THE CONVERSATION

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SensaSlim goes SLAPP, public interest crusader cops a legal whack

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The SensaSlim company's recent defamation suit against Dr Ken Harvey of La Trobe University highlights some of the regulatory problems facing complementary products in Australia.

Dr Harvey initiated a complaint against the weight loss advertisements of SensaSlim in March this year with the Complaints Resolution Panel (CRP), which deals with complaints about breaches of the Therapeutic Goods Advertising Code 2007.

The complaint was also sent to the Therapeutic Goods Administration (TGA) (which did not acknowledge it) and the Australian Competition and Consumer Commission (ACCC), which is now taking action against the company. The hearing is being held in a Federal Court in New South Wales tomorrow.

There are also allegations the original research which validates the product is fabricated.

Dr Harvey's complaint alleged SensaSlim's advertisements breached a number of sections of the Therapeutic Goods Advertising Code 2007; the substance of Dr Harvey's complaints was that he could find no evidence to justify the sensational claims made for the product.

On the 31 March Dr Harvey was served with a warning to withdraw his complaint. SensaSlim also threatened AusPharm with legal action for publishing an account of the complaint.

When Dr Harvey refused to withdraw his complaint he was served with a defamation claim for $800,000.

Of particular interest is the effect the defamation claim has on the complaint lodged with the CRP. Basically, it stops the CRP investigation in its tracks.

According to Regulation 42ZCAJ (2) of the Therapeutic Goods Regulations 1990, "If, after a complaint has been made to the Panel, a proceeding begins in a court about the subject matter

of the complaint, the Panel cannot deal with the complaint until the proceeding is finally disposed of."

This means SensaSlim is free to advertise and promote its products and the CRP cannot investigate it for as long as the defamation action against Dr Harvey continues.

SensaSlim subsequently sent out a newsletter to its members which stated:

"This defamation action, which could be in the courts for a year or two or even longer, basically gives an iron clad protection that nobody can raise a complaint against SensaSlim to the CRP and hurt us.

There are nine complaints that were received in a three day period two weeks ago. These were not complaints by members of the public, but clever legal crafted arguments by people acting on behalf of our competitors and big pharmaceutical companies. These are the same people who have written to the CHC [Complementary HealthCare Council] to delay and hinder our progress and having our advertisements approved.. and they also wrote to the TGA.

But let me say this. We will not allow their dirty tactics defeat us. We had a very big win this week with the determination by the CRP that they cannot adjudicate on any matters pertaining to SensaSlim."

Regulation of complementary products in Australia

The preliminary question all this raises is – how are products like SensaSlim approved for use in Australia?

The Therapeutics Goods Administration (TGA) is charged with the responsibility for "listing" about 2000 complementary health products per year on the Australian Register of Therapeutic Goods.

Complementary medicines are regarded by the TGA as relatively low-risk products, so an electronic listing facility (ELF) allows easy and rapid market entry.

Sponsors must pick their ingredients from a computerised drop-down list of substances that the TGA believes are relatively safe; certify that the goods are produced under Good Manufacturing Practice (GMP) requirements; and tick a box that they hold evidence to support the claims made.

On payment of a $600-fee, the computer issues a letter of marketing approval and an "AUST L number".

In theory, sponsors of listed medicines are restricted to making low-level claims for their products relating to health maintenance, health enhancement or non-serious, self-limiting conditions.

But the TGA conducts very limited post-marketing assessment of AUST L products, the results of which have traditionally been regarded as commercial in confidence.

Following recent Freedom of Information (FOI) requests, the TGA has released some of this data. The results are appalling and show that a system relying on trust has failed.

Currently, the complaint system is the main way that these matters can be redressed but the CRP is under-resourced, overloaded and lacks effective sanctions to ensure compliance with its determinations.

There are, at present, several government enquiries into these matters. However, just as many other enquiries have come to nought over the last decade so we are not holding our breath that there will be reform this time around. Any changes are also bitterly opposed by industry.

What's more, when complaints *are* made, Regulation 42ZCAJ(see above) encourages strategic litigation against public participation (SLAPP) writs by suspending investigation of the complaint while the litigation plays out in the courts.

SLAPP - preventing public participation

Effectively, SLAPP refers to the lodgement of a lawsuit to prevent the publication of criticism or to gag public discussion of an issue. On the face of it, SensaSlim's legal action appears to be a SLAPP writ although the company has denied this is so.

A famous example of a SLAPP writ comes from the United Kingdom where cryptologist and author Simon Singh was sued for libel by the British Chiropractors Association for saying that many chiropractors advertise "bogus treatments" for childhood illnesses like colic and frequent ear infections, and problems with sleeping and feeding.

Singh eventually won his court action on the basis of the defence of fair comment but had to spend considerable financial resources to defend himself.

A SensaSlim representative has been reported as saying, "This is not about gagging Dr Harvey. We will continue to pursue our right to protect our franchisees and their investment in our product."

But it's hard to reconcile this statement with the earlier statement of the company that the writ would provide SensaSlim with "iron clad protection" against CRP investigation.

One of the risks associated with SLAPP litigation is that it can backfire. SLAPP suits often generate counter-publicity so that their attempt to silence public debate fails miserably.

This is referred to as the "Streisand effect", after Barbara Streisand's failed attempt to sue a photographer for publishing a photo of her house as part of a coastal erosion project.

The suit generated massive publicity, resulting in over 400,000 internet visits to the photo.

Simon Singh's legal fight against the British Chiropractic Association had a similar effect, with a quarter of British chiropractors having complaints lodged against them for false advertising after he was sued.

A Google search of "SensaSlim Harvey" currently shows over 5600 websites featuring Dr Harvey's story. Articles have already appeared in major newspapers across the world and in journals such as the British Medical Journal and Medical Journal of Australia.

If SensaSlim was aiming to shut down discussion of its advertising the choice to litigate may have become counterproductive.

Lessons for the future

Regulation 42ZCAJ (2), which stops the CRP from investigating complaints when litigation commences, is clearly a bad idea.

It needs to go, both because it stops the regulator from being able to function as a regulator and because it is fundamentally anti-democratic.

It maintains the commercial interests of the manufacturer in the face of genuine public concerns about the putative benefits and broader risks of the product in question.

The public needs to be able to rely on the CRP to get on with the job of deciding whether the product has been advertised appropriately and in accordance with the rules.

Sensaslim and companies like it are free to defend themselves in that process and can provide scientific evidence to back their claims.

The effect of the current regulation is to silence the person who is pursing the protection of the public and to stop the regulator from functioning.

It has a chilling effect, which does not serve the public interest.