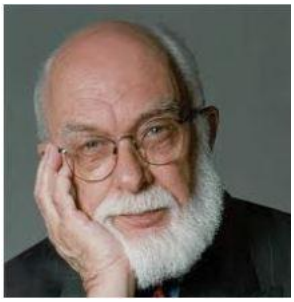
Friends of Science in Medicine

Newsletter 27—05 February 2021

The power of one!



James Randi
7 August 1928 – 20 October 2020

James Randi (Randall James Hamilton Zwinge), a Canadian-American stage magician, inspired generations of skeptics and science communicators. They continue his push back against the false claims of pseudoscience, the paranormal and the supernatural, as well as against those who profit from them.

As 'The Amazing Randi', he performed stage magic and escape acts world-wide. Notably, by remaining in a sealed metal coffin submerged in a swimming pool for 104 minutes, he broke one of Harry Houdini's records on live TV.

Randi had no time for pseudoscientific health-care fraud. He exposed many charlatans with his inside knowledge of magicians' tricks.

Always the showman, he would swallow massive overdoses of homeopathic sleeping pills, before explaining why homeopathic medicine was a placebo.

In 1996, the James Randi Education Foundation, which he co-founded, offered $1,000,000 to anyone who could, under scientific testing, prove a supernatural ability. Since the challenge was originated by Randi in 1964, about a thousand people have tried, failing at the first round.

On 20 October 2020, aged 92, the magician, turned fraud debunker and scientific skeptic, passed away due to "age-related causes".

He will be greatly missed.

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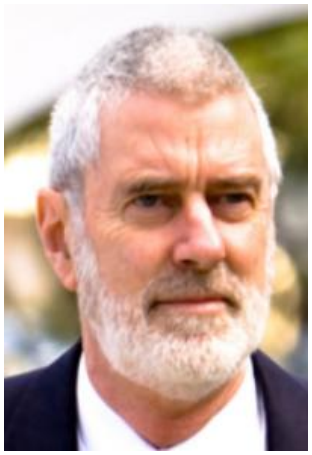
Inside this Issue:

Regulation of listed goods by the Therapeutic Goods Administration



Ken Harvey

The Therapeutic Goods Administration (TGA) regulates more than 10,000 listed products, mainly complementary medicines. Unlike registered prescription medicines, listed products have no pre-market evaluation. The TGA 'trusts' each product's sponsor to obey the rules. There are only two TGA checks on the regulation of listed products: a small number of post-marketing reviews and the advertising complaint system.

TGA post-marketing surveillance assesses around 160 listed products a year (out of more than 10,000). Over the last five years, on average, around 75% of products assessed have consistently been found non-compliant, mainly because companies are unable to produce evidence to substantiate claims for efficacy.

Since July 2018, the TGA has had enhanced investigative and compliance powers to take over the advertising complaint system. The previous Complaint Resolution Panel (CRP) had upheld virtually all the complaints it received but had no power to sanction companies which repeatedly breached the Therapeutic Goods Advertising Code. While there was support for the TGA takeover, there were also concerns that the TGA had rarely acted on non-compliance with Panel determinations previously forwarded by the CRP.

Under the new complaint system, the TGA classified most complaints as 'low priority' and closed them by sending an 'educational letter' to the company concerned. This letter reminding the company of their regulatory obligations, but also pointed out that no further action would be taken.

Australian Government
Department of Health
Therapeutic Goods Administration

In the first year of the TGA takeover, there were around 2,000 complaints; in the second year, there were more than 3,000. Delays in dealing with complaints increased. A review by consultants recommended that the TGA should stop dealing with individual complaints. As a result, outstanding and most new complaints were now closed by sending complainants a letter stating that their complaint will be used for 'intelligence' to set priorities.

Why, if this is the only response, would anyone bother to submit any more detailed complaints? Perhaps the TGA has hoped for just this reaction. They will then be able to cite a falling-off of complaints as 'evidence' that unethical advertising has been brought under control.

So, why did I resign last year as the Australian Consumers' Association (Choice) representative on the Therapeutic Goods Advertising Consultative Committee?

Despite efforts to get the Therapeutic Goods Administration (TGA) to act on misleading, deceptive, and often dangerous advertising of complementary products, the TGA took less action on complaints in 2020, not more. In addition, the 23-person Therapeutic Goods Advertising Consultative Committees is dominated by industry and media representatives. There was no meaningful engagement with consumer protection issues.

