choice The People's Watchdog

Snake oil trumps science:

the failure of regulation to protect consumers from shonky complementary and alternative medicine

Dr Ken Harvey MB BS, FRCPA
http://www.medreach.com.au

Malcolm Schonell Memorial Lecture, St George Hospital, Feb 14, 2013

LA TROBE UNIVERSITY AUSTRALIA

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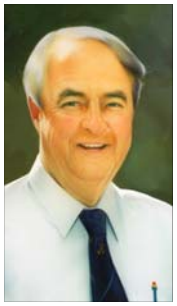
Professor Malcolm Schonell



- We both:
  - Worked in Sydney in the early 1970's.
  - Interested in infectious diseases, especially tuberculosis.
  - Taught at UNSW.
  - Passionate about teaching.
  - Wrote / contributed to textbooks.
  - Sought evidence, gave good advice to patients (and consumers).

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My disclosure of interests

- Member:
  - Expert group that formulated the 1988 WHO Ethical Criteria for medicinal drug promotion.
  - PHARM Committee that devised the Quality Use of Medicines plank of Australian Medicines Policy.
- Consumer representative (Choice):
  - Government Working Group on Promotion of Therapeutic Products.
  - TGA Transparency Review Panel.
  - TGA Group on Complementary Medicines.
  - Government Natural Therapy Review Advisory Committee.

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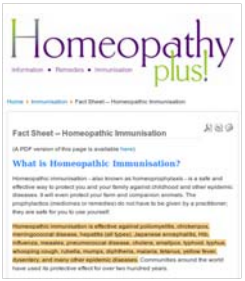
Talk outline



- Problems with
  - Promotional claims and practitioners
  - Regulatory system
- Solutions?
  - TGA reform agenda
  - NHMRC Natural Therapies Working Committee
  - DoHA Natural Therapy Review Advisory Committee
  - Options for regulation of unregistered practitioners
- Conclusions.

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Problems

25 November 2011, 2.54pm AEST
SensaSlim banned after medico's exposure of bogus scientific claims

Claim that Undoit pill blocks all fat and carbs is baseless
Justin Norrie, 3 July 2012
THE CONVERSATION

Vitamins firm told to pull 'misleading' ads
Sarah Colyer, March 6, 2012

22 October 2012, 11.05am AEST
TGA, once again, fails to reign in shonky weight-loss product

19 April 2012, 8.07am AEST
Swisse Vitamins highlights the failure of industry self-regulation

Homeopathy regime is rejected as judge tells parents to immunise child
November 28, 2012
smh.com.au The Sydney Morning Herald

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Therapeutic goods regulation

- In Australia, the Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods including medicines (prescription, OTC and complementary), medical devices, blood and blood products.
  - "Complementary medicines" (CMs) contain herbs, vitamins, minerals, nutritional supplements and traditional medicines such as homoeopathic products.
- Unless specifically exempt or excluded, all therapeutic goods must be registered, listed or included on the Australian Register of Therapeutic Goods (ARTG) prior to their supply.
- The TGA does not regulate healthcare practitioners.

Therapeutic goods regulation

- The TGA uses a risk-based pre-market assessment of therapeutic goods.
- Registered medicines (labelled AUST R) are thoroughly evaluated for quality, safety and efficacy prior to market release (with the exception of some "grandfathered" products)
- All prescription medicines are AUST R.
- Listed medicines (labelled AUST L) are regarded as lower risk self-medication products. They are required to meet quality and safety standards but are not accessed for efficacy.
- Most CMs are listed (AUST L) on the ARTG

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Therapeutic goods regulation

- The TGA's electronic listing facility (ELF) allows listed medicines rapid and low cost entry onto the ARTG.
- Sponsors self-certify via ELF 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.
- Limited random and targeted post-marketing surveillance is performed.

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Therapeutic goods regulation

- **Medical devices** are regulated by the TGA using a risk classification system:
  - Class I (low-risk),
  - Class IIa (low-medium risk),
  - Class IIb (medium-high-risk),
  - Class III (high-risk),
  - AIMD (Active implantable medical device).
- Certification (evaluation) by the TGA or an overseas notified body is required for higher risk devices.
  - EU rules for licensing medical devices (70 private agencies) are "fragmented, privatised, and largely opaque; safety is dealt with in an unsatisfactory way and efficacy not at all".
- As with Listed medicines, sponsors of lower-risk devices self-certify they are "fit for purpose".

