For the Chair:

Dr Ken Harvey is a medical graduate and Associate Professor in the School of Public Health and Preventative Medicine, Monash University.

He was a member of the expert group that formulated the World Health Organization's 'Ethical Criteria for Medicinal Drug Promotion'.

He represents Choice (the Australian Consumers' Association) on the soon-to-be-abolished Therapeutic Goods Advertising Code Council and also TGA complementary medicine and advertising stakeholder consultations.

Amy Vaux and Michael Dong are medical students who both won Summer Vacation Scholarships to work with Dr Harvey at the Monash School of Public Health and Preventative Medicine.

They have been examining the promotion of traditional medicines.

choice

Multicultural Australia

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Australia is a multicultural and pluralistic society and it's appropriate that we respect, understand and allow access to traditional, alternative and complementary medical traditions and products.

However, it's also important that we restrain purveyors of these medicines from taking advantage of consumer ignorance and that we protect consumers from misleading and deceptive claims about the products (and services) provided.

The TGA regulates products, not practitioners, so this presentation is restricted to complementary medicine products.

choice

Traditional, alternative, complementary medicines

- Common products, under the jurisdiction of the TGA, promoted and sold in Australia:
  - Vitamins and minerals,
  - Western herbal medicines,
  - Traditional Chinese medicines,
  - Ayurvedic medicines,
  - Homeopathic medicines.

3

In 2016, the Australian complementary medicine industry achieved revenues of $4.7 billion.

This represents a compound annual growth rate which is almost ten times faster than the growth rate of the overall Australian economy.

Australian consumers spent over $550 per capita on complementary medicines in 2016.

Around 70% Australian report they have used at least one complementary medicine in the last 6 months.

This use is out of all proportion to the limited scientific evidence justifying the use of these products

choice

Traditional, alternative, complementary medicines

- Challenges for Member States identified by WHO:
  - Development and enforcement of policy and regulations,
  - Ability to control and regulate advertising and claims,
  - Ensure consumers can make informed choices.

4

The World Health Organization has published a strategy for Member States on traditional medicines in which they also include what others call alternative or complementary medicines.

choice

Australian therapeutic goods regulation

- Most CMs are listed (AUST L) on the ARTG.
- They have no TGA pre-market assessment.
- Sponsors self-certify that:
  - Their product is manufactured according to GMP standards,
  - The ingredients are picked from a consolidated list that the TGA regards as relatively low risk,
  - Their products only carry indications and claims for the symptomatic relief of conditions (but not for proscribed serious disease, disorders, or conditions), health maintenance, health enhancement and risk reduction,
  - They hold evidence sufficient to substantiate that the indications and claims are true, valid and not misleading.

It's a trust-based system.

choice

Consequences of a trust-based system

TGA Listed medicine compliance reviews: 2015-16

- TGA compliance activity more than doubled from 212 (2014-15) to 473 (2015-16).
- Medicines with verified compliance breaches increased from 73% (2014-15) to 80% (2015-16).
- Labelling, advertising and evidence continued to be the major compliance breaches for listed medicines.
- More products were found to have safety related issues; zero in (2014-15) compared to 13 (2015-16).
- In addition, for 2015-16, the Complaint Resolution Panel found 98% of 141 complaints justified (and a 40% non-compliance with TGACRP “requests” for redress).

https://www.tga.gov.au/performance-statistics-report-july-2015-june-2016

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choice

Consequences of a trust-based system

- The failure of the TGA to bring the industry into check over many years has resulted in:
  - Loss of trust in the TGA as a regulator.
  - Ongoing harm to consumers:
    - Direct harm from poorly disclosed adverse events from complementary medicines and their interaction with conventional medicines.
    - Indirect harm, by consumers forgoing more evidence-based remedies (often to the detriment of their health) because they are sucked in by misleading and deceptive promotional hype. This also wastes their money which could be better spent.
  - Massive industry spending on promotion, not research. 7

choice

Consequences of a trust-based system

http://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be

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choice

MMD Recommendations rejected by the Government

15 Sept 2016

- Sponsors to include a prominent disclaimer that products have not been independently assessed (r.44);
  - Rejected in line with Government's commitment to red tape reduction. Education suggested instead.
- Sponsors to publish evidence supporting their claims (r.43);
  - Rejected. Government encourages self-publication by sponsors.

9

Rules under review!

One presumes that the disclaimer was rejected because of industry lobbying and TGA acquiescence.

The concept of a disclaimer goes back to 2003 when, following the Pan Pharmaceutical scandal, the 'Expert Committee on Complementary Medicines in the Health System' noted:

- Consumers may not be aware that Listed medicines are not evaluated for efficacy before their supply.
- There is an ethical responsibility on government to ensure consumers are informed about this difference between Listed and Registered medicines.

No action eventuated.

choice

MMD Recommendations accepted by Government

15 Sept 2016


Current Federal Health Minister
Hon Greg Hunt MP

- A limited list of 'permitted indications' to replace 'free text' on the ARTG (r.38).
- A new listing pathway (option 2) where the sponsor can provide evidence acceptable to the TGA to support the safety and efficacy of health claims that fall outside the list of Permitted Indications (r.39).

Improvements to the complaint process, post-marketing surveillance and increased penalties for regulatory breaches (r.56, r.49, r.57).