The advertising complaint system (taken over by the TGA in 2018 and 'reset' in 2020) has also failed to deter misleading and deceptive claims.

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In 2020, the TGA published its list of priorities which included 'hangover cures' and weight loss products. These products, which undermine public health messages, had been the subject of numerous complaints over many years. Regardless of being listed as 'priorities', the TGA, has, to-date, token action on only one or two individual products. They have ignored the underlying issue that these entire *classes* of products do not work.

Numerous representative complaints illustrate additional systemic issues which the TGA has also failed to address. For example:

* Promotional claims remain unchanged, despite new evidence resulting in the products no longer being recommended by current medical opinion. Examples include glucosamine for osteoarthritis and fish oil for 'heart health'.
* Claims are extrapolating from a nutrient's important role in the body to implying that taking this ingredient as a supplement will benefit normal healthy people. Examples include Coenzyme Q10 and nicotinamide riboside chloride (Vitamin B3).
* Ingredients such as probiotics and multi-vitamins are added to unhealthy products such as 'Kids Smart Vita Gummies' and 'Probiotic Choc Balls' to give them a 'health halo'.
* Clinical trial results from *specific*, well-characterised herbal extracts are extrapolated to *generic* herbal ingredients, despite only being applicable to the particular extract used in the trial.
* 'Traditional', rather than 'scientific' claims are increasingly used as proof, removing the need for complementary medicines to have a scientific evidence base.

Why has the TGA failed to tackle these issues? Is it due to:

* Industry lobbying of government (and the TGA) to maintain a profitable and export-orientated industry – despite breaking the law to do so?
* A regulatory culture favouring industry assistance over consumer protection?
* Lack of expertise (insufficient medical, pharmacy and public health staff)?
* Limited financial resources (if so, why not increase the industry charges which fund the TGA)?

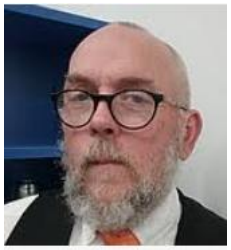
These questions were raised with Adjunct Professor John Skerritt, Deputy Secretary, Health Products Regulation Group, Department of Health at *Skepticon 2020*. His failure to answer precipitated my resignation.

So, given a regulator which refuses to regulate, what should Friends of Science in Medicine do in 2021?

One suggestion is that FSM should now focus on educating consumers and health professionals about the systemic issues listed above, using representative examples of specific products. The FSM executive would be interested in what 'Friends' think of this idea. We would also welcome other suggestions.

Dr Ken Harvey AM, *MBBS, FRCPA, President FSM*

Rights talk and responsibility



Bruce Baer Arnold

Your right to be stupid isn't a right to cause harm. Misunderstandings about rights and responsibilities have been a feature of community responses to COVID-19. They are contrary to effective and respectful public health policy, something that is founded on science-based medicine rather than mystical thinking about Magna Carta. A challenge facing FSM is encouraging awareness of responsibilities alongside appreciation of scientific fact.

Medicine exists within a legal and social framework. Responses to pandemics such as COVID-19, snake-oil cures and the mystical thinking found among anti-vaxxers are complicated by the emergence of Rights Talk over the past twenty years. Rights Talk is an import from the United States, largely propagated through social media. It is a matter of people asserting that they have rights but disregarding responsibilities.

Their assertion, as we see with the growing sovereign citizen movement and many of the protestors in Sydney and Melbourne, is often legally uninformed and indeed nonsensical. It is populist and may have a strong conspiratorial flavour. People for example claim that Magna Carta prevents any restrictions that would contain infection, even though that containment would protect vulnerable individuals and avoid overloading the public health system. Some people claim an absolute right not to be vaccinated or tested, on occasion claiming that 'big pharma' is part of the same conspiracy that uses 5G networks to cause COVID-19 or autism. Some, equally implausibly, claim that they are 'sovereign citizens' who are not subject any law but – so conveniently – are free to use community resources such as roads, parks, schools and hospitals.

Overall Rights Talk centres on 'my' rights overriding 'your rights' and the rights of everyone else. It is a charter for selfishness and irresponsibility. It is at odds with the recognition in Australian of human rights that increasingly reflects our adherence to global agreements such the Convention on the Rights of the Child and the Convention on the Rights of People with Disability. That recognition is inconsistent and often weak, because unlike comparable jurisdictions we do not have a Bill of Rights in our Constitution.