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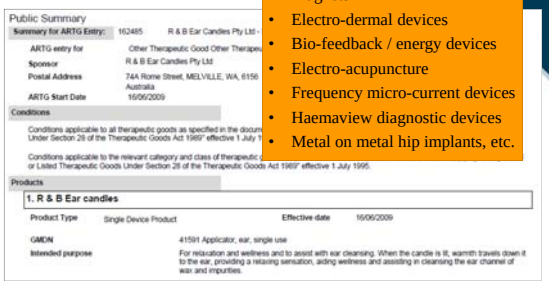
Shonky devices included on the ARTG



- Ear candles
- Magnets
- Electro-dermal devices
- Bio-feedback / energy devices
- Electro-acupuncture
- Frequency micro-current devices
- Haemaview diagnostic devices
- Metal on metal hip implants, etc.

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QXCI (Quantum Xeroid Conscious Interface)

- The QXCI / SCIO is a safe, powerful and effective software controlled, TGA registered biofeedback device designed for natural healing.
- It works wholistically and naturopathically to stimulate and harness the self healing capacity of the human system.
- The QXCI works based on the cybernetic BIOFEEDBACK PRINCIPLE but with added computer software and biofrequencies of thousands of homoeopathic, herbal formulas and flower essences to add into the biofeedback, this allows for much greater rebalancing of the flow of the whole person to truly vibrant health.

http://www.naturecarewholistic.com.au/index.php/treatments

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QXCI (Quantum Xeroid Conscious Interface)

- When analysing the persons energy, it functions similar to those of a virus scan on a computer. They detect weaknesses such as viruses, nutritional deficiencies and allergies by calculating the biological reactivity and resonance in your body.
- After measuring the body's frequencies it feeds back its own frequencies to neutralise destructive wave patterns. Healing takes place through energetic intervention, giving the body the true healthy energy patterns which enhance wellness, facilitate recovery and tune up your inner healing intelligence's ability to manifest fully.

http://www.naturaltherapypages.com.au/connect/cellagenics/service/10805

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QXCI (Quantum Xeroid Conscious Interface)

- In the late 1980s, an out-of-work math instructor in Colorado built an electronic device he claimed could diagnose and destroy disease.
- The U.S. FDA, which regulates medical devices, ordered Nelson to quit selling his machine and making false claims.
- Nelson refused, was indicted on felony fraud charges. He fled the country, never to return.
- Today, Nelson, orchestrates health-care frauds from a century-old building in Budapest, Hungary.
- His latest machine "INDIGO" has now replacing QXCI/SCIO (Quantum Health) and is promoted and used by the Cellagenics (and other) Naturopathic practices.

http://seattletimes.nwsource.com/html/localnews/2004020583_miracle18m2.html

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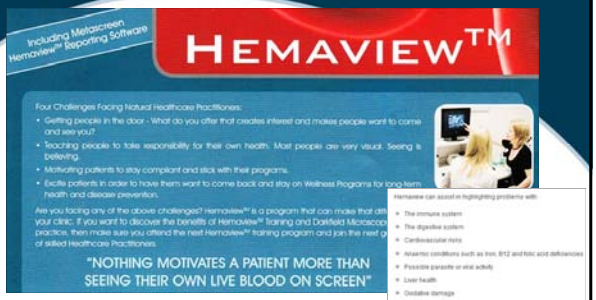
Live blood analysis



"Another gimmick to sell you something"

Stephen Barrett, M.D.

