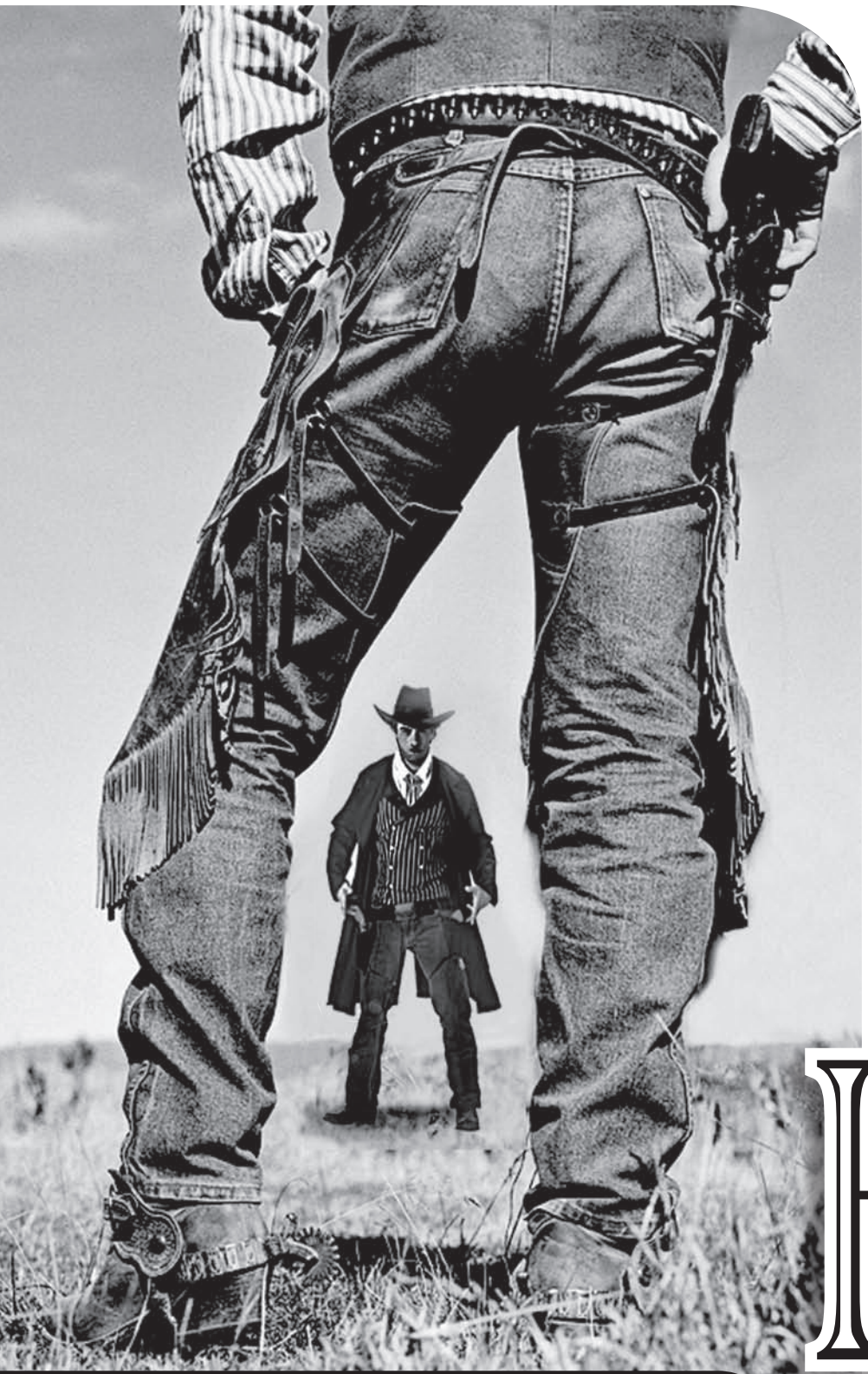


FACE OFF

Tim Mendham looks at the regulators of alternative medicine in Australia, and the activists who often spend blood, sweat and years dealing with them.

