
- Only 9% of 755 CRP referrals to the TGA had a published outcome.
- This resulted in a perception that the TGA was a ‘black hole’ with respect to advertising complaints.⁵

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Concerns about the TGA takeover



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Testing the TGA's new complaint system



Whack-a-mole

- The new system commenced on 1 July 2018.
- Complaints previously upheld by the CRP, but whose sponsors continued to make claims that breached the Code, were re-submitted to the TGA.
- Monash University students provided valuable assistance.⁶
- Pharmacare Laboratories *FatBlaster* and *FatMagnet* products were among the first complaints re-submitted.⁷

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The first complaint re-submitted to the TGA



\$42.49



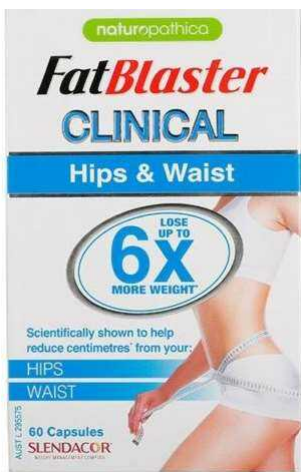
\$29.95

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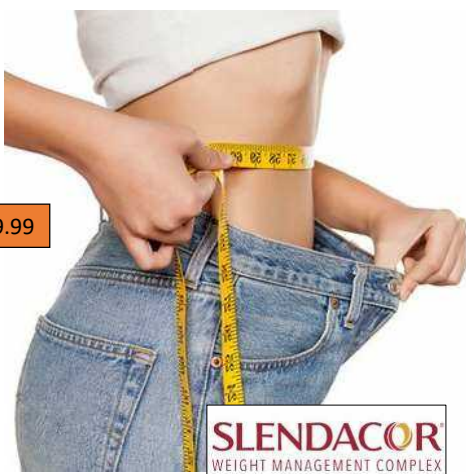
Complaint to TGA, 6 July 2018, [Pharmacare Laboratories FatBlaster FatMagnet products](#), AC-GBKDH2XG/2018

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More complaints submitted



\$69.99



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16 August 2018, [Pharmacare Laboratories Weight Loss Products, Additional information requested, AC-NJ15VLQ9/2018](#).^{8,9}

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Over 12 months after complaints submitted:

DIRECTION ABOUT AN ADVERTISEMENT ¹⁰

Made Under Section 42DV of the *Therapeutic Goods Act 1989*

To: Cat Media Pty Ltd

DIRECT you, as the person apparently responsible for that advertising of the therapeutic goods, to:

1. Cease to connect it can a
2. Cease Clinical that cu

COMPLEMENTARY MEDICINES CANCELLATION ¹¹

Despite this TGA action, FatBlaster Clinical continues to be promoted and sold. Also, no action has been taken on the other FatBlaster products.

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Directions for FatBlaster Clinical: why not the rest?

Cease making claims imply that it can assist with weight loss
Cease using the image of the slim female torso



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Complaint to TGA, 29 July 2019, [103 breaches of the Therapeutic Goods Advertising Code \(No. 2\) 2018, s.26\(3\)\(a\) by 35 companies advertising 19 weight loss products](#), AC-MBNGMHNQ/2019

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New weight loss products added to the ARTG

Categories / Diet supplements / Weight loss



- Meanwhile, two new *FatBlaster* products have been listed on the ARTG.
- They contain the same ineffective SLENDACOR™ herbal ingredients of the

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In summary, of over 20 *FatBlaster* weight loss products complained about over 2018-19, all continue to be promoted at the time this presentation was recorded, and ALL still breach the Code