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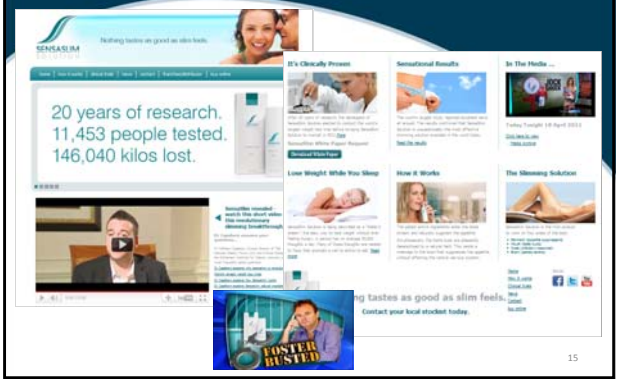
Shonky medicines listed on the ARTG



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Shonky medicines listed on the ARTG

Xantrax, Fatblaster, Fatblaster Max, Fat Magnet, HungerBuster, SlimRight Detox n Burn, Undoit..

http://www.tga.gov.au/industry/artg-searching.htm

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Problems with the TGA

- The TGA's "risk-based assessment" is judged solely on the likelihood of the therapeutic good to produce physical adverse effects.
- Other "risks" are not taken into account:
  - Providing an imprimatur for shonky products, "approved by the TGA";
  - Consumers forgoing evidence-based treatment to the detriment of their health (and sometimes life) while pursuing quackery;
  - Wasting consumers money.

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Problems with the TGA

- Self-certification by the sponsor of so-called "low-risk" therapeutic goods depends on trust.
- The TGA only performs limited post-marketing reviews of self-certified products. Until recently these results have been regarded as "commercial-in-confidence".
- A 2009-10 review (of 31 randomly selected complementary medicines) has now been made public by the ANAO. It found:
  - 20 (65%) had labelling issues such as non-compliance with labelling requirements and/or breaches which may mislead consumers.
  - 22 (71%) were found to have manufacturing and/or quality issues.
  - 14 (45%) did not have adequate evidence to substantiate claims made.
- There is no data available on TGA post-marketing reviews of "low-risk" devices.
- Numerous upheld complaints reiterate evidential deficiencies.

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Problems

- In short, a system based on trust has been shown to fail.
- Removal of products from the ARTG by the TGA for regulatory non-compliance (after protracted due process) does not necessarily stop continued promotion and use.
- In addition, sponsors can readily relist identical products or those with minor changes.
- Unscrupulous sponsors know that the TGA is a paper tiger and the current system can be gamed to their commercial advantage.

TGA

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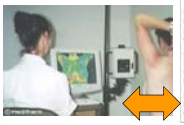
Cancelling a product from the ARTG

- Does not impact on promotion from overseas and does not necessarily mean that users stop using and promoting the good; the TGA has no control over health practitioners.



Notifications under Section 41KA of the *Therapeutic Goods Act 1989* - Public notification and recovery of medical devices

Last updated 25 March 2011

The following devices have been cancelled from the Australian Register for Therapeutic Goods (ARTG) and the sponsors have been required to notify users of the cancellations.

Sponsor: Intermedical Pty Ltd
Product: Bio-energy field mapping device application software; diagnostic system software; sensor and sensor/device ARTG Nos. 179494, 179489, 179490, 179491.
Gazette notice: Commonwealth of Australia Gazette No. GN11, 23 March 2011

Sponsor: Health Screening Technologies (thermography system) - Innovative Technologies and Research Pty Ltd
Product: Electrical impedance scanner ARTG number 152697.
Gazette notice: Commonwealth of Australia Gazette, No. GN2, 19 January 2011

Sponsor: Medical Monitoring Systems T/A Medtherm Pty Ltd
Product: Camera thermographic (MED2000, MED2000 PRO, MED2000 IR3S) ARTG number 143474
Gazette Notice: Commonwealth of Australia Gazette, No. GN1, 12 January 2011

http://qldthermalimaging.com.au/breastscreen.php 27th Oct 2012
Wayne Reilly, BSc MSc (Hons) DCN, member of ATMS, NHAA AIMA

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Regulation of promotion

- Therapeutic Goods Advertising Code
  - Aim: the marketing and advertising of therapeutic goods to consumers should promote rational use, be socially responsible and not mislead or deceive the consumer.
- Underpinned by legislation
  - Therapeutic Goods Act 1989 (TGA) and the Competition and Consumer Act 2010 (ACCC).
- Limited pre-clearance by industry associations of advertisements for medicines (but not devices) in some media such as print and TV (but not the Internet).

