Department of Health Submission to Senate Inquiry into the Therapeutic Goods Amendment (2017 Measures No. 1) Bill: Disclaimers and Advisories

Evidence concerning disclaimers and advisories

The Department of Health noted that, apart from the additional regulatory burden that mandating such a labelling statement would create, the main reason for rejecting disclaimers is U.S. experience that disclaimers are ineffective.

The Department cited several independent studies published in a consumer research and health policy journals that they alleged reached this conclusion. They also stated that face to face meetings between senior TGA and FDA officials confirmed this view. The published research cited is examined in more detail in an appendix.

The research cited refers to the disclaimer mandated for dietary supplements exempted from Food and Drug Administration (FDA) premarket approval or safety testing requirements under the 1994 U.S. Dietary Supplement Health and Education Act (DSHEA) and subsequent regulations. The disclaimer states:

> 'This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.'

The U.S. regulation of dietary supplements is very different to the Australian regulation of complementary medicines.[1,2,3] However, both countries have similar problems, such as promotional claims and sales of dietary supplements / complementary medicines that are out of all proportion to the limited evidence justifying their use. In addition, with international products increasingly available over the Internet, the problem of adulteration of supplements with biologically active compounds, including prescription drugs, has become a global issue. [4,5]

In the U.S., the Federal Trade Commission (FTC) acts against dietary supplement companies for product promotions that violate the Federal Trade Commission Act. The disclaimer suggested by many submissions from civil society organisations is not the FDA disclaimer which the TGA suggests is ineffective. Rather, the advisory suggested was produced in November 2017 by the FTC with respect to one category of traditional medicines, homeopathic products.[6]

The FTC has long recognized that marketing claims may include additional explanatory information to prevent the claims from being misleading. Accordingly, the FTC notes that the promotion of an OTC homeopathic product for an indication that is not substantiated by competent and reliable

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[1] Jiang T. Re-thinking the dietary supplement laws and regulations 14 years after the Dietary Supplement Health and Education Act implementation. Int J Food Sci Nutr. 2009 Jun;60(4):293-301. doi: 10.1080/09637480701777977. Epub 2008 Dec 9.

[2] Marcus DM. Dietary supplements: What's in a name? What's in the bottle? Drug Test Anal. 2016 Mar-Apr;8(3-4):410-2. doi: 10.1002/dta.1855. Epub 2015 Nov 2.

[3] Department of Health, Therapeutic Goods Administration. Listed medicines: The role of Australia's medicines regulator. https://www.tga.gov.au/community-qa/listed-medicines-role-australias-medicines-regulator.

[4] Pawar RS, Grundel E. Overview of regulation of dietary supplements in the USA and issues of adulteration with phenethylamines (PEAs). Drug Test Anal. 2017 Mar;9(3):500-517. doi: 10.1002/dta.1980. Epub 2016 Jun 3.

[5] Department of Health, Therapeutic Goods Administration, Alerts. https://www.tga.gov.au/all-alerts-sorted-date

[6] United States of America, Federal Trade Commission. Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs: November 15, 2016. https://www.ftc.gov/system/files/documents/public_statements/996984/p114505_otc_homeopathic_drug_enforcement_policy_statement.pdf

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scientific evidence may not be deceptive if that promotion effectively communicates to consumers that:

1. There is no scientific evidence that the product works and
2. The product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts.

In addition, to be non-misleading, the product and the claims must also comply with requirements for homeopathic products and traditional homeopathic principles.

The FTC policy statement notes that any such disclosures should stand out, be near the product's efficacy message, and might need to be incorporated into that message. It also warns marketers not to undercut a disclosure with additional positive statements or consumer endorsements reinforcing a product's efficacy.

The FTC notes that a statement a product is based on traditional homeopathic theories might put some consumers on notice as to the basis of the product's efficacy claims. However, because many consumers do not understand what homeopathy is, the Commission does not believe that such a statement alone would adequately put consumers on notice that a product's efficacy claims are not backed by scientific evidence, and could, in fact, enhance the perceived credibility of the claim.

Similarly, the Commission believes that a statement that a product's efficacy 'has not been evaluated by the Food and Drug Administration' does not adequately address the potential lack of substantiation for a product's efficacy claims.

Finally, the Commission believes that a simple statement that a product's efficacy is not supported by scientific evidence does not convey the truly limited basis for the efficacy claim and that, to avoid deceiving consumers, it is likely necessary to explain that it is not accepted by modern medicine.

More recently, the U.S. FDA have proposed a new, risk-based enforcement approach to drug products labelled as homeopathic.[7] The FDA has identified certain categories of drug products labelled as homeopathic, and marketed without the required FDA approval, as potentially posing higher risks to public health. This includes products for vulnerable populations such as infants and children, the elderly, and pregnant women. You will recall that the published Senate submission from the Australian Skeptics Victorian Branch (no 6) specifically referred to such products.

Submissions to the Senate Inquiry by civil society organisations have logically expanded the scope of the above arguments to include all other traditional paradigms covered by the TGA's new permitted indication list: Traditional Chinese medicine (TCM), Ayurveda, Homeopathy, etc. This is in keeping with the Government of India, Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy(AYUSH) established in 2014. Each letter of the acronym 'AYUSH' represents officially recognized Indian systems of medicine other than allopathic medicine.[8]

The Department of Health's response was **not** to add the advisory sought, but rather (for TCM and Ayurvedic only) to place a statement on their label with words to the effect of:

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[7] U.S. Department of Health and Human Services, Food and Drug Administration. Homeopathic Guidance for FDA Staff and Industry. Draft guidance for comment purposes only. December 2017. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM589373.pdf

[8] Katoch D, Sharma JS, Banerjee S, et al. Government policies and initiatives for development of Ayurveda. J Ethnopharmacol. 2017 Feb 2;197:25-31. doi: 10.1016/j.jep.2016.08.018. Epub 2016 Aug 16.