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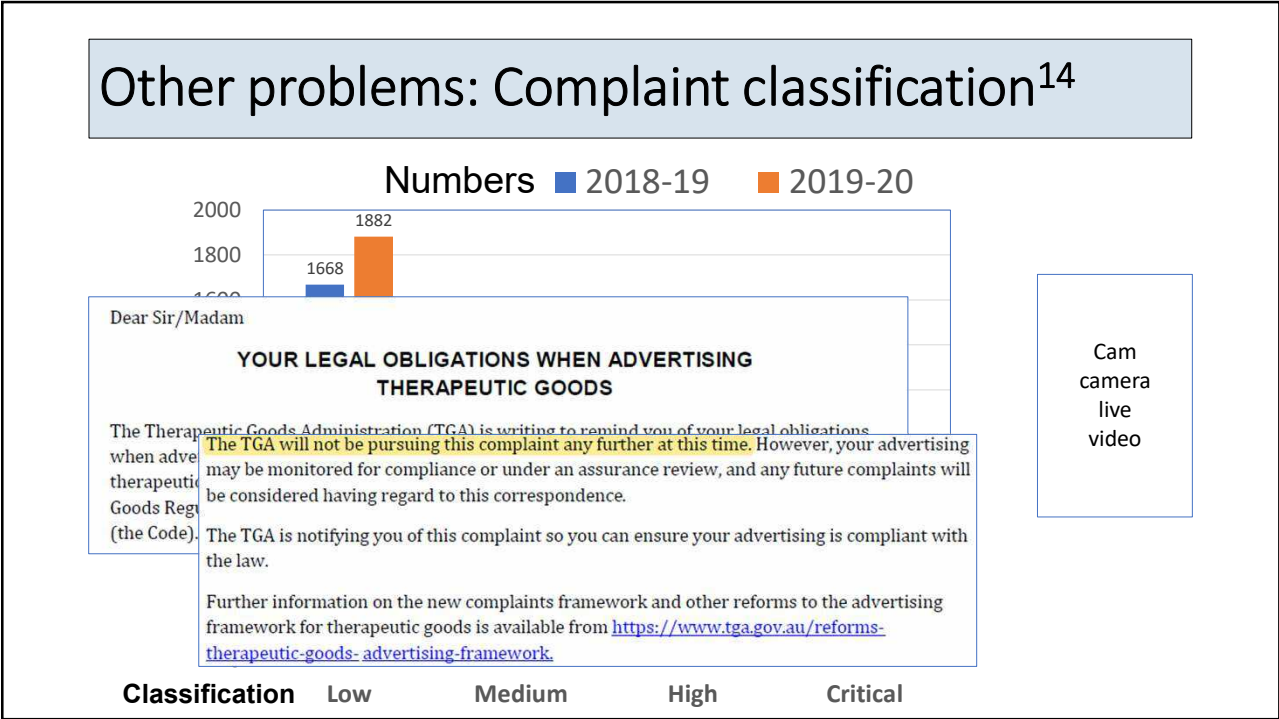
Why has the TGA failed to act?



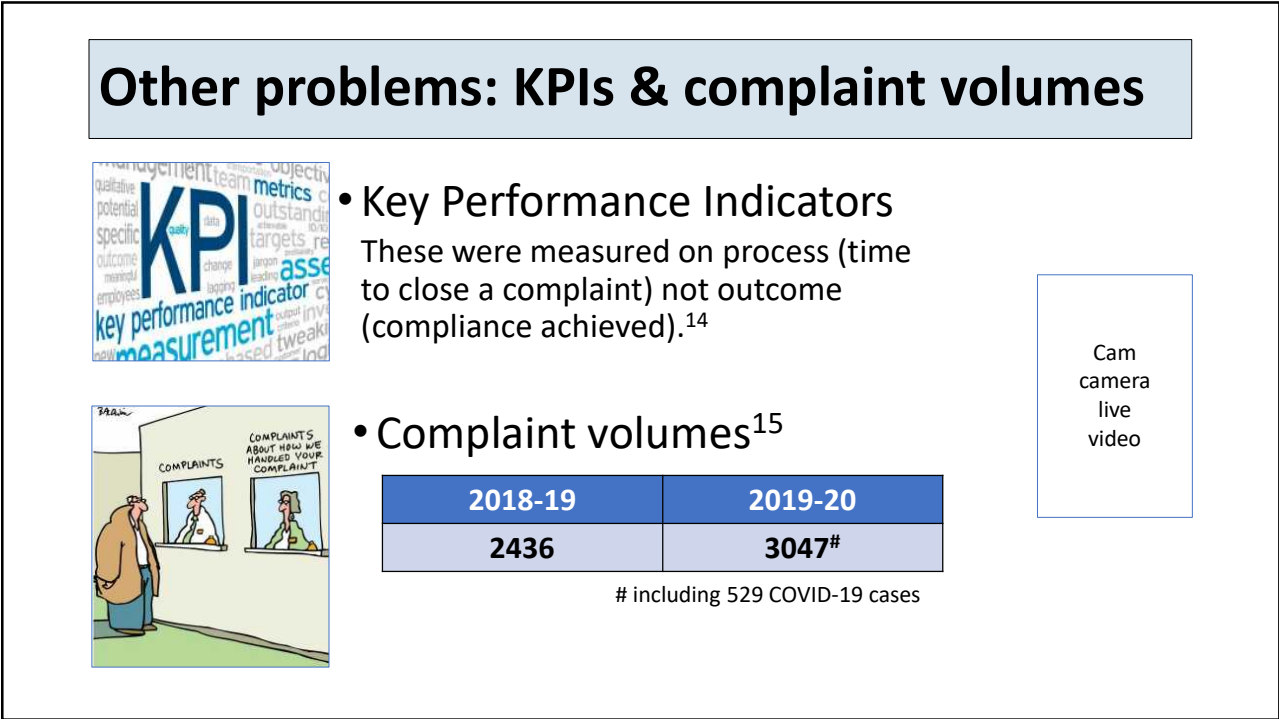
- Why has there been no effective action taken on weight loss products,¹² or other public health problems, such as ineffective hangover products?¹³
- The Independent Review said they found no evidence that 100% funding by industry influenced TGA priorities.
- Panel members may be able to provide other reasons why the TGA failed to act?