Therapeutic Products Advertising Complaints
COMPLAINTS RESOLUTION PANEL

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Problems with promotion

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

- The CRP is under-resourced, overloaded and lacks power to enforce sanctions.
- It currently takes 6-12 months for complaints to be heard and the determination made public.
- Non-compliance with CRP "requests" is common; these are passed to the final regulator, the TGA.
- Due to the low financial penalties currently available in the Act it is not cost-effective for the TGA to initiate legal action against advertising breaches; no prosecution has ever been attempted.

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Problems with promotion

Homeopathy websites ignore retraction orders

Australian Broadcasting Corporation Print Email
Broadcast: 08/04/2010
Reporter: Steve Cannane

The Therapeutic Goods Administration is being criticised after revelations that last year a third of the companies found to have breached advertising rules failed to publish retractions and withdraw misleading information.

Transcript

TONY JONES, PRESENTER: The panel that handles complaints against misleading advertisements for medical products and services is being criticized tonight for failing consumers.

Lateline can reveal that last year a third of the companies were found to have breached the Therapeutic Goods Administration's rules on advertising and they failed to publish retractions and withdraw misleading information.

RETRACTION

FRAN SHEFFIELD: Well, obviously I'm disagreeing with them, and that's why the retraction hasn't gone up.

http://www.abc.net.au/lateline/content/2010/s2867990.htm

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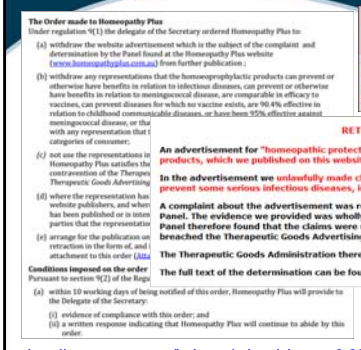
Problems with complaints



The Order made to Homeopathy Plus

Under regulation 9(1) the delegate of the Secretary ordered Homeopathy Plus to:

(a) withdraw the website advertisement which is the subject of the complaint and determination by the Panel found at the Homeopathy Plus website (www.homeopathyplus.com.au) from further publication;

(b) withdraw any representations that the homeoprophylactic products can prevent or otherwise have benefits in relation to infectious diseases, can prevent or otherwise have benefits in relation to meningococcal disease, are comparable in efficacy to vaccines, can prevent diseases for which no vaccine exists, are 90.4% effective in relation to childhood communicable diseases, or have been 95% effective against meningococcal disease, or that with any representation that t categories of consumer;

(c) not use the representations in Homeopathy Plus satisfies the contravention of the Therapeu Therapeutic Goods Advertising

(d) where the representation has website publishers, and wher has been published or is inten parties that the representation

(e) arrange for the publication on retraction in the form of, and attachment to this order (Attac

Conditions imposed on the order
Pursuant to section 9(2) of the Regu

(a) within 10 working days of being notified of this order, Homeopathy Plus will provide to the Delegate of the Secretary:

(i) evidence of compliance with this order; and
(ii) a written response indicating that Homeopathy Plus will continue to abide by this order.

2012 Skeptics
Bent Spoon Award Winner

RETRACTION

An advertisement for "homeopathic protection", "hoemprophylaxis", or "homeoprohylactic" products, which we published on this website, should not have been published.

In the advertisement we unlawfully made claims that the homeopprohylaxis products could prevent some serious infectious diseases, including meningococcal disease.

A complaint about the advertisement was recently upheld by the Complaints Resolution Panel. The evidence we provided was wholly inadequate to support the claims we made. The Panel therefore found that the claims were unlawful, misleading, and unverified and breached the Therapeutic Goods Advertising Code.

The Therapeutic Goods Administration therefore ordered that we publish this retraction.

