Adjunct Prof John Skerritt FTSE FIPAA (Vic)
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PO Box 100 Woden ACT 2606 Australia

By Email: John.Skerritt@health.gov.au

Dear Professor Skerritt,

Re: SBS Insight program debate; areas of dispute with the TGA [SEC=UNCLASSIFIED]

My comments on your letter of 9 February 2019 follow:

Advertising compliance statistics

You are being disingenuous in asserting that, "For the 70 % of complaints in the "low level category" no official finding of a breach or otherwise is made as a formal investigation of these complaints has not been carried out; there is insufficient evidence to support any finding".

In complaints I have submitted, classified by the TGA as low priority, I have put forward considerable evidence as to why these advertisers have breached the Therapeutic Goods Advertising Code 2015. For example:

02 November 2018, Swisse Ultiboost Co-enzyme Q10, AC-9ZFYC2IB/2018
08 November 2018, Nature's Care CoEnzyme Q10, AC-GV0EUHBY/2018
28 November 2018, Swisse Ultiboost Lecithin, AC-JBQA7UJM/2018

You also said if, "there have been repeat complaints about a product the complaint is categorised as either medium, high or critical for review by the TGA".

This is not my experience. I have submitted new complaints about products that have had repeated complaints upheld by the CRP. These should have been classified as higher priority complaints according to your risk-based regulatory model, but they were not. For example:

24 July 2018, Numerous sponsors, The ongoing and dangerous promotion of ear candles, AC-5TMWIYHC/2018
3 August 2018, Brand Developers Australia Pty Ltd – Pain Erazor, AC-E7JS15BB/2018
21 August 2018, Detox Foot Patches / Pads, AC-UA26W8I4/2018

In addition, as my paper pointed out, the TGA has declared higher priority complaints closed because compliance was said to be achieved, when it was not. The TGA have also failed to deal with many serious complaints forwarded by the CRP in the 6-month transition period leading up to the TGA takeover.

Post-marketing surveillance statistics including products that lacked evidence.

You conceded that 75-80 % of the audited listed products are found to breach at least one regulatory requirement. You noted that TGA compliance audits result in more than two thirds of these products returning to being compliant with the remainder of the products cancelled – either by the TGA, or the sponsor company – which in either case removes these products from the market.

You failed to note that many cancelled products are often relisted with similar problems. Sponsors know that the chance of being re-audited is low; if this does occur, they can merely cancel the product, relist, and start this profitable cycle over again.

Another problem is that the TGA lumps together the results from random and targeted compliance reviews with the latter running around twice as many as the former. This means that the percentage of verified compliance breaches will depend on whether the TGA targets products likely to have a

higher or low compliance rate. In a letter to you dated 7 March 2016, Friends of Science in Medicine requested that compliance breaches should be broken down into random and targeted reviews This has yet to be done.

TGA GMP requirements

You noted the legal requirement for an initial GMP inspection of a manufacturer prior to providing products to the market, and regular inspections thereafter. However, you did not identify the frequency of the latter. You also stated that most breaches found were minor. It would be more helpful if the severity of the defects found were published. We have supported compliance ratings, hopefully to be introduced later this year.

Choosing garlic and cranberry products

You asserted that, "if the medical literature is used to support a claim made about a particular garlic extract then the evidence must be on the same plant part, extracted the same way, at the same dose and in the same patient population.

Yes, this statement is in the TGA 2019 Evidence Guidelines. But it does not appear to be obeyed by the industry, or policed by the TGA, as the appended e-mail and attached article on garlic products shows.

Consumer confidence

Given the above, it is not surprising that consumer confidence in the complementary medicine industry, and the TGA as a regulator, leaves much to be desired. During June and July 2018, the TGA conducted its first survey of Australian adults. It employed a dual sampling methodology: a quota driven population-based sample (Panel) and an (Opt-in) sample sourced through known TGA contacts, networks and consumer stakeholders. The responses of survey participants to statements about complementary medicines follow:

Participants agree that:	Panel (n= 1,045)	Opt-in (n=684)
Complementary medicines are safe	38.5%	25.8%
Appropriately regulated	32.2%;	14.5%
Manufactured to high standard	38.4%;	14.5%
Trusted	37.6%;	23.9%
Government monitors safety	41.8%;	18.2%

Conclusion

Consumers and health professionals and want complementary medicines that address real medical need and deliver proven health outcomes. The current TGA trust-based, light-touch regulatory system fails to deliver this outcome. Instead, it has produced a market-place flooded with over 11,000 dubious products, marketed by celebrity endorsement and promotional hype, not clinical evidence.