Speaking at the Australian Skeptics National Convention in 2011, the then national manager of the Therapeutic Goods Administration, Dr Rohan Hammett, explained that the TGA is hamstrung by regulation and lack of resources.

He compared the TGA's staff numbers of about 610 FTE (full time equivalent) and a budget of A$113m with that of the US Food & Drug Administration (about 17,000 people and a budget of US$4 billion), and Canada's Health Products & Food Branch (2100 people and C$289m). And this despite the fact that all groups monitor roughly the same number of products – about 64,000.

He said that decisions on which particular products to investigate more closely were based on the risk 'continuum' – the higher the risk of harm, the increased level of TGA regulatory interest. Complementary medicines were low down on the list, he said, while prescription medicines and class III medical devices (cardiac stents, pacemakers) were high.

Taking part in the same panel at the 2011 convention was Dr Ken Harvey, one of Australia's leading campaigners against shonky medical products. Over the years, he has had an often tempestuous relationship with the TGA and its associated organisation, the Complaints Resolution Panel, which judges on complaints about advertising and general published information on therapeutic goods. Not long before the convention, Harvey had served

on the Australian National Audit Office Transparency Review Panel, so he knew the organisation well from both inside and out. His assessment was blunt: it needs teeth.

2011 hadn't been a particularly good year for the TGA.

In July, the ANAO review found the organisation had been conservative in its actions and that it could do a lot more to keep the public informed of its deliberations and processes.

With a suggestion that the TGA was serving the industry rather than end-users, the report said that "It is necessary for the TGA to recognise that it serves multiple stakeholders and that it must adapt its communication strategies accordingly. Consumers and health practitioners have as much interest in therapeutic goods as the industry that produces and markets those goods."

The TGA suffered another hit in 2011: the final settlement of a class action brought against it following its actions against Pan Pharmaceuticals (see separate article in this issue). $67.5 million was awarded to 162 sponsors, suppliers and distributors of Pan products, on top of $55 million to former CEO Jim Selim.

Has the situation improved since 2011? What of all of the other complaints resolution and industry regulation authorities? Are they any better than 'toothless tigers'?

We asked a number of Australia's leading regulation activists about their experiences and their views on the authorities themselves. And it's not a pretty picture.

TGA AND CRP

The TGA is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose. These include goods Australians rely on every day, such as vitamin tablets and sunscreens, through to goods used to treat serious conditions, such as prescription medicines, vaccines, blood products and surgical implants.

As such, it manages the Australian Register of Therapeutic Goods, which is a list of products that can be lawfully supplied in Australia. Suppliers can choose to 'register' or 'list' their products on the ARTG.

Medicines assessed as having a higher level of risk must be registered. According to the TGA, "the degree of assessment and regulation they undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data." All registered medicines must display an 'AUST R' number on their label as proof of registration. Those medicines that are evaluated as 'low risk' are 'listed'.

2011: Ken Harvey, Marcus Bezzi (ACCC) and Rohan Hammett

Listed medicines are usually considered to be relatively benign, so the regulations allow for sponsors to 'self assess' their products in some situations. The majority of listed medicines are self-selected by consumers and used for self-treatment, primarily complementary medicines, such as vitamin and mineral formulations, herbal preparations, homeopathic preparations, and essential oils. They are all unscheduled medicines with "well-known low-risk ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens". All listed medicines must display an 'AUST L' number on their label as proof of listing, and must not contain substances that are scheduled in the Poisons Standard.

> "The funding model for the TGA creates a perceived potential conflict of interest."

Listed medicines are assessed by the TGA for quality and safety but not efficacy. This means that the TGA has not evaluated them individually to see if they work. In fact, sponsors of listed products are supposed to have evidence of efficacy, but only a small proportion are ever asked to substantiate such claims.