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- 'Seek advice from a registered Chinese medicine practitioner or Ayurvedic medicine practitioner to ensure this medicine is right for you'.

These statements are also contained in the 'Draft Permitted indications for listed medicines guidance' These advisories are:

> **Illogical** – as they only apply to a subset (206) of 1019 permissible indications. All products containing one or more of the 1019 permissible indications can be advertised and sold to the public because the sponsor has certified they hold evidence (traditional or scientific) to support the claims made. Why recommend consulting a practitioner for a sub-set when all products with permissible indications will be readily available in retail outlets and via the Internet?
>
> **Inconsistent** – because they do not apply to medicines invoking other traditions such as homeopathy, Western herbalism, etc.
>
> Why not suggest consumers seek similar advice from homeopaths for medicines invoking the homeopathic tradition?
>
> Why not a similar advisory for medicines invoking scientific rather than traditional evidence. For example, 'Seek advice from a registered pharmacist or doctor to ensure this medicine is right for you'?
>
> **Ineffectual** – because they do not educate consumers that traditional indications lack a scientific evidence base as requested. In addition, how many consumers would act on such advice?

I reiterate my concern (and that of others) that for the TGA to accept an industry provided list of 879 traditional indications is encouraging the industry to evade the need to prove their products work. Why else would they provide such a lengthy list?

Finally, the Department of Health's submission noted that the TGA will conduct further consultation, in conjunction with consumer groups, on ways to better educate consumers about the medicines listing system, including about the difference between listed complementary medicines and registered medicines.

In the light of the research outlined in the appendix, and my own experience with talking to elderly consumers about their lack of understanding of TGA regulation,[9] I argue there is an urgent need for appropriate independent research, in association with consumer organisations, into the best way of helping consumers make an informed choice about complementary medicines. NPS MedicineWise might be an appropriate partner in this endeavour.[10] Until this has been conducted the illogical, inconsistent and ineffective measures suggested by the TGA should be put on hold.

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[9] Harvey K. U3A Melbourne City Short Course – Complementary Medicine: Exploring the Issues. http://www.medreach.com.au/?p=2314
[10] https://www.nps.org.au/about-us#what-we-do

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Appendix: The 'evidence' cited by the Department of Health that disclaimers are ineffective.

Kesselheim et al., noted that only a small number of controlled studies have tested the impact of the DSHEA disclaimer on consumers. Most of these studies found that consumers were generally unaware of the disclaimer or attached no weight to it in their perceptions of the product. However, nearly all these studies were conducted in experimental settings instead of among real patients making health-related choices. The DSHEA did not include funding for studies to determine whether the disclaimer was having its intended effect.[11]

Mason et al., showed that heavy product users responded differently to the disclosures than did light product users and nonusers. Their results noted the importance of understanding the influence of individual differences on the interpretation of product disclosures by specific consumer segments. The concluded that that additional legal and educational efforts may be needed to provide effective consumer protection.[12]

France and Bone found that general beliefs about the supplement industry affected product-specific efficacy judgments. They suggested that consumers with negative beliefs regarding supplements may eliminate a potentially helpful product from their evoked set, an error of omission. Alternatively, those with positive opinions regarding the industry, who are innovative and motivated to protect themselves, may use many supplements that are not useful. [13]

They suggested that policy makers take a more holistic approach to policy design, one that actively accounts for pre-existing beliefs and dispositions that influence the consumers' actual decision making and behaviours. They also noted that the more distal the belief, the more resistant it is to change. They concluded there was a need for theoretically interesting and important research. Such an approach would involve consumer education programs partnering with governmental, non-profit, and industry organizations to improve consumer knowledge.

Dodge et al., showed that addressing deficits in individuals' knowledge about the DSHEA influenced beliefs about dietary supplements. Specifically, educating individuals about the DSHEA made them more skeptical of the safety and effectiveness of dietary supplements. They also showed that beliefs about the effectiveness and safety of dietary supplements were relevant for predicting willingness to use dietary supplements, but which beliefs were relevant depended on the supplement under consideration.[14]

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[11] Kesselheim AS, Connolly J, Rogers J, Avorn J. Mandatory disclaimers on dietary supplements do not reliably communicate the intended issues. Health Aff (Millwood). 2015 Mar;34(3):438-46. doi: 10.1377/hlthaff.2014.0515.

[12] Mason, M. J., Scammon, D. L. And Fang, X. (2007), The Impact of Warnings, Disclaimers, and Product Experience on Consumers' Perceptions of Dietary Supplements. Journal of Consumer Affairs, 41: 74–99. doi:10.1111/j.1745-6606.2006.00069.x

[13] France, RK. and Bone, FP. (2005), Policy makers' paradigms and evidence from consumer interpretations of dietary supplement labels. Journal of Consumer Affairs, 39: 27–51. doi:10.1111/j.1745-6606.2005.00002.x

[14] Dodge T, Litt D, Kaufman A. Influence of the dietary supplement health and education act on consumer beliefs about the safety and effectiveness of dietary supplements. J Health Commun. 2011 Mar;16(3):230-44. doi: 10.1080/10810730.2010.529493.