

Supplements - what is really going on?

By Martin Oliver

Forget asbestos, cigarettes and pesticides, if you were to read a mono-diet of mainstream news, you could be forgiven for believing that vitamin supplements are humanity's greatest health threat. This negative media reached new lows in March with 'Vitamins kill' news items, prompted by a study apparently showing increased mortality levels among subjects taking the antioxidants beta-carotene, vitamin A and vitamin E. (Article continued below.)

According to an analysis by the UK health freedom group Alliance for Natural Health (ANH), these findings, which originally appeared in the Journal of the American Medical Association, were achieved through the use of synthetic vitamins (which behave in the body very differently from natural forms), coupled with a remarkable manipulation of the original data.

Sometimes the negative messages originate from more unlikely quarters. State and federal health authorities recently teamed up with Horticulture Australia to launch the fruit and vegetable promotion 'Go for 2 and 5.' As part of its message, consumers are discouraged from taking supplements through a poster featuring an ugly face constructed from pills and tablets and a happy face made from a variety of produce. Are we forced to choose between the two? Furthermore, do health authorities have a role to play in discouraging disease prevention through improved nutrition?

If the mainstream view is correct, we should be able to obtain all of our nutrient requirements from food. In reality, this is becoming more difficult; over the last few decades, staple foods in developed countries have become progressively nutritionally depleted as a consequence of unsustainable chemical farming practices.

Whereas many drugs are covered under the Pharmaceutical Benefits Scheme (PBS), supplements are exempted from similar subsidies. Unlike drugs, complementary medicines are also subject to an added GST component. Yet despite the negative campaigns and an uneven playing field, around 75% of Australians continue to use supplements at least occasionally. An estimated one third of the country's health consultations are with naturopathic practitioners.

It might come as no surprise to learn that in some parts of the world access to supplements is being restricted. While it is tempting to look at these issues from a narrow Australian perspective, they are essentially global in nature. What takes place on the other side of the world today might affect us tomorrow, and cannot be ignored.

The Pan disaster

The Australian body entrusted with regulating pharmaceuticals, therapeutic goods and complementary medicines is the Therapeutic Goods Administration (TGA), which receives 100% of its income in the form of licensing fees, most coming from drug companies.

Dramatic events unfolded in early 2003 following the observation of aggravated side effects in Travacalm, an anti-motion sickness pharmaceutical drug made by Sydney manufacturer Pan Pharmaceuticals. The TGA went into action by instituting the largest product recall in Australian history, involving around 1,500 supplement lines made by Pan for its own label and

other Australian companies. Other than Travacalm, no pharmaceutical made by Pan was recalled. Significantly, this was a blanket Class 1 recall (indicating a serious risk of death or injury.)

As a full recall list was being compiled, the TGA urged consumers to stop taking all supplements as a precautionary measure, while reminding the public that pharmaceutical drugs were unaffected. As shelves were swept of their offending vitamins, the industry received a blow from which it is yet to fully recover. Some smaller brand names, pharmacies and health food shops were forced into bankruptcy. Similar recalls were instigated in several overseas countries.

Strangely there had been no reports of adverse effects from taking any supplement made by Pan, although in the ensuing media circus certain staff members came forward with claims that quality control was lax and that mixing machines had not been properly cleaned. The giant US chain Wal-Mart had its Pan -manufactured products independently assayed, and found no problem with them.

After Pan had been shut down, the media lined up to engage in vitamin-bashing, hoping to create negative perceptions of the complementary medicine industry as a whole. Particularly notable were the comments from Martyn Goddard of the Australian Consumers Association (editors of Choice magazine), who referred to 'a smoke and mirrors industry', 'quackery' and 'snake oil salesmen.'

Regulation.....or over-regulation?

Nobody would disagree with the idea that the natural health sector needs a regulatory framework. Difficulties only arise if under the guise of public safety, a regime disproportionate to their low risk is used to further slant the playing field against complementary medicines. While a pharmaceutical drug might not be recalled until numerous deaths have occurred, a naturopathic substance will face a ban if it is suspected of causing one allergic reaction.

Most developed countries classify supplements as foods due to their low-risk status, but in Australia they are regulated under a similar framework to that of pharmaceuticals. The TGA shifts the burden of responsibility onto industry by administering a 'positive list' of allowed ingredients, to which approval can be granted if expensive safety tests have been carried out. In contrast, most other governments assume the burden of responsibility by maintaining a 'negative list' of prohibited substances.