The TGA is totally funded by the industry it regulates through fees and charges (with the exception of Government funding provided for the alignment of Australia and New Zealand therapeutic arrangements, and departmental funding for the operation of the Drug Control Section and Medicines Scheduling Secretariat). Estimated expenditure for 2014-15 is $147,736,000.

Some critics have expressed concern that the funding model for the TGA creates at least a perceived potential conflict of interest between the interests of consumers and the community, and those of the pharmaceutical industry.

The TGA has the power to delist or deregister products, or issue warnings and instructions if complaints against specific products are upheld. It does not, however, have jurisdiction over the practices of healthcare professionals.

The Complaints Resolution Panel (CRP) is the body that hears and assesses such complaints, and then gives the TGA advice based on its findings. It has no power to issue penalties or instructions in its own right.

The TGA prioritises its investigations according to two main criteria:

- Issues that may have adverse health consequences for consumers as a result of public access to dangerous or inappropriate goods; and
- Issues that affect the "TGA's reputation among key stakeholders leading to a loss of confidence in our regulatory processes and subsequently a loss of confidence in available therapeutic goods".

"We value all information we receive about cases of potential non-compliance and regularly adjust our strategies for prioritisation in response to new information or trends", but there is no guarantee that any complaint is followed up.

Ken Harvey knows the TGA and CRP from the inside. Apart from sitting on bodies that have reviewed their

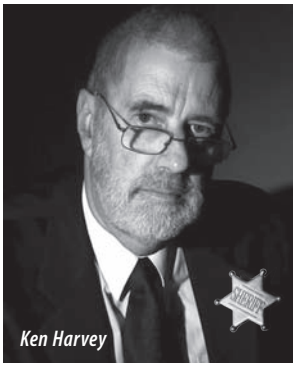
Face-Off

Continued...

operations, he has also made a number of complaints about specific products and product promotion to the CRP, all of which has been upheld (though that doesn't necessarily mean all have reached a successful conclusion). And, of course, the long legal battle over the pseudo-diet product Sensaslim, an action that stymied the CRP for a frustrating period due to its regulation on not dealing with claims when the participants are before the courts.

"The first port of call [with a complaint] is the CRP, but the problem is it's overloaded and overworked; it's taking six, twelve months to get a determination.

"If a company ignores the determination, the CRP sends it off to the TGA who are obliged to do a completely separate investigation, which takes another year. Along the way the promotion [of the suspect product] continues. The TGA might come to the same conclusion as the CRP and ask for a Regulation 9 order for an audit of the company, but that will be challenged and go through appeals tribunals. So years can go by and nothing happens. At which time they can take the product off the market and put out a new one with exactly the same ingredients and call it something else.


Ken Harvey

"The CRP can only request – and the request has absolutely no authority whatsoever.

"The TGA can order, which sounds good, but again it seems to be totally ineffective. If that's ignored and the appeals have gone through, they can themselves remove the product from the marketplace, but that's not very effective because the company can just relist the product under another name and away they go. It would be preferable if the TGA had the power to impose some significant fines without having to go through the Crown Prosecutor. The advice from the public prosecutor is that the miniscule fines that are available at the moment aren't worth the effort. So the TGA should have some administrative powers to fine people without having to take them to court, without all the hoo-ha, and if they also automatically got stuck into reviewing new products coming up or that had been delisted by the sponsor – simple things that the National Audit Office had suggested in their review some years ago – target your post-marketing reviews especially onto companies that were gaming the system. But they don't seem to be doing that, because the same guys keep doing it. Complaints are upheld but ineffective.

"Essentially we either give the CRP the powers to do its own thing without having to refer it to the TGA, or preferably give it to the TGA because the CRP gets criticised as not having the expertise of the TGA and they are the ultimate regulators.

"My own view is probably that the CRP should go and the TGA should be beefed up to handle complaints in a timely fashion with appropriate penalties. At least if we only had one body instead of two that would take a couple of years out of the process."