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choice

The problem: Free text on the ARTG

TGA eBS

Clinically trialled*to shorten your cold by 3 days

Public Summary

Summary for ARTG Entry: 178380 Sambucol Cold & Flu

In a clinical trial, patients given Sambucol recovered on average 3 days faster compared to those given a placebo.

ARTG Start Date	15/12/2010
Product category	Medicine
Status	Active
Approval area	Listed Medicines
Conditions	

CLINICALLY TRIALLED*

Complaint No.	Date	Product	Complainant	Respondent
2016/10/025	16/02/2017	**Sambucol**	Requested anonymity	**Pharmacare Laboratories Pty Ltd**

FINDING: Justified

Sections Found Justified: *Act section 42DM(1); Code sections 3(1)(a), 4(1)(b), 4(2)(a), 4(2)(c), 5(2)*

Sections Found Not Justified: *Code sections 4(2)(b), 4(2)(d), 4(2)(h)*

ACTION: *Withdrawal of representations, Withdrawal of advertisement*

Recommendation to the Secretary Date: *26 June 2017*

Because advertising claims must reflect indications and claims contained on the sponsor submitted ARTG Public Summary document, many sponsors add creative ‘free text’ to enable equally creative advertising claims to be made.

Upheld complaints take a long time to take effect.

choice

The TGA list of Permitted Indications

December 2017

- The latest TGA list (submitted by industry) contains 1019 indications:
  - 140 (14%) to be supported by 'scientific evidence',
  - 879 (86%) could be supported by 'traditional evidence' such as *materia medica*, monographs and publications relevant to Traditional Chinese Medicine, Ayurveda, Homeopathy, etc.

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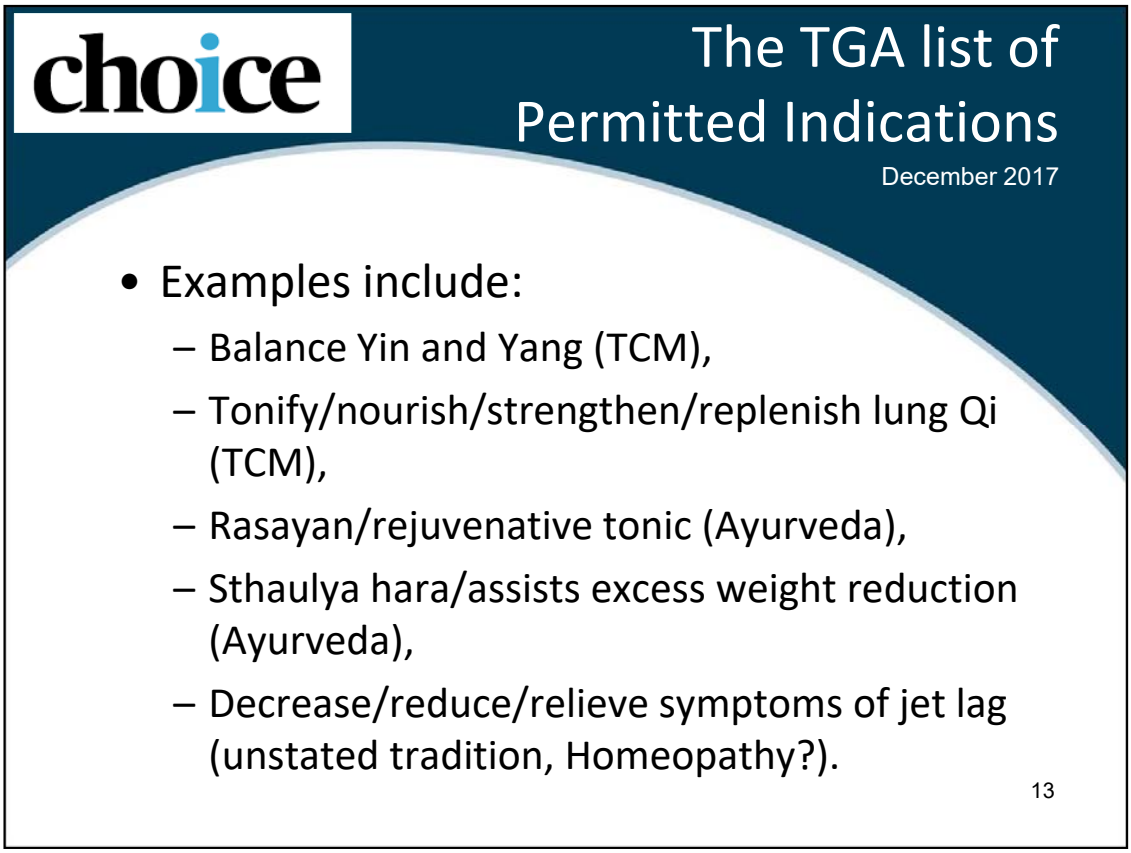
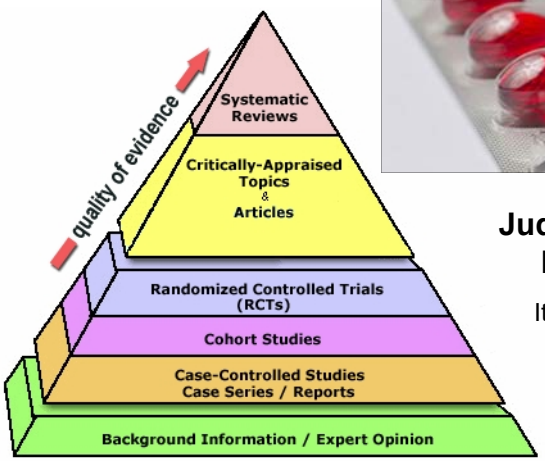


Scientific investigation has not substantiated many aspects of these traditions, such as the traditional Chinese medicine concepts of meridians through which the life-energy known as “qi” flow and the homeopathic principles of “like cures like”

choice

What's evidence?