The full text of the determination can be found at: www.tgacrp.com.au/complaints

Complaint No 2011/05/004
Regulation 9 "Order" issued
December 19, 2011

http://www.tga.gov.au/industry/advertising-reg9-2011-05-004-homeopathy-plus.htm

Problems with complaints

The 2012 Choice Shonky award for Woo water goes to... Nature's Way Kids Smart Natural Medicines

http://www.choice.com.au/reviews-and-tests/awards/shonky-awards/shonkys/the-2012-shonky-awards.aspx#Natures way

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Problems with complaints

- Last year the TGA agreed to publish the outcome of ***certain*** investigations into complaints about therapeutic goods advertising directed to consumers which have been referred to the TGA by the CRP for follow-up action.
- Since then there have been at least 47 such referrals to the TGA. To-date, only eight outcomes have been reported; some have taken 12 months or more and are still under dispute.#
- The TGA may write "Reregulation 9" letters "ordering" compliance but, due to the low financial penalties available, the TGA has ***NEVER*** prepared a brief of evidence for consideration of prosecution (ANAO report).
- In short, the current TGA "Regulation 9" processes are appallingly slow, inefficient and appear loaded in favour of the sponsors.

http://www.tga.gov.au/industry/advertising-reg9.htm

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Problems with the TGA

- The current "light-touch" regulation of CMs, especially the lack of timely and significant penalties for breaches of the Therapeutic Goods Advertising Code and the Therapeutic Goods Act, encourages unscrupulous sponsors to flood the market with shonky products and unethical claims.
- The TGA (and industry) has failed to educate consumers and health professionals that CMs (especially herbals) are usually complex products and the concept of therapeutic equivalence of generic ingredients that is applicable to PBS products does not apply to CMs.
- Just as all red wine is not Grange Hermitage neither are all preparations of St John's Wort, or glucosamine for example, therapeutically equivalent. Clinical trial results only apply to the specific, well characterised product that was tested, they CANNOT be extrapolated to other products containing the same generic ingredient.

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Case study

Vlad SC, LaValley MP, McAlindon TE, Felson DT. Glucosamine for pain in osteoarthritis: why do trial results differ? Arthritis Rheum 2007;56:2267–77.2. Reginster JY. The efficacy of glucosamine sulfate in osteoarthritis: financial and nonfinancial conflict of interest [editorial]. Arthritis Rheum 2007;56:2105–10.

Problems

- AUST R labelling for CMs is flawed by grandfathering unevaluated products and failure to update old assessments in light of new knowledge.
- Research has shown that the public does not understand the difference between AUST R and AUST L labelled products.
- Thus, there is currently little incentive for sponsors to undertake expensive research, compile an extensive dossier and pay the higher fees required for TGA registration.
- A better return on investment comes from spending the money on marketing.

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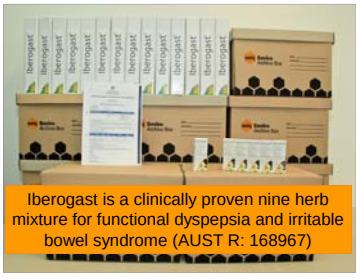
Flordis Iberogast registration dossier



- 14,200 pages Clinical data
- 7000 pages Toxicological data
- 5,600 pages Quality data
- 105 pages Local data

Total: 27,455 pages

$150,000 submission cost

TGA list of evaluated registered CMs

- Of the 25 products on the list most are unremarkable: Iron, Calcium, Vitamin D, Psyllium fibre and Ispaghula husk for constipation, Clove oil for toothache.
- More innovative products are:
  - IBEROGAST (Flordis). A specific nine herb mixture, "for the treatment of functional dyspepsia and irritable bowel syndrome".
  - KALOBA (Schwabe) containing a specific extract of *Pelargonium sidoides* (EPs 7630,) for "for the treatment of acute bronchitis and sinusitis".
  - FLEXAGIL (Blackmores). A specific extract of *Symphytum officinale* (Comfrey) for topical application for the "relief of lower back pain, painful joints and strains".

http://www.tga.gov.au/industry/cm-basics-regulation-evaluation.htm

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Problems with the TGA

- TGA consultations on regulatory reform have been opposed by industry and never brought to a conclusion. For example:
  - Regulation of homoeopathic and anthroposophic medicines in Australia (2008)
  - Guidelines for Levels and Kinds of Evidence for Listed Medicines with Indications for Weight Loss (2009)
  - Advertising consultation (2010).