However, our legislation and judgments by Australian courts clearly deal with rights as a matter of inescapable tensions between individual wants/needs and community benefit. That law considers rights as being inalienable but not absolute. Accordingly we may on occasion restrict rights of association (for example protest marches and sit-ins) and expression. In Australian and international law there is no exhaustive right of 'free speech'. In strengthening public health and protecting the vulnerable it remains both legal and necessary to restrict some statements, especially communication that is harmful and expressed as fact rather than opinion.

One consequence is that bodies such as the TGA, ACCC and Medical Board can restrict vendors advertising 'quantum' devices that will supposedly prevent COVID-19, clinicians peddling nonsense cures or naturopaths claiming medical qualifications. Governments in Australia and overseas are slowly moving to require responsibility on the part of global digital platforms such as Facebook, Twitter and Google that profit from disseminating 'fake health news' but claim immunity based on free speech.

A robust health system needs that multi-faceted regulation as the basis for community education about science and respect, not individual privilege.

Dr Bruce Baer Arnold, *Asst Professor, CELTS Fellow and Juris Doctor Program Director, Canberra Law School, Faculty of Business, Government & Law, University of Canberra*

The pharmaceutical promotion of opioids

Paul Rolan

FSM's key message is that treatments should be supported by evidence, not by industry promotion. To validly criticise those who promote interventions lacking evidence, we must also look at our profession for biased practice. Tragic widespread opioid abuse teaches us that medical practice was influenced by pharmaceutical promotion and "follow my leader".

Opioid use has a long history, going back 5,000 years. We should, by now, have learnt how to use it!

Until around the 1980s-90s, because the addictive properties were well-known, their use was mainly for post-operative pain and palliative care. However, in 1980, the *NEJM* published a letter claiming that addiction post-operatively was rare. Six years later, a case report on 38 patients with chronic non-cancer pain showed good outcomes and no dependence – except in 2 previously dependent participants. Given the high unmet burden of chronic pain, doctors, supported by some professional bodies. were encouraged to prescribe opioids for chronic non-cancer pain.

The clinical pharmacologists also played a role. The assumption that controlled-release products were safer and more effective was based on the *belief* that avoiding peaks would increase safety and that extending duration would increase efficacy. Such claims were often based on simplistic pharmacokinetics, excluding the complexities of pharmacodynamics. Such outcomes were never demonstrated in clinical trials. The pivotal regulatory studies showed equivalence to short-acting formulations in studies no longer than three months. Post marketing-surveillance to monitor long-term efficacy or safety was absent.

Aggressive promotion and marketing of a sustained-release oxycodone preparation (*OxyContin*, Purdue Pharma, Stamford, CT), contributed to the problem. Purdue pursued an "aggressive" campaign promoting opioids in general and OxyContin in particular. In 2001 alone, the company spent $200 million influencing OxyContin prescribing. This included a systematic effort to minimise risk addiction risk in the treatment of chronic non–cancer-related pain.

We now have a litany of resulting problems. Individuals develop tolerance and dependence to variable degrees. Long-term complications include hyperalgesia, cortisol and gonadotrophin suppression, immune suppression, and dental loss due to xerostomia. With concurrent benzodiazepines, fatal respiratory depression often occurs. Some medication was sold or passed on, entering the criminal supply stream and contributing to further harm.

The pendulum is swinging the other way, with increasing restrictions. Much is appropriate, but might lead to patients being stigmatised and forced off medication without their consent – not consistent with best practice.

A nearly identical story occurred with benzodiazepines a decade or so earlier, although with less harm.

We doctors need to learn from these examples and be sceptical when new psychopharmaceuticals arrive or we are encouraged to use them widely. Although 'likability' studies drug are required for new psychoactive substances, the abuse potential is sometimes not apparent for some time. For example, pregabalin, now used principally for neuropathic pain, was thought to have little abuse potential; this is now longer the case.

Prof Paul Rolan, *MBBS, MD, FRACP, FFPM(UK), FFPMANZCA, Clinical Pharmacologist, Vice President, FSM*

Anti-vaxxers take aim at the COVID-19 vaccine

John Dwyer

With the COVID-19 virus killing more than 2,000 Americans daily, the Surgeon General noted "A vaccine is of no use if you are dead and no use to you if you don't get vaccinated". The latter point matters; some 42% of Americans are reluctant to be vaccinated.