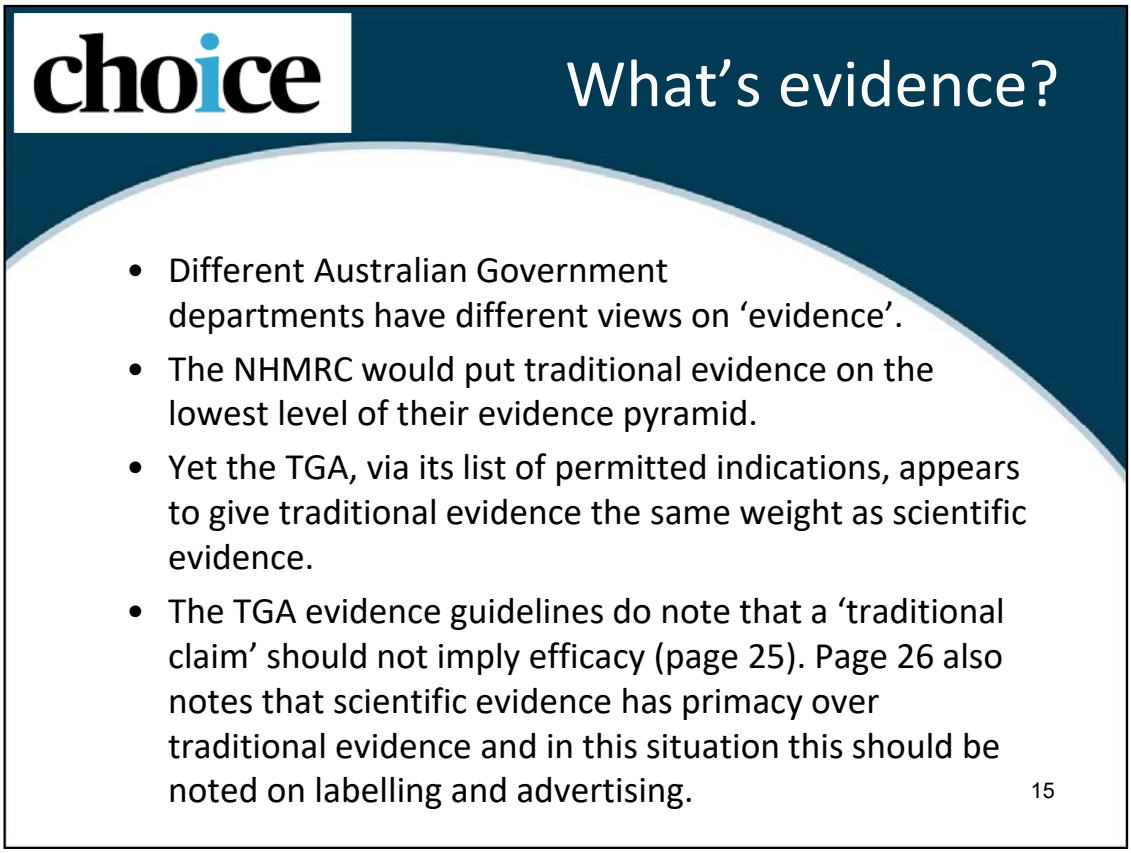
Judge cites Cochrane to take down Nurofen's claim to superiority

