EDITORIAL

Critical appraisal: court in the Act

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Freedom of expression may be under threat in Australia from companies using legal action, or the threat of it, to try and silence their critics. A recent case involves a health professional being sued for questioning the efficacy of a complementary medicine.

The product, SensaSlim, was said to be a combination of weight loss ingredients. Spraying it into the mouth was claimed to suppress appetite. Supporting evidence was said to come from 'the world's largest weight loss trial'. This was reported to have had 'sensational results' with 87% of the participants losing at least 10% of their body weight. Advertising for the product appeared in print and electronic media. Investors had the opportunity to buy franchises, reportedly for around $60 000 each.

In March 2011, Dr Ken Harvey complained about the promotion of the product to the Complaints Resolution Panel. This consists of members from the complementary medicines industry, advertising agencies, health professionals, consumers and government. It considers whether advertising has breached the Therapeutic Goods Advertising Code, the Therapeutic Goods Regulations or the Therapeutic Goods Act.[1]

The complaint gave a detailed analysis of the advertising claims and the lack of evidence to support them. As Dr Harvey had formed the opinion that the sensational results were most likely to have been fabricated, the complaint was also sent to the Therapeutic Goods Administration (TGA) and the Australian Competition and Consumer Commission (ACCC).

Shortly after these complaints were lodged, Dr Harvey was contacted by the company marketing SensaSlim. He was threatened with legal action if the complaint was not withdrawn. Similar pressure was applied to AusPharm, which had published information about the complaint on its website for pharmacists. AusPharm complied and withdrew the information, but Dr Harvey resisted the threat and within days a defamation action was launched in the Supreme Court of New South Wales. This claim sought damages of $800 000.[2]

The court action may have been intended to get the complaint withdrawn, but it also had the effect of silencing the Complaints Resolution Panel. An arcane regulation prevents the Panel from dealing with complaints about products which are the subject of court action. The litigation therefore enabled the company to continue promoting its product knowing that the Panel could do nothing while the action continued. Although it had been alleged that the advertising had breached the Therapeutic Goods Act, the TGA did not appear to be taking any action against the company.

While the legal process continued, questions began to be asked about the company. A doctor from the UK who had appeared in some of the company's promotional material withdrew his support. Investigative journalism then raised further questions. Pictures of the executives of the Intercontinental Research Institute, which supposedly carried out the trial, turned out to be photographs of American doctors who had no relationship with the company. Some of the pictures were also used on the website of an apparently non-existent Australian clinic called The Mountebank Clinic. This time the doctors were said to have Australian qualifications.[3] Given the dictionary definition*, would any doctor want to work at the Mountebank Clinic?

While the TGA appeared to be powerless, the ACCC considered that there may have been misleading and deceptive conduct by the company. The ACCC obtained a court order freezing the company's assets.[4] Around the same time, the company was placed into administration and a liquidator was subsequently appointed.

* mountebank: a swindler, a charlatan, a clown or an itinerant quack (Concise Oxford Dictionary)

From the Editor

Our approach to the treatment of asthma has changed. Helen Reddel explains why the focus is now on asthma control rather than severity.

Hypertension is another condition where treatment is adjusted to gain control. Peter Donovan discusses hypertension in pregnancy, while Julian Ayer and Gary Sholler consider childhood hypertension.

Children and adults with a history of anaphylaxis need to have immediate access to injectable adrenaline. Sandra Vale, Jill Smith and Richard Loh review the devices for autoinjection.

A new device for treating depression uses magnetic fields. Paul Fitzgerald describes the technology of repetitive transcranial magnetic stimulation.

Despite these developments, the TGA remained publicly silent and the defamation action against Dr Harvey continued. In August 2011 the case was dismissed in the Supreme Court of New South Wales. Although costs were awarded they are unlikely to be recovered from a company in liquidation. However, this was not the end of Dr Harvey's ordeal as the company's director launched a new defamation action in the Supreme Court of Queensland. This time damages of over $1 million were sought, but the case was eventually dismissed in February 2012.

The regulation of complementary medicines in Australia appears to be weak. The system should at least protect the public. Inaction in this case enabled false and misleading advertising to continue. The TGA may well have been working behind the scenes, but its strategy of silence and secrecy gave the appearance that it was doing nothing. The Complaints Resolution Panel had in fact recommended that the TGA consider cancelling the listing of SensaSlim on the Australian Register of Therapeutic Goods, but this did not occur until December 2011.

It is unacceptable that a health professional can face financial ruin for informing the government's medicines regulator that its rules are being broken. There may be dangerous precedents here. Could reporting adverse effects be potentially defamatory?

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Clearly there needs to be some protection for people who make genuine complaints about medicines. As the TGA prefers a 'light touch' when regulating complementary medicines, there needs to be a robust and timely complaints procedure with effective sanctions. If the medicines industry does not want more regulation, then it too should take an active role in identifying and reporting rogue operators to the TGA. Otherwise complementary medicines could be seen as fertile ground for pushing placebos to enrich entrepreneurs, charlatans and crooks. <

Conflict of interest: none declared

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Letters to the Editor

Medicines labelling

Editor, – I have major concerns about Ropivacaine Sandoz, which has appeared in several private hospitals.

This product is labelled ropivacaine 150 mg/20 mL. Nowhere on the packet or the ampoule does it say that this is equivalent to 0.75% ropivacaine, or 7.5 mg/mL. When ropivacaine was first marketed about ten years ago it was marketed as 2 mg/mL, 7.5 mg/mL or 10 mg/mL strengths. More recently this was changed to percent labelling (0.2%, 0.75% and 1%) to make it consistent with all the other available local anaesthetics.

My concern is that nowhere on the packaging does it say that this is 0.75% ropivacaine or 7.5 mg/mL. It only has the total amount of milligrams in the bottle. This is a great potential source of confusion and particularly if ropivacaine is being used on the ward. Many nurses have expressed to me their confusion when looking for the requested local anaesthetic.

I think the labelling is inadequate and unsafe. It is clearly a potential source of medication error.

Paul Herreen
Specialist anaesthetist
Calvary Wakefield Hospital
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Editor, – There are two aspects of prescriptions that can cause problems to patients, pharmacy staff and doctors.

Firstly, repeat authorisation forms are confusing – all the information is there, but there are three boxes

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