Cansema is a naturopathic product from Queensland used against melanomas, and tumours located close to the skin. According to the manufacturer, applying for TGA approval would cost millions of dollars, with no ultimate guarantee of success. As Cansema is an unapproved therapeutic substance, anybody advertising it faces up to five years in jail and a fine that could total tens of thousands of dollars. While the product's maker has been warned by the TGA not to sell Cansema for human use, it is legal to purchase for use on animals.

Under a new TGA advertising code that came into force in March, complementary medicines are virtually prohibited from making any kind of health claim. Somewhat strangely, the TGA has also delegated regulation of complementary medicine advertising in the electronic media to the Australian Self-Medication Industry (ASMI) whose membership largely consists of drug companies.

A couple of years ago, Marcus Blackmore of the well-known vitamin company criticised over-regulation that he believes is curtailing the industry's growth and stifling innovation. Following the Pan recall, with further regulatory tightening and an increase in compliance costs, some businesses are now looking at moving overseas.

Prof. Ian Brighthope of Nutrition Care Pharmaceuticals sees the TGA as essentially taking a hostile stance towards complementary medicine. This view is echoed by health freedom activist and writer Eve Hillary, who has encountered a pattern of the TGA targeting individual small manufacturers with extra-onerous demands, with the result that some have gone out of business.

As part of its monitoring practices, Medicare analyses the average length of each GP's consultations. Where these are significantly longer than average, it indicates that a naturopathic approach is probably being followed, and the practitioner will commonly be subject to a disruptive investigation. In Australia, naturopathy has so far been excluded from mainstream health strategies, although there is scope for allopathy and naturopathy to be used side-by-side, as is the case in Germany.

A link to Big Pharma

Hedging their bets, in recent years several pharmaceutical companies have taken over vitamin companies or launched their own supplement ranges. These are usually a sideline rather than a core part of the business. Participation in the industry also provides drug companies with a place at the bargaining table through membership of various supplement trade associations, many of which are dominated by what has been dubbed Big Pharma.

For the drug industry, the ideal outcome would be a strict regulatory regime mandating that supplements can only be sold in ineffectual dosages at astronomical prices, with expensive compliance requirements that only giant corporations can afford. Many believe that Big Pharma wants to dominate the supplement industry rather than wipe it out, and in this light it may be significant that drug companies already control the market for raw materials used in supplement products.

As a result of pharmaceutical influence in Germany and Norway, allowable 'safe upper limits' for various vitamins have been slashed to below therapeutic levels, while prices have jumped enormously. In Norway, vitamin levels exceeding the RDA are classified as drugs and require an expensive prescription, while in Germany, high-potency supplements can only be purchased at a pharmacy.

The Codex controversy

Codex Alimentarius is the name for an international set of food standards that are administered under the auspices of the World Health Organization (WHO) and Food and Agriculture Organization (FAO.) Among these are the 'Guidelines for Vitamin and Mineral Food Supplements'.

For many years, drug industry delegations have been working behind the scenes at Codex to bring in a tough set of rules. In addition, many vitamin trade associations are dominated by pharmaceutical sector members, and some of these trade bodies, in their role as Codex representatives, have been lobbying for rather than against the adoption of a restrictive framework.

In July, 2005, years of vitamin negotiations culminated in a set of draconian international supplement rules that are intended to become effective by 2010: vitamins will be regulated as drugs, dosages exceeding levels naturally found in food will be prohibited, and multi-million dollar testing regimes will send prices skyrocketing. This outcome was reached despite opposition from China, India and South Africa, which is interested in using traditional medicines as immune boosters for people living with AIDS.

The philosophical stance of Dr. Rolf Grossklaus, chairman of the Codex Committee on Nutrition and Foods for Special Dietary Uses, can be surmised from his 2003 statement 'nutrition has no

place in medicine'. His views are echoed in the Codex introduction, which states that nutrients may not be used to 'prevent, treat or cure any disease or condition.' Through such a stance, Codex is imposing an outdated medical model on a world that may be more interested in new discoveries.

Two years ago, a DVD focusing on the threats posed by Codex titled *We Become Silent* was released by a company called Well TV, and can be downloaded from the Internet. The title was inspired by Martin Luther King, who once said 'Our lives begin to end the day we become silent about things that matter.'

Will Codex affect Australia?

One hot topic since 2005 has been the possible extent of Codex influence in Australia. Like the TGA, peak bodies such as the Complementary Healthcare Council of Australia (CHC) and the Australian Traditional Medicine Society (ATMS) take the position that Codex will not affect Australians' access to supplements, and there is nothing to worry about. This is based on our regulatory system treating supplements under a 'drug' rather than a 'food' framework.