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Harm caused by the present system

- **Direct harm,** resulting in adverse patient outcomes, e.g. when a complementary medicine interacts adversely with a prescription medicine.
- **Indirect harm,** resulting from a delay of appropriate treatment or from unreasonable expectations that discourage patients and their families from accepting and dealing more effectively with their medical condition and lack of incentives to research and develop evidence-based products.
- **Economic harm,** as a result of expenditure on harmless but inefficacious treatment or products, important because many patients already forgo necessary PBS medicines because of the cost of co-payments.

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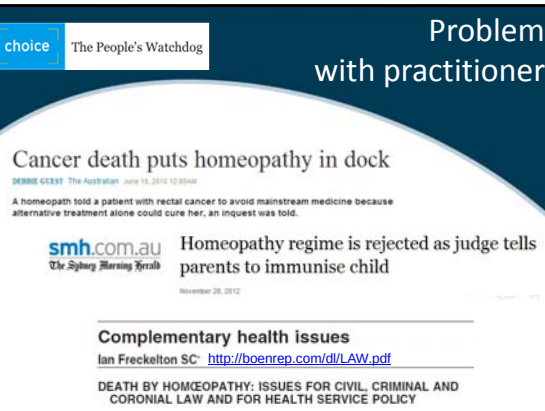
Problems with practitioners


Cancer death puts homeopathy in dock

DEBBIE GUEST The Australian

A homeopath told a patient with rectal cancer to avoid mainstream medicine because alternative treatment alone could cure her, an inquest was told.

smh.com.au The Sydney Morning Herald

Homeopathy regime is rejected as judge tells parents to immunise child

Complementary health issues

Ian Freckelton SC: http://boenrep.com/dl/LAW.pdf

DEATH BY HOMŒOPATHY: ISSUES FOR CIVIL, CRIMINAL AND CORONIAL LAW AND FOR HEALTH SERVICE POLICY

Problems with practitioners

- National registration of some health professions (AHPRA) aims to ensure a minimal level of education and training, appropriate standards of professional behaviour and effective and efficient complaint mechanisms.
- Homeopaths, naturopaths and many other CAM practitioners have not achieved national registration, in part because of division in their ranks, but also because of their varied training.
- This means that currently anyone can legally call themselves a homeopath (or naturopaths), although private health insurers will only acknowledge the services of practitioners belonging to a professional organisation for the purposes of rebates on consultations.
- While CAM practitioners may be members of professional associations this does not necessarily ensure evidence-based practice, continuing professional education or good complaint handling processes.

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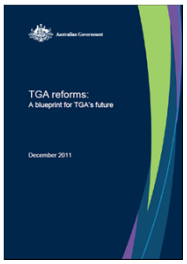
Problems with practitioners

Solutions: government inquiries?



- Australian Government. TGA reforms: A blueprint for TGA's future, 2011. http://www.tga.gov.au/pdf/media-2011-tga-reforms-111208-a.pdf
- Australian Government. Delivering reforms - Implementation plan for TGA Reforms: A blueprint for TGA's future, 2012. http://www.tga.gov.au/about/tga-reforms-blueprint-implementation.htm

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What did we want (TGA)?

- A regulatory system with teeth!
- Mandatory labelling, "This product has ***NOT*** been evaluated by Australian Health Authorities to see if it works".
- Increased and better targeted post-marketing surveillance.
- Timely and meaningful sanctions for regulatory violations (civil penalties, enforceable undertakings).

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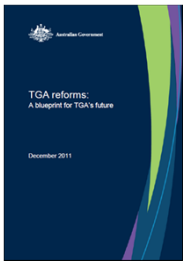
What did we get?

Over 4 years the TGA will:



- Update and include in the regulations the TGA document, *Guidelines for the levels and kinds of evidence to support indications and claims* (two drafts have already been produced)#;
- Amend the Electronic Listing Facility (ELF) to provide increased guidance to sponsors and risk profile information to the TGA (to assist targeted reviews);
- Increase the number of coded indication in ELF to eliminate "creative" use of free text;
- Broaden pre-clearance requirements to include medical devices and advertisements on pay TV (but not the Internet);

http://www.tga.gov.au/newsroom/consult-cm-evidence-listed-medicines-120423.htm

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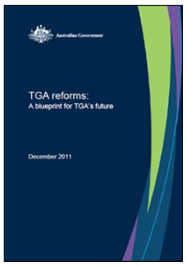
What did we get?