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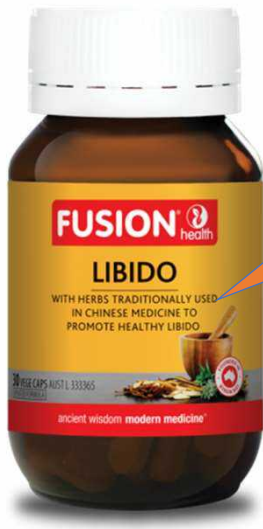


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Other problems: Permissible indications



- 86% of 1021 indications, could be justified by 'traditional' rather than 'scientific' evidence, e.g.

In Traditional Chinese Medicine (TCM), *Jing* is a form of life force energy that's in the kidneys and naturally decreases with age.

Fusion Libido contains Schisandra, traditionally used to boost kidney *Jing* in TCM.

- The RACGP, FSM, Choice and others want mandatory educational statements on these products, e.g. 'These claims are based on traditional beliefs and practices, not modern scientific evidence'.

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More recent action by the TGA:



Pete Evans' company fined \$25,200 for alleged COVID-19 advertising breaches

- This year, the TGA issued over \$600,000 of fines for COVID-19 advertising breaches.¹⁶
- Why not similar action on the plethora of complementary medicines that lack evidence of efficacy, for example:
 - Glucosamine / Turmeric,
 - CoQ10 / Fish oil,
 - Detox / Homeopathic products,
 - Many probiotic products,
 - Numerous Traditional Chinese, Ayurvedic and Western herbal medicines, etc.?

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Why has the TGA failed to deter unethical promotion?

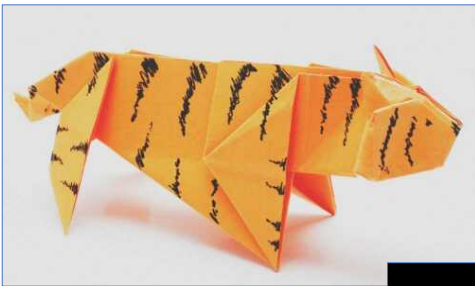
Is it due to:

- Industry lobbying government (and the TGA) to maintain a profitable and export orientated industry despite breaking the law to do so?
- A regulatory culture that favors industry assistance over consumer protection?
- Lack of expertise (insufficient medical, pharmacy and public health staff)?
- Limited financial resources (if so, why not increase industry charges)?
- And who is responsible?

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Finally, how is the TGA perceived?



OR



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Over to the Panel (and the audience)



Rosemary
Sinclair AM



Adj Prof John
Skerritt



Allan Asher



Michael Marshall

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