It's not better than Panadol, the weight of scientific evidence suggests

https://www.australiandoctor.com.au/

14

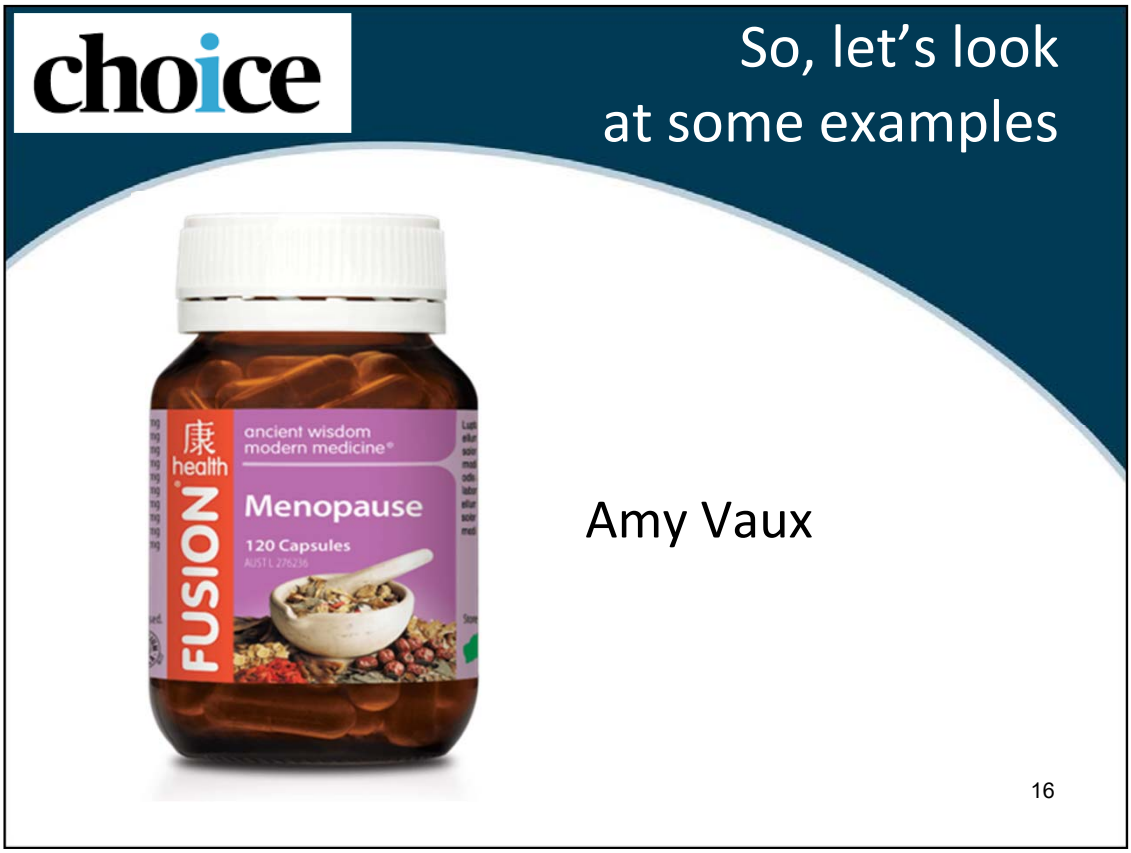
The NHMRC (and other evidence-based authorities) have defined a hierarchy of evidence.



The NHMRC assisted the Department of Health's 'Review of the Australian Government Rebate on Natural Therapies for Private Health Insurance'.

They found there was not reliable, high-quality evidence available to allow assessment of the clinical effectiveness of any of the natural therapies for any health conditions, including homeopathy, herbalism, naturopathy and aromatherapy.

Regrettably, TGA 'guidelines' are not enforceable and their suggestions are inevitably ignored. Hence the need for a mandatory advisory and its incorporation in the Therapeutic Goods Advertising Code which is meant to be revised as part of the MMD reforms



This product claims to relieve the physical and emotional symptoms of menopause. “Relieves hot flushes, night sweats, sexual disinterest, sleeplessness, fatigue, muscle and joint pain, headaches, dry skin, vaginal dryness and other physical symptoms of menopause”.

The herbal formula “contains a carefully formulated blend of Chinese herbs traditionally used to balance Yin and Yang during menopause.”

These aren’t exactly modest claims, and, coupled with scientific jargon, not to mention stating the main active ingredient “has been the subject of extensive scientific research", mean that the product’s advertisement is likely to mislead consumers into believing the product claims have been validated by scientific enquiry.

A 2016 Cochrane Review, ‘Chinese herbal medicine for menopausal symptoms’ which included 22 RCTs (2902 women) concluded that ‘When Chinese herbal medicine was compared with placebo (eight RCTs), there was no statistically significant difference between the groups for the following pooled outcomes: hot flushes per day and overall vasomotor symptoms per month measured by the Menopause-Specific Quality of Life questionnaire.’

In short, there was no good scientific evidence that Chinese herbal medicine was any different to a placebo for the relief of menopause symptoms. Regardless, this Fusion Health Menopause product claims efficacy and does not mention the conflicting evidence contained in the Cochrane review.

It is important to recognize the right and entitlement for products such as these to be marketed and used on the basis of traditional and cultural purposes, as a part of recognizing our wonderful multicultural society. Even if tablets and capsules are not the historic method of consumption of traditional herbal remedies.

choice

So, let's look at some examples

Amy Vaux

- Ashwagandha is an adaptogen herb that has traditionally been used in Ayurveda as Rasayana (a rejuvenative tonic) to help:
  - Relieve stress and mild anxiety
  - Relieve mild nervous tensions,
  - As a sleep aid,
  - Support memory enhancement,
  - Support rejuvenation.

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However, the difference between products that have been approved for reasons of traditions versus those approved on scientific merit, is not made clear enough by the simple inclusion of the phrase "traditional use" on the packet.

This does not indicate to consumers that the claims have not been scientifically verified, and the approval of the TGA may been seen to validate the products claims.

To repeat, consumers do not know that product claims of "traditional use" do not require evidence of efficacy.

Which is why many others and I agree that a claim based on "traditional use" should be required to contain a prominent disclaimer such as,

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

Now let us move to another aspect of the system, the food-medicine interface.

When you think of a capsule, tablet, or pills, contained in a white bottle alongside therapeutic claims what do you first think of? Medicine? Or food?

Consider the claims made for this product, "Livgood". "A Liver care formula", "Ayurveda herbal ingredients", "helps expel the build-up of toxins from the liver which accumulate from a diet that includes fried & highly processed foods." "Useful in the treatment of: Acne, Gastritis, Gout, Liver disorders, Psoriasis."