'Beefing up' implies increased resources, and currently the funding arrangement for the TGA doesn't look promising.

Harvey believes there has been a problem with the culture of the TGA in the past. "But since the National Audit Office got stuck into them and since they've had so-called TGA reforms, they have improved; they're showing more rigor."

"They are good people but they are hamstrung by the lack of resources," Harvey says. "If you need higher fees on the industry to get the system to work, then so be it. They pay fuck-all at the moment anyway."

Loretta Marron is an infamous and prolific campaigner against dodgy medical devices and even dodgier practitioners. She is a three time winner of the Australian Skeptic of the Year – twice in her own right and once as part of the Friends of Science in Medicine.

Her concern with the TGA is the listing process itself.

"ARTG goods are, in reality, self-regulated, so anything goes. Part of the TGA's job is to help people with their applications for listings, so sponsors have learned how to word their applications to ensure acceptance of their devices onto the ARTG.

"Apart from a few yes/no questions aimed at classification, there is only a small list of' 'prohibited words' which will stop an online device application going through, and a small 'restricted word' list which will trigger a review. These hurdles are well known and easily circumvented. For instance, sponsors learn how to advertise their invalid product by using "may assist with". There is no effective way of stopping a sponsor from applying to put a 'low risk' product that has been removed from the ARTG for any reason, including safety and/or performance, straight back onto the ARTG with the same 90 per cent probability of no review.

"Fewer than 10 per cent of new 'low risk' entries onto the ARTG are randomly selected for post-market review, which means that more than 90 per cent of new complementary medicine entries are only scrutinised for compatibility with a number of key rules during the online application process.

"There is no pre-market scrutiny of the actual product specification, label, instructions, packaging, advertising or evidence, and low-risk devices receive virtually no pre-market scrutiny.

"I'm not aware of any sponsor being threatened with prosecution for providing false and/or misleading information in an application."

ACCC

The Australian Competition and Consumer Commission (ACCC) is an independent Commonwealth statutory authority whose role is to enforce the Competition and Consumer Act 2010 (formerly the Trade Practices Act 1974)

and a range of additional legislation, promoting competition, fair trading and regulating national infrastructure for the benefit of all Australians.

This is a tall order and a broad reach, which means getting any one particular complaint heard can be difficult against so many competing claims.

Earlier this year, Rod Sims, current chairman of the ACCC, told a meeting of the Committee for Economic Development of Australia (CEDA) that the ACCC receives around 200,000 enquiries and complaints a year. It usually investigates over 500 matters, and takes about 30-40 cases to court each year.

"We are very aware of the effect we can have. Just making contact with a company can change behaviour. At the other end of the spectrum, when cases are taken to court, the effect is often considerable. … Indeed, we constantly hear of significantly changed behaviour across an entire industry when a case is taken against one company in that industry."

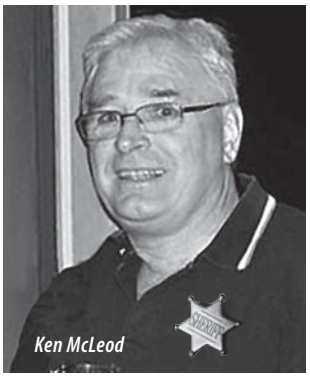
Sims said there are both competition and consumer issues in the medical and health sector which need increased attention, and that this is a new priority area.

Marron says she is aware of the ACCC's limited funds: "They have to be selective in the cases they take on, so they only choose those that put the health of the public at risk."

They did this – with some helping and prodding from noted Skeptics – very effectively with the Power Balance wristbands. A simple message that the bands were useless - about as effective as rubber bands - put the company supplying them out of business.

Another example is the ongoing case against Homeopathy Plus (see the timeline sidebar in this article).