The best data suggest that a 70% uptake is necessary to produce 'herd immunity' – which could stop the spread. Irresponsibility, and outrageous even for Fox News, Laura Ingraham recently interviewed a 'retired microbiologist,' who warned that COVID-19 vaccines are dangerous. "Why is that?" she asked. "Well, your producer told me the interview was limited to three minutes and it would take about 15 minutes to explain my concerns." Promising a follow-up, Laura apologised for the brevity. The damage was done!

There is nothing new about anti-vaccination propaganda. During the UK smallpox epidemic in rhe 1870s, charlatans, offering useless 'alternative' options, warned of the damage. Major London newspapers were chortled when a vocal medical critic of vaccination had had himself vaccinated!

Today, scaring people about vaccination is particularly dangerous. While a few countries, such as ours, have successfully used – at times draconian – public health measures to *contain* the epidemic, vaccination is the only remedy likely to *end* the scourge.

The anti-vaxxers' dangerous nonsense ranges from vaccines containing mind-altering substances allowing governments to control citizens, to fears of autism and triggering autoimmune diseases. What an invaluable tool they have found through irresponsible social media!

The torrent of misinformation, often delivered with vitriol, has led to the formation of the 'Centre for Countering Digital Hate' (CCDH). Its principals strongly criticised social media for allowing the anti-vaccine movement onto their platforms. Their research shows that social media accounts held by anti-vaxxers have, since 2019, increased their following by at least 7·8 million people. "The decision to continue hosting known misinformation content and actors online left anti-vaxxers ready to pounce on the opportunity presented by coronavirus". The WHO has warned of an 'infodemic' of false information online.

The CCDH notes that 31 million people follow anti-vaccine groups on Facebook, with 17 million on YouTube. They have calculated that the anti-vaccine movement could realise US $1 billion in annual revenues for the social media platforms. As much as $989 million could accrue to Facebook and Instagram alone, largely from advertising targeting the 39 million anti-vaccine followers.

Around one in six British people are unlikely to agree to vaccination. A similar proportion had yet to decide. Individuals relying on social media were more hesitant. A recent six-country study reported that around a third of respondents had, during the previous week, seen "a lot or a great deal of false or misleading" information on social media.

Widespread vaccination is likely to be available here by April or May 2021. Although we *do* have high rates of vaccination, we must *not* presume that Australians are immune to anti-COVID-19 propaganda. In May, rallies around Australia, organised by the Australian branch of 'Millions March Against Mandatory Vaccinations', saw a Sydney crowd of several hundred voicing their concerns about, not just vaccinations, but 5G wireless technology, the coronavirus lockdown and general government overreach into people's lives.

Clearly, we need to start our own pro-vaccination advocacy now, emphasising both the safety and the importance of a massive uptake. A media blitz from the Federal Department of Health on the benefits, including on social media platforms, should be an urgent priority.

Professor John Dwyer AO, *PhD, FRACP, FRCPI, Doc Uni (Hon) ACU. Emeritus Professor of Medicine and co-founder and inaugural president of FSM*

Veterinary Medicine and CAM

Column by Tanya Stephens

Pets and Pointless Pills: The Animal 'Wellness' Industry

Tanya Stephens

Australia is a country of pet lovers. Almost 62% own at least one pet (HILDA statistical report 2020), dogs being the most popular. This is similar to the USA, but much higher than the UK. Most pet owners are young couples. They spend more money on their pets than ever before ($12.2 billion annually) – in the form of 'premium' foods, dietary 'supplements' and pet accessories.

The growing Australian 'complementary medicines' sector for humans was valued at AUD $5.6bn in 2019, when seven out of ten Australians had used at least one 'complementary medicine'. Is it any wonder that pet owners believe that what makes *them* feel better will also benefit their pet, increasingly seen as a member of the family? The 'trickle down' effect from the human 'wellness' culture is not surprising. Pet supplement purchasers more likely, themselves, to be millennial supplement takers and owners of 'fur babies'.