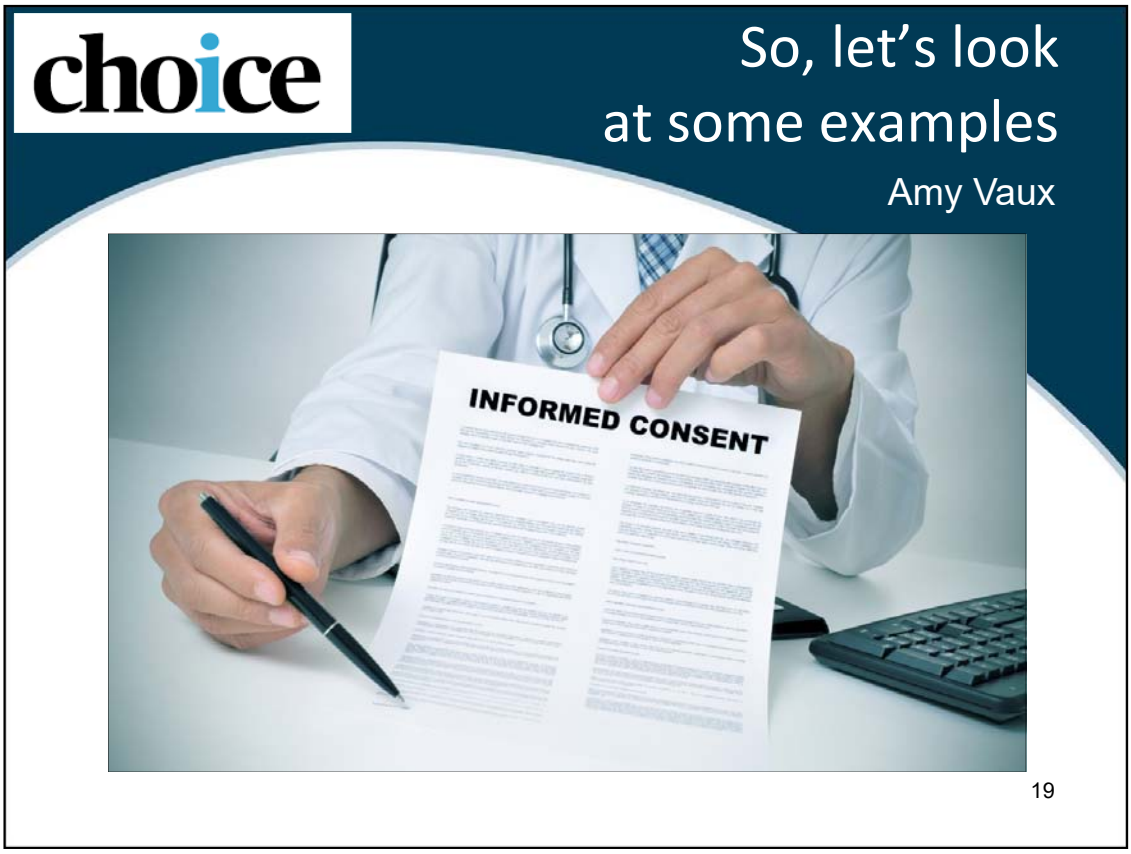
This product is on the market without TGA listing, marketed as a "dietary supplement", the branding trying to suggest it is a food product.

The categorization of what defines a food vs a medicine in the current system is tricky business. Products can fall (or hide themselves) somewhere in-between. Particularly when it comes to products that brand themselves as "dietary supplements" or "nutritional support". The TGA regulate medicines while State and Territory Health Departments regulate foods.

The latter are understandably more concerned about food-poisoning outbreaks and food disease control than they are about therapeutic claims made on so-called dietary supplements.

This system means that complaints about products at the food-medicine interface can be handballed back and forth between the different regulators resulting in no action being taken; the products essentially going unregulated.