An amendment successfully moved by the Australian delegation at the 2005 Codex meeting added the word 'only' to the sentence 'These guidelines apply only in those jurisdictions where products defined in..... are regulated as foods.' Other inputs were less successful. Although the Australian delegation had requested that wording stating that Codex standards were 'not a substitute for or an alternative to national legislation' be retained from a proposed deletion of text, this was disallowed.

For Codex particularly, the key seems to be finding a middle path between excessive complacency and excessive alarmism. The Alliance for Health Freedom Australia and the Natural Health Care Alliance (NHCA) both reject the idea that we can breathe a sigh of relief. They believe that under the World Trade Organization dispute system Australia's supplement rules could be challenged as a 'technical barrier to trade', using Codex texts as a benchmark

A further, so far unacknowledged, issue is that the adoption of Codex standards by many countries in 2010 will restrict for Australian consumers the availability of affordable, therapeutically effective supplements that are manufactured overseas.

A challenge to the EU

Remarkably similar to Codex rules was the highly controversial EU Food Supplements Directive that passed in 2002 by a narrow margin. Its main features are probably beginning to sound familiar. From mid-2005, every ingredient not included in a 'positive list' would have been withdrawn from sale without rigorous and prohibitively expensive testing being carried out. Supplements would have been placed under the same regulatory system as drugs.

Three hundred natural ingredients, representing 75% of vitamin and mineral forms, would have been affected. Across the EU, the Directive would have impacted on 5,000 products, and many manufacturers would have gone out of business. Fortunately, in response to this grim prospect, the ANH was quickly created, and proceeded to initiate a David and Goliath legal challenge against the EU in a bid to save Europe's threatened supplement industry.

In a preliminary legal opinion, the EU's Advocate General stated that the Directive was invalid under EU law. In passing, he observed that the positive list had an unusual preference for the synthetic forms of vitamins, despite the fact that natural forms are better tolerated by the body.

Although the European Court of Justice later ruled in favour of the Directive, natural nutrients of the type found in foods were exempted. The burden of proving safety was shifted from the

manufacturer onto the regulator, and had to be undertaken using independent scientific data. The radically modified Directive comes into effect on December 31st 2009.

Trans-Tasman harmonisation

In a further piece of this complex global jigsaw, Australia and New Zealand have been working towards 'harmonising' their respective regulatory agencies with the formation of the Australia New Zealand Therapeutic Products Authority (ANZTPA, formerly referred to as the Joint Trans-Tasman Agency).

While Australia has a strict regulatory regime, the one operated by Medsafe in New Zealand is fairly liberal. In the estimation of a campaigning group called the New Zealand Health Trust, many smaller Kiwi companies would be unable to survive the joint agency's higher compliance fees and extra red tape. The balance of power in the new agency would inevitably lie with Australia.

Despite its likely harmful effects on the New Zealand supplement industry, the ANZTPA has the full support of the country's ruling Labour Party. Passed at its first reading by the closest possible margin of 61-60 last December, the ANZTPA Bill is currently blocked in parliament by a dissenting independent MP.

A unified front

Unfortunately Australia's complementary medicine sector is significantly weakened by the absence of one single peak body that has the full weight of industry support behind it.

The NHCA was formed following the Pan events in 2003 with the goals of protecting natural health, representing it in government, and becoming an umbrella for the other peak bodies. Unfortunately it has not succeeded in getting the whole industry on side due to differing philosophical stances between groups. For example, the ATMS does not see a need to defend the industry, and was supportive of the Pan recall.

Terms such as 'complementary', 'alternative' and 'supplements' all carry the implication of something that is operating on the fringes of mainstream medicine. Perhaps it is time for the Australian supplement industry to start setting the agenda within the regulatory leeway that it still possesses, and to coin another name.

Above all, consumers cannot afford to be complacent, or they might eventually find that the supplements that they take for granted may suddenly disappear from the shelves again, this time for good.

Resources

Alliance for Health Freedom Australia
www.ahf-au.org

Natural Health Care Alliance
www.nhca.com.au

New Zealand Health Trust
www.nzht.co.nz

Alliance for Natural Health
www.alliance-natural-health.org

Dr. Rath Health Foundation
www.dr-rath-foundation.com

We Become Silent video
www.alliance-natural-health.org

Therapeutic Goods Administration
www.tga.gov.au

Codex Alimentarius
www.codexalimentarius.net

Australia New Zealand Therapeutic Products Authority
www.anztpa.org

Martin Oliver is a writer and researcher based in Lismore, Northern NSW.

This entry was posted on Thursday, June 7th, 2007 at 4:21 pm and is filed under [Martin Oliver](#), [Issues](#), [Issue 96 June 2007](#)