Harvey says that some submissions from industry say that the TGA and CRP should be taken out of the process and leave it to the consumer authorities. "But the ACCC is the first to say they've got an enormous lot of things on their agenda – banking and all sorts of other consumer issues – and they really don't have the resources to be effective in an area like complementary medicine. 'We expect the TGA to get its act together, they say. 'We will act where we think there's something particularly bad that needs public appraisal.' But most of the time they can't put it as a priority."


Ken McLeod

HCCC (NSW) AND OTHER STATES

The Health Care Complaints Commission (HCCC) of NSW "must investigate complaints that raise significant issues of public health and safety or significant questions about the care provided. In relation to individual practitioners, we must investigate complaints that, if substantiated, would provide grounds for disciplinary action or involve gross negligence. The Commission also investigates health practitioners who are not required to be registered, when evidence suggests that they have breached the Code of Conduct for unregistered health practitioners and are a risk to the public health or safety."

> "TGA: They are good people, but they are hamstrung by the lack of resources."

It played a significant role in the prosecution of the Australian Vaccination Network, and though initially there were serious problems with the prosecution process (a witness was not personally harmed by the AVN) a new Act of Parliament – a strong indication of the depth of support of the government for dealing with the AVN and similar groups – meant that the HCCC was given new powers to proactively prosecute.

Nonetheless, there were problems along the way.

Ken McLeod, an early member of the Stop the AVN group and an integral player in the AVN case (himself suffering serious abusive claims from AVN president Meryl Dorey), says that "If I'm going to criticise the HCCC for one thing, it's that I know of three cases where people have lied outrageously to the HCCC and there is provision in the act to prosecute, and they have declined. And they knew it was a lie because I told them. In the case of Meryl Dorey she lied and they put those lies into their report.

"Meryl Dorey in her response defamed me outrageously. I saw that there is a provision in the act that if anyone who harasses or punishes a complainant should be prosecuted. I wrote to the commissioner and he wrote back saying they wouldn't prosecute and suggested that I myself could use a provision to sue for defamation. That advice was wrong, according to a QC I consulted. So I wrote to the HCCC and told them that their advice was wrong and they had misinformed me. But I never got a response to that. On the whole they have been pretty good, but they will not prosecute."

Peter Tierney, author of the Reasonable Hank blog and instrumental in revealing the activities of certain chiropractors "sneaking" into maternity wards to perform treatments on newborns, also cites communication issues with HCCC, with some passion.

"I was involved in the second HCCC campaign following the AVN's initial victory. We prepared a huge, damning document of evidence. I got several responses of 'we have received your correspondence'; but, no feedback – absolutely nothing. This was over a two year period, I recall. We were really very patient. Should we give them a nudge, we asked ourselves? No, let's wait.

"I emailed again, after the second Public Warning was published - stating Dorey was still making the very claims for which she was found in breach the second time - asking for a prohibition order. I think that went on for about six months.

"I counted up all the emails I'd sent them for last three years, in specific regards to the continued AVN breaches – and

Face-Off

Continued...

they had emailed me twice. Infuriating.

"Finally they told me they couldn't do a prohibition order against an organisation. They can only issue prohibition orders against a single health care practitioner, which Dorey is not. Why didn't they tell me that before?

"The AVN is still operating – though in a diminished way – and still in breach of the orders set out in the second Public Warning. There's nothing anyone could do about it due to loopholes still present in the Health Care Complaints Act. The HCCC needs to be granted the power to issue prohibition orders against organisations and/or individuals in an organisation. The HCCC would have some real regulatory teeth, with real penalties attached, if that were to happen.

Tierney knows that a key problem is that the HCCC is overburdened and under-resourced, and has sympathy for the HCCC personnel. But he also knows this is an on-going problem.

"With my prohibition request, I found out I'd been sending emails for six months to someone who had resigned, but no messages were bouncing and no-one told me that the person was no longer there."

"It's happening again with a complaint against a NSW chiro which has to go through the HCCC. It's been a year; I've sent several emails and addenda. I had responses to my initial correspondence, but the last few? Nothing.