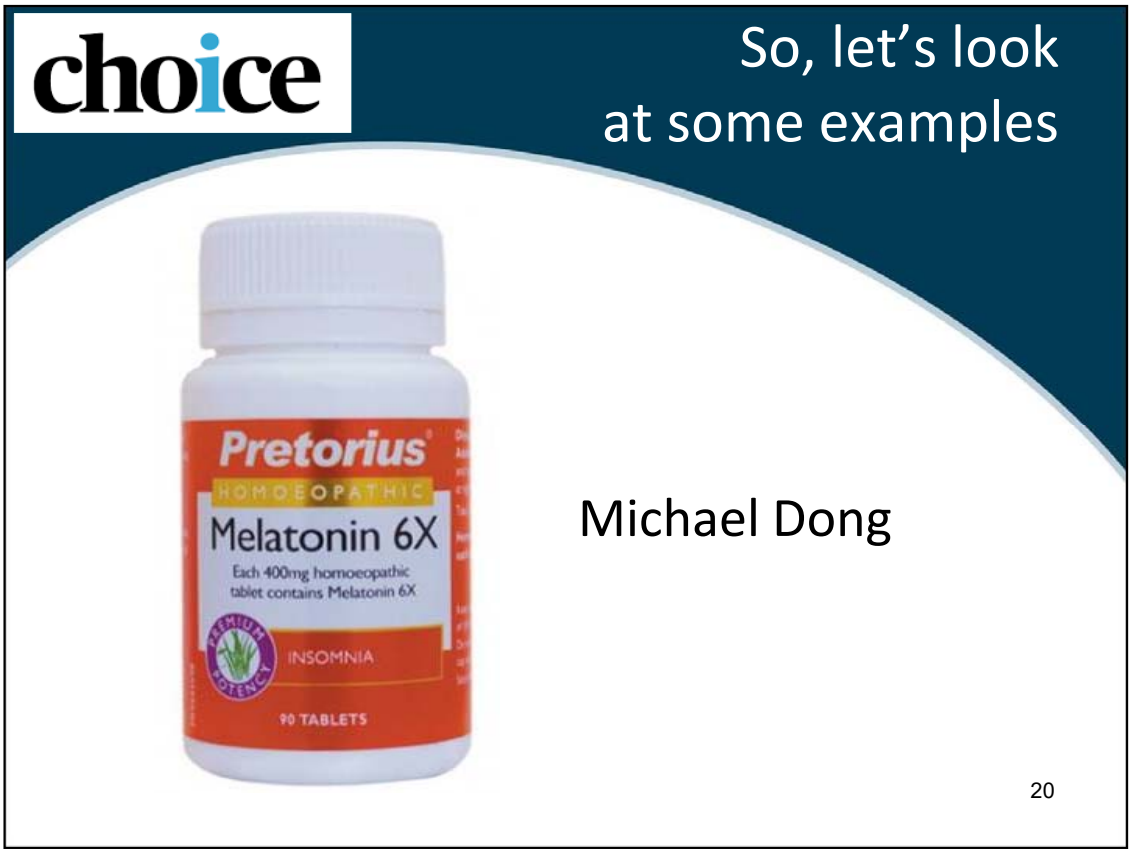
As you will hear from the PHAA later, the clear solution is to broaden the scope of the Therapeutic Goods Advertising Code and Complaint System that of a Therapeutic Claims Advertising Code. This way there will be one body responsible for all products making therapeutic claims, avoiding confusion in the distinction between foods, medicines or medical devices.



As medical students from day one of our course we have been taught the importance of informed consent. Informed consent is not just an important guiding principle for medicine, but for law, business and society as a whole.

When a consumer or patient is in a pharmacy seeking help either to treat or prevent disease, they have a right to informed consent in their treatment.

Through products that make "traditional use" claims, as well as those that make claims as food products without proper oversight, this right is taken away as consumers assume that products are regulated to only be able to make claims that have undergone critical and scientific assessment by regulators.



This $25 homeopathic melatonin product claims to have the same therapeutic effect as the $99 prescription product (Circadin). A 6X dilution of 400 mg of melatonin is a dilution of 10^6 or 1 in 1,000,000. Thus, each tablet only contains 0.0004 mg of melatonin. As a result, consumers are being deluded into purchasing a product that contains no therapeutically active ingredient.

The homeopathic terminology of 'C 'and 'X' dilutions are confusing, yet these products with their misleading labels are widely available in chemist stores, and online, alongside proven medications.

These products also defy the definition of a homeopathic preparation as defined by the TGA: a ***"homoeopathic preparation*** means a preparation: formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate…"

Melatonin produces sleep, not insomnia; it is therefore not a homeopathic preparation in accord with the homeopathy "Law of Similars" (like cures like). Coffee, not melatonin, is used in homeopathic preparations to treat insomnia.

In addition, the use of melatonin is not in accord the TGA evidence guidelines on traditional evidence. These state:

"Traditional indications are based on evidence of a history of medicinal use of the ingredients or medicines that exceeds three generations (75 years) of use."

Melatonin was first discovered in 1958 by dermatology professor Aaron B. Lerner and colleagues at Yale University and thus cannot be used for a "traditional indication".

The Therapeutic Goods Advertising Complaint Resolution Panel has upheld numerous complaints about homeopathic products. But the TGA does nothing.

At the very least, a disclaimer is required.

choice

So, let's look at some examples

Michael Dong

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Biomedica is a company that produces "Homeoceuticals" that are being marketed to practitioners to be dispensed and sold to patients.

In the "Anxiostat" example, the product contains three prescription drugs: Alprazolam, Diazepam and Chlorpromazine (albeit at dilutions that will have no therapeutic effect).

Once again, this company (and practitioners who prescribe and sell these products) are not only breaching the regulations governing homeopathic products, they are also deluding and ripping off consumers.

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!

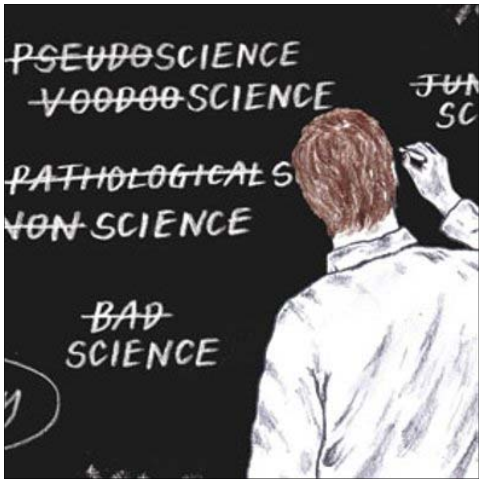
For consumers to make an informed choice about these medicines we submit that a claim based on "traditional use" should always have a disclaimer along the lines of what the US Federal Trade Commission uses for homeopathic products.

