Submission to Senate Community Affairs Legislation Committee on Therapeutic Goods Amendment (2017 Measures No.1) Bill

Dear Senate Committee Members,

My name is Peter Hogan and I'm a committee member of the Victorian Skeptics, a branch of Australian Skeptics. I'm also a member of their Homeopathy Investigative Sub-group that is concerned about the false claims made by the purveyors of homeopathic medicines.

We are concerned that this Bill (Schedule 6 - Advertising) fails to protect the public from misleading and deceptive claims by homeopathic products.

We became interested in this topic in February this year when we noted a 2016 U.S. FDA warning about the possible risk to infants and children of Hyland homeopathic teething tablets and gels.

We found around dozen Melbourne pharmacies who sold Hyland homeopathic teething products, including the Drew Wood pharmacy at the Royal Children's Hospital.

In April 2017, the U.S. FDA formally requested a recall of these products because laboratory testing had shown inconsistent amounts of belladonna, a toxic substance, in certain homeopathic teething tablets including Hyland's, sometimes far exceeding the amount claimed on the label. The company concerned agreed.

It took until October 2017, for the Australian TGA to institute a similar recall.

Several days ago, the FDA proposed a new, risk-based enforcement priorities to protect consumers from potentially harmful, unproven homeopathic drugs. This has attracted widespread media coverage in the U.S, for example:

- FDA to crack down on 'snake oil' homeopathy
- US health officials to target high-risk alternative remedies
- FDA to target 'potentially harmful, unproven' homeopathic drugs under new proposal

One of the concerns of the FDA was products that target vulnerable populations such as babies and young children. This is also one of our concerns. For example, see the following products in the Brauer Homeopathic Baby & Child range

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Each 2 mL dose contains 2 µL of each of: Aconitum napellus 6C, Allium cepa 3C, Arsenicum album 4C, Bryonia 4C, Eupatorium perfoliatum 3X, Euphrasia 3C, Gelsemium 6C, Nux vomica 6C, Pulsatilla 6C, Rhus toxicodendron 5C.	Each 2 mL dose contains 2 µL of each of: Aconitum nap. 6X; Belladonna 6X; Cimicifuga 6X; Euphorbium 6X; Ferrum phos. 6X; Gelsemium 6X; Merc. sol. 12X; Pulsatilla 6X.
https://shop.brauer.com.au/products/baby-child-cold-flu-100ml	https://shop.brauer.com.au/products/baby-child-pain-fever-relief-50ml

Most consumers do not understand homeopathic principles, are not aware that these principles lack scientific validity, and are confused by Latin terminology, such as Rhus toxicodendron (poison ivy), which obscure the names of the ingredients and exploits the lack of knowledge of consumer, as does the use of decimal (X) and centesimal (C) dilutions.

Indeed, most parents are unaware that at the dilutions cited (3X, 6C, etc.) these products do not contain any therapeutically active ingredient. Which is just as well, as many of these ingredients are potentially toxic. If the manufacturing process is flawed, then similar problems to those found in the Hyland product above are possible. For example, Aconitum napellus (monkshood) is a poison, as is Arsenicum album (arsenic), as is Nux vomica (strychnine), etc.

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It is our view that these therapeutically inactive and potentially dangerous homeopathic products should not be allowed to be marketed in Australia. At the very least, if homeopathic products are to be marketed, they must be accompanied by a mandatory disclaimer such as that recommended by the US Federal Trade Commission:

> "This product's traditional claims are based on alternative health practices that are not accepted by most modern medical experts. There is no good scientific evidence that this product works".

These matters have been the subject of numerous recommendations which the TGA has consistently ignored:

- In 2003, the Expert Committee on Complementary Medicines in the Health System recommended that homoeopathic medicines that make therapeutic claims should be regulated to ensure they meet appropriate standards of safety, quality and efficacy. No action was taken.
- In 2008, the TGA held a consultation on the regulation of homoeopathic and anthroposophic medicines in Australia. Numerous submissions were received but no action eventuated.
- In 2015, the NHMRC released a statement concluding that there is no good quality evidence to support the claim that homeopathy is effective in treating health conditions. Once again, the TGA did nothing.
- In 2017, the TGA conducted a consultation titled, "Options for the future regulation of 'low risk' products including homeopathic products. The consultation document made no reference to previous consultations and, in our opinion, it failed to provide a viable solution to the problems outlined.

In conclusion, we ask the Senate Community Affairs Legislation Committee to recommend to the government that these therapeutically inactive and potentially dangerous homeopathic products should not be allowed to be marketed in Australia. At the very least, if they are to be marketed, they must be accompanied by a mandatory disclaimer such as that recommended by the US Federal Trade Commission.

Peter Hogan
On behalf of the Homeopathic Investigative Sub-group
Australian Skeptics, Victorian Branch
20 December 2017.