"I then sent another, CCing someone higher up – as the chiropractor was still freely posting misinformation on their Facebook page - and got a response saying the investigation was closed, and had been closed since before the previous three addenda. So, we can see where a timely response to emails would be helpful.

In its annual report for 2013-14, the HCCC notes that a Joint Parliamentary Committee on the HCCC "found that there was a perception that all complaints were treated the same and underwent the same process during their assessment. Responding to the feedback, the process for the management of new complaints was reviewed and redesigned."

It says it is giving assessment officer greater ownership of their caseload, to see if a specific communication strategy is required for each case, improving data entry standardisation and reducing errors, and "improved monitoring and analysis of the timeliness of handling complaints".


Loretta Marron

Marron says that after being invited to go undercover for Channel 9's A Current Affair, she witnessed a terminally ill cancer patient having dilute bleach (Miracle Mineral Supplement (MMS) infused into her. "I emailed my oncologist who told me to contact the Queensland Health Quality and Complaints Commission [HQCC; now replaced by the Queensland Ombudsman] which I did the next day. They looked up MMS and confirmed that it was a form of bleach. They acted within a few days and confiscated the goods and shut down the clinic.

"After years of being fobbed off by the TGA, I tried another approach. I documented the false and misleading claims on around 800 practitioner websites and divided them into the relevant states, sent reports (a different project each month for 6 months) to the various health complaints commissions around Australia.

"I was contacted by the complaint commissions from Victoria and Western Australia, who told me that they would have to send the complaints to the TGA. I knew that they would ignore me, but I doubted that they would ignore the states. As a result, an investigator looked at the devices and over 30 were cancelled off the ARTG."

THE SCORE CARD

Harvey believes that the ACCC is a good and effective regulatory body "when they have the ability to get stuck into a problem".

"They've got the power to go right through to court, take the people to the cleaners, insist on retractions and fine people and put them out of business. They've got the power and they've used it on several occasions to send a very clear message to people that doing the wrong thing can be penalised. The problem is that there's a limit on what the ACCC can deal with given their wide-ranging priorities."

He says he doesn't have a problem with the CRP. "You can ring them up and get advice; they will talk to you. I've never had a problem with their determinations. It's just that they can't enforce them."

Perhaps the TGA is less approachable, he says, more formal. "With the TGA, you'll put in a complaint and ask for an acknowledgement and hear the outcome, but usually you never do. They're not good at communicating with complainants. The CRP is very good – they may be slow, but you will get an acknowledgement and you will get an outcome sent to you, eventually. The TGA, you usually have to look things up yourself, and ask a couple of years later why nothing has happened and you may or may not get an answer."

McLeod is reasonably happy with the HCCC (more so, obviously, than Tierney), but much less so with the NSW Office of Liquor Gaming and Racing, which controls charities. "We brought deliberate frauds to their attention and they did fuck all. OLGR did withdraw AVN's charity status, but that took forever."

He says it is the same for the Australian Charities and Not-for-Profits Commission (ACNC), with which he has dealings – albeit, one-sided – regarding supposed research funding in the chiropractic industry.

The various state-based Fair Trading organisations tend to be overwhelmed with cases, so responses are unsurprisingly limited.

Marron has been in touch with the Medical Board of Australia, and individual state-based Medical Boards. She says they have dealt with complaints satisfactorily – "It just seems to take a

long time for them to collect enough evidence and expert opinions that will stand up in court."

ADVICE & SOLUTIONS

The overall problems highlighted by the activists interviewed for this article are the lack of financial and people resources and the need for a proactive and reactive culture.

This was indicated by the responses from the regulators that we contacted for this article. We asked about their priorities, and which areas where they thought they were most (and possibly least) effective. When they did respond, it was normally "look at our website" or a copy-and-paste job from the same site. No value add, no meaningful information.

"A toothless weak regulatory system which encourages bullshit," according to Harvey.

So what can be done, outside of wholesale rip-it-up and start again?