The critique by Royal Commissioner Haynes on regulatory failure in Australia's financial services industry is equally applicable to the TGA. A failure to enforce the law undermines the authority of the regulator whose fundamental responsibility is to do just that. It also encourages others to break the law, leading to a race to the bottom and consumer detriment.

These are important Federal election issues. As are the comments about organisational culture by Graeme Samuel, who is about to embark on a sweeping review of the banking watchdog in response to the Royal Commission findings.

Sincerely
Ken

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Subject: Re: Last night's SBS Insight program recording; areas of dispute with the TGA
Importance: High

Dear John, et al,

I should like to follow-up several issues about the regulation of complementary medicines and their advertising which we publicly disagreed about last night.

1. **The TGA makes no judgement as to whether complaints classified as low priority breach the Therapeutic Goods Advertising Code**.

   Yet the TGA assesses and triages all complaints received and reports some were, “not in the TGA’s jurisdiction” and for others, “no breach of advertising legislation was found”. So how can you say that the TGA makes no judgement that, “those [complaints] classified as low priority and closed by sending a compliance notice with educational material” are not in breach of the Code?

   I also note that a letter sent to advertisers in response to one of my own complaints (attached) listed specific sections of the Code for the advertiser to review. If the TGA made no judgement that these sections of the Code were not breached, why list them?

   In my paper on these matters (attached) I noted that at the time of writing (17 January 2019), 628 complaint outcomes with a 2018 reference number have been published on the TGA website. Four were judged not in the TGA’s jurisdiction. Of the remaining 624, 10 (1.6%) were judged not to breach the Code while 614 (98.4%) did. Of the latter, 591 (96.3%) complaints were classified as low priority and closed by sending the advertiser a compliance notice with

educational material. The remaining 23 (3.7%) complaints were classified as higher priority, all were said to be closed with, or without, formal action.

This statistic of around 98% of all complaints were found to breach the Code is similar to what the old CRP found.

Do you deny that, on the basis of complaints received both by the old CRP and by the new TGA complaint system, there is a major on-going problem with non-compliant advertising?

2. Only 30% of TGA post-marketing reviews of listed products are found to lack evidence to justify the claims made

The following tables are compiled from tables 25 & 26 of https://www.tga.gov.au/sites/default/files/annual-performance-statistics-report-july-2017-june-2018.pdf

Compliance status determined				
	2016-17		2017-18	
No breach	87	21%	42	25%
Breach found	***330***	***79%***	***129***	***75%***
- Manufacturing, quality	62	19%	27	21%
- Labelling	94	28%	58	45%
- Advertising	86	26%	59	46%
- Unacceptable presentation	140	42%	63	49%
- Lacked evidence	***180***	***55%***	***50***	***39%***
- Safety	22	7%	0	0%
- No response	8	2%	5	4%
Total	**417**	**100%**	**171**	**100%**

Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	74	51

It is likely that many medicines cancelled by the sponsor to avoid a compliance review also had significant regulatory breaches.

In short, TGA post-marketing reviews of listed products show a much higher rate of compliance breaches than you stated.

3. TGA GMP requirements assures product quality of complementary medicine.

First, the breaches of manufacturing quality found in the post-marketing reviews (above) show that the TGA's occasional inspection of manufacturing facilities for GMP does not guarantee product quality.

Second, and more important, is the failure of the TGA to check for clinically active ingredients in often complex herbal products. I've attached a paper co-authored by a member of last night's audience, Joanna Harnett, "An evaluation of garlic products available in Australian pharmacies". The authors noted that the quality indicators evaluated in their study, including evidence for the formulation used, labelling, product, safety, manufacturing information and key constituents, varied significantly between the garlic products available in Australian pharmacies.

Given these results, how can health professionals and consumers recommend or choose garlic products for the management of hypertension and/or dyslipidaemia?

The audience member with quadriplegia who used a cranberry product in the hope of preventing recurrent urinary tract infection, is also likely to be disappointed. The effectiveness of cranberry products appears to depend on the concentration of proanthocyanidins, which prevent uropathogenic P-fimbriated E. coli from adhering to bladder cell receptors. If the bacteria are not able to adhere to cells, they cannot grow and cause infection. As the attached Cochrane review notes, cranberry preparations need to be quantified using standardised methods to ensure they contain enough of the 'active' ingredient, before being evaluated in clinical studies or recommended for use.

Health professionals and consumers want complementary medicines that address real medical needs and deliver proven health outcomes. The current TGA trust-based, light-touch regulatory system fails to deliver this outcome. Instead, it has produced a market-place flooded with over 11,000 dubious products, marketed by celebrity endorsement and promotional hype, not clinical evidence.

With respect to complementary medicines, the TGA has failed to deliver the object of the legislation under which it operates: assuring the quality, safety, efficacy of therapeutic goods.

Sincerely,
Ken