Blackmores' recent slump in sales has resulted from the coronavirus pandemic, the fall in the Chinese market, and the cost of meeting new TGA product claim and labelling regulations (futurefoodsystems.com.au). It's responding by expanding its pet supplement market. Over the next year, the company intends to launch a series of pet supplements for export to China, a huge market, currently worth $175.6 million, and forecast to nearly double by 2024.

The company also aims to double the size of its existing *PAW* brand by the end of 2022. Australian pet health supplement sales have a projected compound annual growth rate of 9% over the next four years – to almost $100 million.

The Australian Pesticides and Veterinary Medicines Authority oversees the registration of complementary animal health products (CAHPs), which include herbal remedies, probiotics, therapeutic diets, homeopathic remedies, oral vitamins and minerals, nutraceuticals and naturally derived remedies, such as shark cartilage – but there is no requirement to prove efficacy.

Advertised pet supplements offer a dazzling array of products. In addition to vitamins and minerals, high potency Vitamin C, homeopathic drops, organic hemp nectar, 'Turkey Tail Medicinal Mushroom Powder' and, of course, various cannabinoid products. Products containing glucosamine and chondroitin are particularly popular. The RSPCA has jumped on the bandwagon, with RSPCA Joint Health Tablets for Dogs and Hip and Joint Care tablets for dogs and cats, distributed by Indyvet Animal Health Products Pty Ltd.

Do pets need supplements? Most likely, no. There is no evidence, at individual or population levels, that supplements are needed or provide benefits. Data are lacking. There is little evidence for chondroitin or glucosamine, high dose Vit C (cats and dogs make their own), or most of the other so-called 'supplements', including probiotics.

The well-documented 'caregiver placebo effect' can convince pet owners that their pet, on supplements, is sprightlier, happier and healthier. One thing is certain – pet supplements put smiles on the faces of pet supplement sellers and contribute to *their* financial 'wellness'.

Tanya Stephens *BVSc (USyd) MSc IAWEL (Edin) MANZCVS FRCVS (Animal Welfare).*

Tips for better thinking: Anecdotes are not reliable

Jonathan Jarry

Testimonials are seductive but to know if a health intervention truly works we need better evidence.

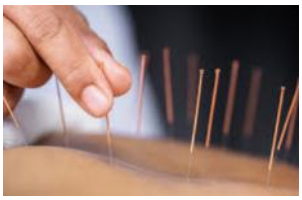
There is a popular saying in the skeptical community: the plural of anecdote is not data. The clever putdown is meant to remind the person you are speaking to that no matter how many people swear by, let's say, homeopathy, their testimonials do not prove homeopathy's worth.

I happen to disagree with the saying. The plural of anecdote is data. If a physician begins prescribing a new drug and three patients come back complaining of a weird and sudden skin rash, this trio of anecdotes is worth exploring. It's just that these anecdotes on their own are not conclusive and this is a crucial point to make.

Anecdotes and testimonials are incredibly convincing to us. We love a good story, and hearing the compelling narrative of someone who was ill and recovered makes us want to know what led to the improvement. What was this thing that made such a dramatic difference? The problem is that figuring out what this thing is is more difficult than meets the eye.

We may believe that homeopathy helped us overcome the flu, but the flu is a self-limiting illness. Our immune system kicks in and our symptoms do not last forever. Therefore, whatever extra step we take may look like it's curing us of the flu, but the real slayer here is our immune system. (As for claims that products can boost our immune system, they tend not to survive scrutiny.)

We may hear that energy healing helped someone get cured of their cancer, but was it the energy healing that did it or the combination of chemotherapy, radiotherapy and surgery? Did energy healing contribute anything to this assortment of approaches? Based on this testimonial alone, it's impossible to know.



We may think an expensive series of acupuncture sessions is really helping with our chronic pain, but if we don't record our pain levels daily, our pain may remain just as bad but we end up noticing the days when it's better and forgetting the days when it's worse. Investing in something predisposes us to believe it's going to work, because to spend money on something useless would be foolish.

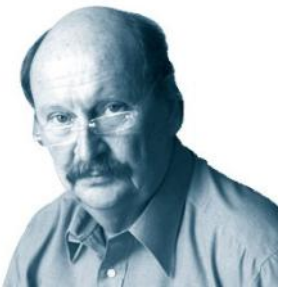
That is not to say that testimonials about health products and interventions are always wrong; it's that they are not reliable. They can be contaminated by phenomena that are well known to skeptics: regression to the mean, self-limiting illnesses, multiple treatments used at once, confirmation bias, and the placebo responses. We need to conduct robust scientific studies to eliminate all of these phenomena and figure out if something truly works on its own.