'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'

choice

What's pseudoscience?

Michael Shermer



- The boundary between science and pseudoscience is fraught with definitional disagreements.
- The term is also used for adjectival abuse against any claim one happens to dislike for any reason.

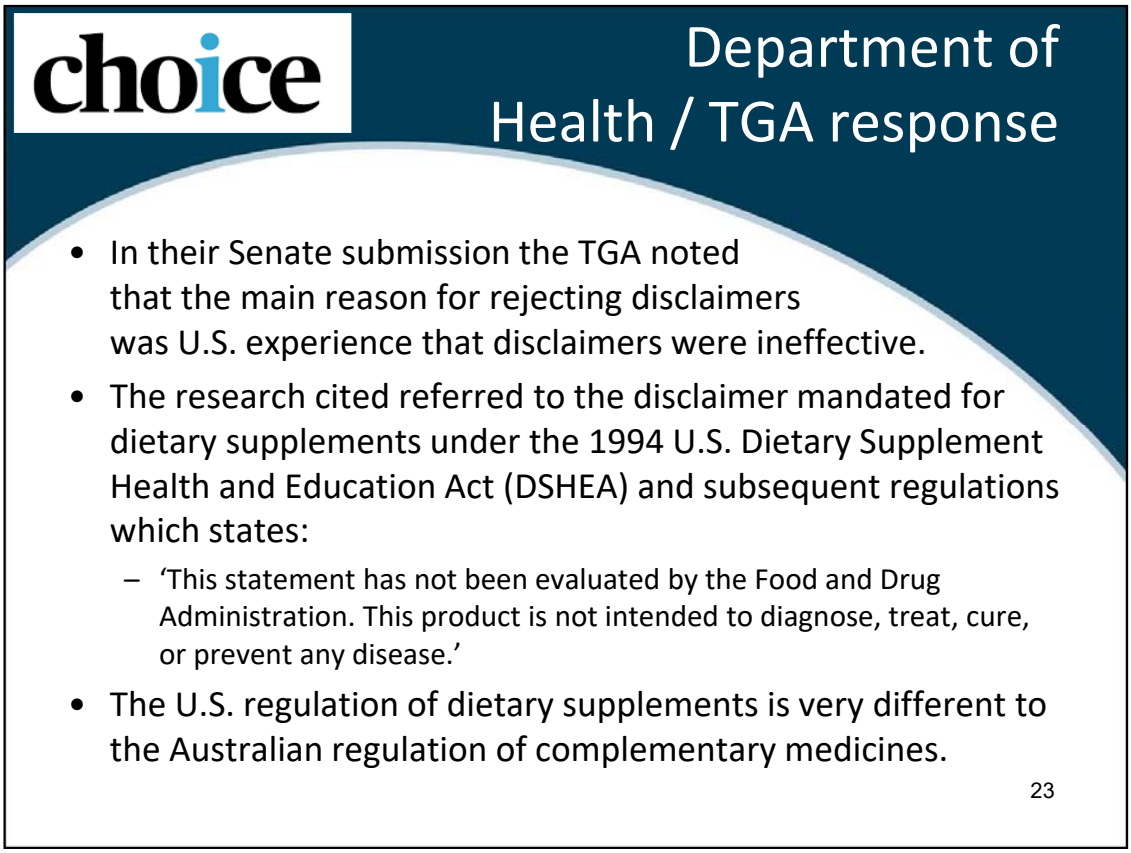
https://www.scientificamerican.com/article/what-is-pseudoscience/ 22

Michael Shermer says, 'We can demarcate science from pseudoscience less by what science is and more by what scientists do. Science is a set of methods aimed at testing hypotheses and building theories. If a community of scientists actively adopts a new idea and if that idea then spreads through the field and is incorporated into research that produces useful knowledge reflected in presentations, publications, and especially new lines of inquiry and research, chances are it is science'.

Homeopathy was a sensible response to the dangerous and ineffective medical practices at the time Samuel Hahnemann (1755-1843) developed it. But the theories on which it was based such as, 'Like cures like' no longer accord with scientific knowledge. If people who continue to promote (and practice) homeopathy ignore research that disproves its theories and fail to show its treatments are better than a placebo then, in my opinion, homeopathy fits with the authors' concepts of what is pseudoscience.

Equally, if purveyors of Traditional Chinese Medicine continue to promote their products by claiming they, 'Balance Yin and Yang' and 'Soothe/descend the flow of Stomach Qi' when these concepts have failed to be validated by modern scientific, in my opinion they are also promoting pseudoscience. The same applies to many Ayurveda indications in the TGA's list such as, 'Relieve aggravated Vata' and 'Pacifies Pitta'.