Over 4 years the TGA will:



- Provide more detailed and targeted post-marketing monitoring and reporting by the TGA;
- Create a central point at the TGA for all complaints about advertising, with the TGA to deal with those regarding efficacy or the intended purpose, not the Complaint Resolution Panel;
- Harmonise industry self-regulatory codes of conduct to support consistent ethical standards across the therapeutic goods industry;
- Improve labelling to assist consumers make informed choices;
- Explore enhanced sanctions and penalties for regulatory violations including advertising breaches.

NHMRC Natural Therapies Working Committee

- NHMRC is currently reviewing the evidence for the effectiveness of "natural therapies" such as massage, aromatherapy, homeopathy, naturopathy, western herbalism and nutrition.
- This will comprise a systematic review of available evidence on their effectiveness in treating a variety of clinical conditions in humans and also assess evidence provided by stakeholders.
- The findings of this review will inform the government's Natural Therapy Review Advisory Committee.

http://www.nhmrc.gov.au/your-health/complementary-and-alternative-medicines

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Natural Therapy Review Advisory Committee

- The review's purpose is to ensure that taxpayer funds that are paid through the rebate to subsidise natural therapies are underpinned by a credible evidence base that demonstrates their clinical efficacy, cost effectiveness and safety and quality.
- The Natural Therapy Review Advisory Committee will use the NHMRC review of natural therapies and will make recommendations to as to which therapies are underpinned by a credible evidence base.

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Natural Therapy Review Advisory Committee

- Services subsidised under Medicare by health professionals regulated under the National Registration and Accreditation Scheme will not be affected by the review. These include Chinese Traditional Medicine, Chiropractic and Osteopathy.
- The Committee will be chaired by Chief Medical Officer, Prof Chris Baggoley, and will provide advice to the Australian Government.
- It is expected to meet first on March 6 and then on three further occasions before 31 August 2013.

http://www.health.gov.au/internet/main/publishing.nsf/Content/phi-natural-therapies

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Options for unregistered practitioners

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In conclusion: What's evidence?

- Patients, colleagues, social media (and testimonials) might say, "It worked for me".
- But the plural of anecdote is not evidence.
- There are a number of reasons why consumers (and practitioners) convince themselves that a treatment is effective when it is not. These include:
  - The natural history of disease (symptoms may wax and wane) ,
  - Confirmation bias (seeing what you expect to see),
  - Cognitive dissonance (ignoring results not in accord with expectations),
  - Endorsement by "celebrities" who receive multi-million payments (be especially suspicious).
- In short, personal evaluation is quick, convincing and often wrong, while double-blind, placebo-controlled clinical trials are slow, complex, and costly.
- However, the latter are important as they often show that initially promising results are not replicated by larger and better conducted studies.

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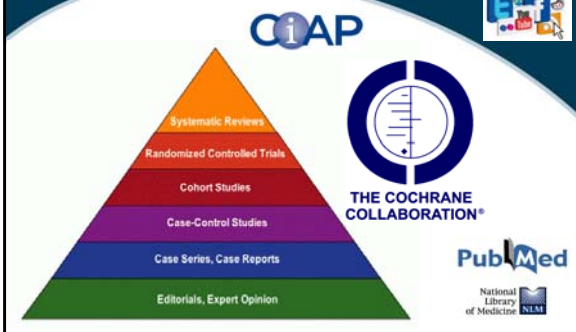
In conclusion: What's evidence?



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In conclusion: What's evidence?

Finally

- To give good advice about CMs:
  - ALWAYS ask patients about ALL the medicines they take.
  - Use an NPS recommended CM resource regarding therapies /ingredients / interactions / etc.
  - Ask the sponsor for all published clinical trials performed on their specific product.
  - Use Medline, Cochrane and other resources to see what else has been published.
  - Check the CRP and TGA complaint registers to see if complaints about a product's claims have been upheld:
    - www.tgacrp.com.au
    - http://www.tga.gov.au/industry/advertising-reg9.htm.
  - Polish your critical appraisal skills (try putting in complaints).
  - Be skeptical.

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choice
The People's Watchdog
Australian Skeptics
http://www.youtube.com/watch?v=p2FT8kNCYMs
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