The major focus of all agencies is on harm minimisation, so stressing the harm that could be done to consumers is vital.

Marron says that the regulators all appear to be complaints-based: "It is rare for them to act without a lot of 'noise' from consumers."

Barrister and member of the committee of Australian Skeptics Inc, Martin Hadley says "You have a much better chance of getting an agency interested if you can serve up the evidence to them as a package, ready to run, in contrast to a pile of allegations that they have to sort through."

Complaints against practitioners have to stand up to legal scrutiny. This requires a lot of work by the regulator who has taken on the complaint, so they will not take on complaints unless they are confident that they will win in court.

Use the media. Richard Saunders was instrumental in bringing down the Power Balance wristband supplier in Australia. Beginning with a YouTube clip showing how so-called applied kinesiology works (it doesn't), he followed with a news story on Channel 7's *This Day Tonight* in Adelaide with the supplier being tested on his own products … and failing. That led to a mention by Choice and finally the ACCC putting their head up for the final blow.

The campaign against the visit by anti-vaccinationist Sherri Tenpenny was based on using social media as a call to action, followed by mainstream media attention, and the ultimate stopping of the tour.

You need to learn to cope with a reticence on the part of some industry bodies. As McLeod says, "There's a vacuum in the medical and scientific professions for such lobbying. Until recently the AMA, government, scientists etc almost without exception were silent. They say they don't want to give the baddies the 'oxygen of publicity'. That's common around the world. I think that is counter-productive."

Of course, there are organisations, like the Australian Health Practitioner Regulation Agency and the various industry boards, that we have not covered in these pages – yet. And likewise there are many noteworthy activists doing battle with regulators who haven't had their say in this discussion and who could all give great advice based on their experiences: Dr Rachael Dunlop (involved in many campaigns); Mal Vickers (who, in association with Ken Harvey, has recently submitted a study of chiropractors' use of claims that are condemned by their own board); the executive members of the Friends of Science in Medicine; bloggers Dan Buzzard and Peter 'Ratbag' Bowditch; Wendy Wilkinson (SAVN); etc etc. Our apologies to those many others we haven't mentioned.

But whatever the activity the regulator, the message from Loretta Marron is clear and sums up the views of the many: "Keep complaining - it makes a difference." ■

Homeopathy Plus - A Regulation Timeline

April 2012: ACCC investigates Homeopathy Plus website. HP ordered to remove article about pertussis vaccination claiming "short-lived and unreliable" and "no longer effective".

November 2012: Revised article posted but still contains offending claims

February 18, 2013: ACCC advises HP content is potentially deceptive and misleading. Advised the matter could be resolved by consent if HP agreed to orders by ACCC. HP refused to agree to orders.

February 20, 2013: ACCC informs HP/Fran Sheffield that she was being taken to court.

March-November 2013: Eleven court dates, most were administrative to set dates, granting extensions, etc

December 22, 2014: Court declares that HP/Fran Sheffield "engaged in conduct that was misleading and deceptive or was likely to mislead and deceive, in contravention of section 18 of the Australian Consumer Law" and that "there is no reasonable basis, in the sense of an adequate foundation, in medical science to enable [HP and Fran Sheffield] to state that homeopathic treatments are safe and effective as an alternative to the vaccine for the preventon of whooping cough".

April 22, 2015: Penalties hearing. ACCC asked for $62,500 for HP and $12,500 for Fran Sheffield. Sheffield claimed financial difficulty and ill health(!). Judge disdainful of financial claims – lack of evidence, "not even a bank statement". Judge commented that Sheffield did not appreciate the seriousness of the findings. HP claimed it was a "Mum & Dad corner shop" operation.

May 13, 2015: Court orders that ACCC has leave to file any supplementary submissions by May 25; HP/Sheffield has leave to file their own supplementary submissions by June 5; and ACCC has leave to file any submissions in reply by June 12.

Thanks to Maureen Chuck for the timeline.