So the next time you are tempted to believe something works based on an anecdote, remind yourself that anecdotes are dirty data: they are adulterated with many factors that may have played a role in the outcome we observe. Ask for better evidence if you don't want to risk wasting time, money, and even jeopardizing your own health.;

Jonathan Jarry MSc *(https://twitter.com/crackedscience?lang=en)*
Originally posted by the McGill Office for Science and Society

A SPECIAL REPORT FROM EDZARD ERNST

30 years ago: regular sauna bathing and the incidence of common colds



Edzard Ernst

Thirty years ago, I had just been appointed chair of Physical Medicine and Rehabilitation at the University of Vienna and was about to move – as the first clinical department – into the brand new AKH (General Hospital) of Vienna thus gradually enlarging the team I had taken over from about 20 to 120 co-workers. During this period, I found little time to do original research; however, I did manage to finally write up and publish a study, we had conducted several years before while I was still in Munich. As it is (almost) on the subject of so-called alternative medicine (SCAM), and as it relates to the prevention of a viral infection, I think it might be of interest to give it another outing.

Here is its abstract:

The high morbidity of common colds means that their economic importance is considerable, with colds causing more loss of productivity than any other infection. As no effective prophylaxis is available, this trial was to test the hypothesis that sauna bathing can reduce the incidence of common colds. Twenty-five volunteers were submitted to sauna bathing, with 25 controls abstaining from this or comparable procedures. In both groups the frequency, duration and severity of common colds were recorded for six months. There were significantly fewer episodes of common cold in the sauna group. This was found particularly during the last three months of the study period when the incidence was roughly halved compared to controls. The mean duration and average severity of common colds did not differ significantly between the groups. It is concluded that regular sauna bathing probably reduces the incidence of common colds, but further studies are needed to prove this.

In the discussion section of the paper, we stated the following:

Preventive methods with comparable efficacy have not been described in the literature (2, 12). Vitamin C is of doubtful value (7, 15, 16); vaccination is not feasible since far too many virus types exist (2, 17); virucidal kerchiefs are effective (8, 18) but not available commercially and protect only the environment of a common cold sufferer rather than the sufferer him-/herself.

I believe most of this is still true today (but I might be wrong, as I did not keep up with this particular line of research). Re-reading the paper, I find that our trial was far from optimal:

* we had to conduct it with zero funding,
* it was small,
* it was not randomised,
* it lacked objective endpoints.

Anyway, sauna bathing is most agreeable, and I can recommend it just for this reason. However, I would doubt that public saunas are a good idea during the present health crisis.

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* Even in a deadly pandemic, germ theory denial persists
* Looking back on 2020: Too many physicians behaving badly

Skeptical Raptor

* Anti-vaccine Peter Doshi attacking COVID-19 vaccine clinical trials
* Unprotected sex and COVID-19 vaccine – another ridiculous anti-vax myth

Skeptical Inquirer

* CFI Inoculates against COVID-19 Misinformation
* Clear thinking about conspiracy theories in troubled times
* In Memoriam: The Amazing Life And Legacy Of James 'The Amazing' Randi

The Question of Science Institute (IQC)

* To understand what a vaccine "efficacy" is
* Ministry of Health opens 2021 pushing chloroquine and disinformation

FSM Executives in the Media

Coronavirus, Therapeutic Goods Administration and Lobbying are some of the topics the FSM Executive was interviewed about or published about since the last newsletter.

* ‘Madness’: Immunologist criticises ‘premature’ call to hold the Australian Open
* Those in the public health arena are ‘going too far’
* Top doctor resigns TGA role over concerns with policing of fringe medicine
* Discount pharmacy chains handed cease-and-desist notices
* Complementary medicines advertising policy Part I: unethical conduct in the Australian market before July 2018
* Complementary medicines advertising policy Part II: unethical conduct in the Australian market after July 2018
* LobbyLand: Unhealthy Business? Health sector lobbyists
* Study confirms genetic link in cerebral palsy
* 'It's ineffective and dangerous': Elle Macpherson comes under fire for promoting colloidal silver - a 'toxic' substance that can turn the skin blue

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