Many submissions to the TGA (and the Senate inquiry) have pointed out that including numerous traditional indications on this list will confuse the average consumer as the terms used will not be understood, endorses pseudoscience and encourages industry to evade the requirement to have scientific proof of efficacy for their products. Why else would industry have submitted such a large list? Hence the need for the recommended advisory statement…



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

choice

Department of Health / TGA response

- In addition, the disclaimer suggested by many submissions from civil society organisations is ***not*** the 1994 FDA disclaimer which the TGA alleged was ineffective.
- Rather, the advisory suggested was produced in November 2017 by the U.S. Federal Trade Commission (FTC) with respect to one category of traditional medicines, homeopathic products. The FTC suggested much stronger words such as:
  - 'There is no scientific evidence that the product works; the product's claims are based only on theories of homeopathy from the 1700's that are not accepted by most modern medical experts.'

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choice

Department of Health / TGA response

- Civil society submissions logically expanded the scope of the above argument 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 of these modalities represents an Indian officially recognized system of medicine other than allopathic medicine.

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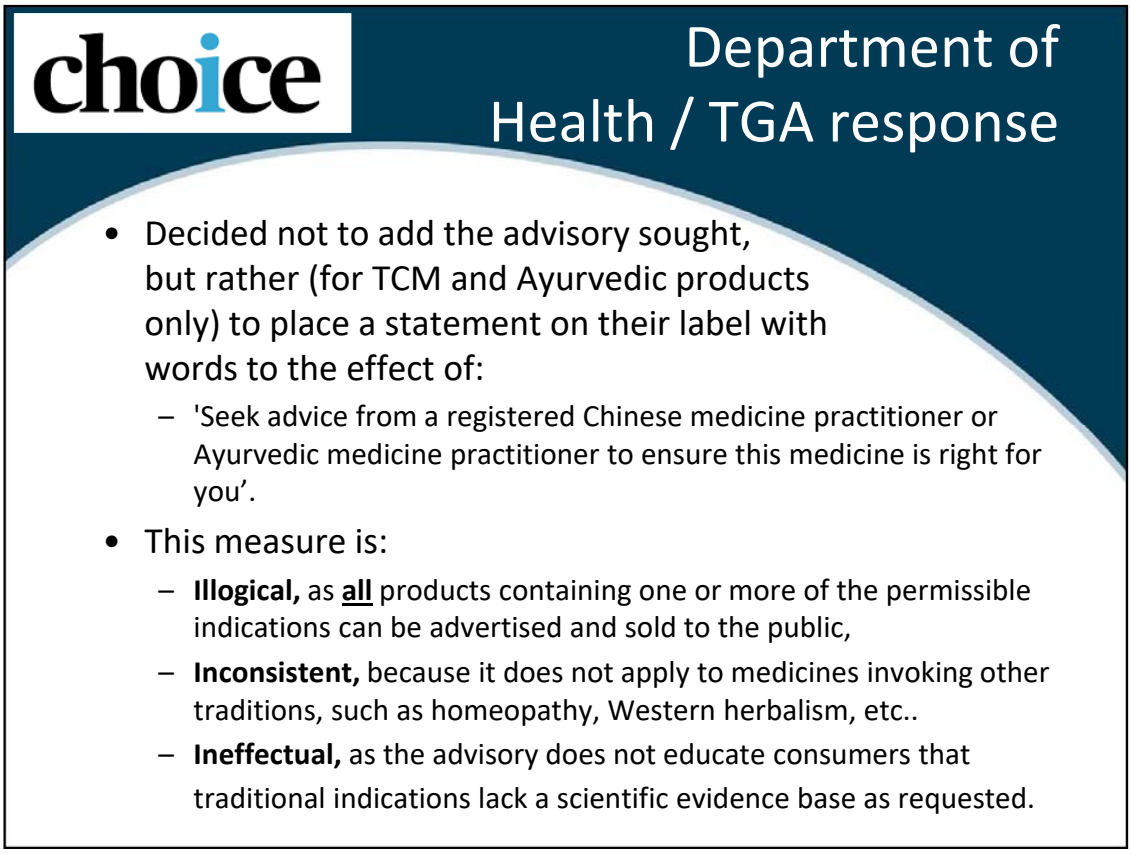

I reiterate my concern (and that of others) that for the TGA to accept an industry provided list of 879 traditional indications is encouraging the industry to evade the need to prove their products work. Why else would they provide such a lengthy list?

It is my experience in running U3A classes for elderly consumers over several years that they know little about the practicalities of TGA regulation. They do not understand the difference between products labelled AUST R or AUST L; they do not understand what a 'traditional' indication is.

choice

Department of Health / TGA response

- My colleagues and I argue that 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 to assist with such research.
- Until this has been conducted we are advocating that the illogical, inconsistent and ineffective measures suggested by the TGA should be put on hold.

choice

In conclusion I

- My colleagues and I have no desire to impede the passage of many excellent provisions of the Therapeutic Goods Amendment (2017 Measures No. 1) Bill.
- We simply want the Senate to recommend that the three aspects of the Bill debated today be excised, so that the positive aspects can proceed, while the contentious aspects receive proper debate.

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In conclusion II

- If our concerns are taken on-board then Australia could be a world leader in complementary medicines regulation.
- Despite the substantial and increasing use of supplements, no other country has developed a regulatory system that:
  - Helps consumers and health professionals separate the evidence-based wheat from the chaff,
  - Improves confidence in the industry and regulator,
  - Stimulates more evidence-based ingredient and products &
  - Has the potential to boost exports.

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In addition, the Australian approach will greatly assist developing countries who lack the capacity to regulate supplements.