

Natural Health Products: Guilty Until Proven Innocent?

by

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The complementary medicine industry is huge. World-wide it nets billions of dollars annually, and in developed countries more than half the population is increasingly turning to complementary medicine for their preferred treatment.

Given these statistics it is hardly surprising that governments wish to rationalize the industry along similar lines to the medical industry. Currently, there is very little legislation in place that sets the standard for practitioner training or practice management (standards and monitoring tends to be under umbrella organizations that represent practitioners), and most health-related products tend to be listed, rather than registered. A lack of regulation does not mean that there is risk to the public from these products or services, it simply means that the industry has few guidelines at legislative level.

However, governments are now looking to set up international standards which will then be adopted and transposed into the national law of each country. When an international standard is applied then this technically reduces duplication of processes at national levels, lifts some restrictions and improves trading. For the health market this could facilitate availability of products and therapeutic advances.

What more could we hope for? Most consumers want guaranteed quality service and products. We want to know that what we buy works and that we are not wasting our money. We want safe products and readily available access to these. What we don't expect is to see products such as vitamin C, which have been used for well over 25 years at doses greater than the recommended daily allowance (RDA) of 50mg/day, stripped from our shelves, placed into a drug/medicine category which may become a prescription-only item at double the cost, plus a consultation fee.

What is a drug?

To most people this would be incredible. We all know that vitamin C is not a drug – or is it? Well let's take a few definitions of what a drug is. The pharmaceutical classification of a drug or medicine is any product that "restores, corrects, or modifies physiological functions" in the body. So technically all our food supplements, herbs and other natural health products that make any therapeutic claim (either on the label, through advertising or educational articles) could be classified as drugs. In Australia, the political stance of the National Medicines Policy 2000 of Australia¹ states "The term "medicine" includes prescription and non-prescription medicines, including complementary healthcare products." In the UK, food supplements come under a food directive (as opposed to a pharmaceutical directive) but they are still defined as "substances with a nutritional or physiological effect." If the pharmaceutical lobby pushes ahead to have their broad definition enshrined in law then there will be plenty of hair-splitting over products that have been used safely and effectively by a large percentage of the community over many years.

Our Protector - The Codex Commission!

We are told that we are being protected. Our interests are represented by various government and industry bodies at the Codex Commission², an international organization of 146 nations (backed by the WTO and UN) established in 1962 with the aim of setting international standards and codes for foods. The majority of representations are from the pharmaceutical industry with little representation from either consumer groups or the natural health care industry. Through a series of meetings regulatory frameworks are drawn up by the commission through delegate consensus.

Bringing you up to date on activities, on November 4, 2003, the Codex Commission met to discuss a science-based framework to establish upper limits on vitamin and mineral supplement dosage, where any finalized recommendations become the international standard. They announced a positive outcome which would pave "the way for the global sale and marketing of dietary supplements based on objective standards that will simultaneously preserve consumer safety and fair trade."³

However, the Codex Commission deals with food regulations, and their stance is that under their specific directive you cannot make statements that ascribe therapeutic action or even the prevention of disease to a food or food supplement as the two do not go together. In simple terms, as soon as a therapeutic action is attributed to a product or food it becomes a medicine. So we have an organization that is going to regulate the industry according to the view that vitamins and minerals must only be sold in amounts to prevent deficiencies and designed to be taken as small unit quantities. Easily obtaining your large dose of vitamin C, which you take when you get a common cold, could become an impossibility in the future.⁴

To the consumer, who knows through personal experience the value of natural health products, this appears ridiculous. However, it is happening. The European Union is currently harmonizing its regulations among its member states and transposing them into national law. Germany has already passed laws to reclassify all supplements and herbs as drugs and, as an example of these restrictions, the current upper limit on vitamin C, available as an over-the-counter product, is 50mg. Iceland, Sweden Norway and Denmark have also implemented similar regulations and the governments will actively pursue suppliers who break the law.⁵

Alliance For Natural Health – a consumer's group

In the UK, a professional pan-European international campaign and advisory organization, Alliance for Natural Health (<http://www.alliance-natural-health.org/>) is currently fighting EU legislation to maintain continued access to and the supply of safe, innovative and effective dietary supplements. If it hadn't been for the ANH lawsuits⁶ lodged against the Food Supplement Directive, then probably all food supplements in Europe would now be classified as drugs. Already the EU has passed a law which will come into effect in 2005 to ban the sale of 300 nutrient forms from the list of 420 that are currently available. This will affect over 5,000 products (85% of vitamin/mineral products). The nutrient-forms that have been banned are the more bio-available food-derived forms that have appeared over the last decade or so as a consequence of innovative research. In short, we will be back to low potency, inorganic, synthetic nutrients such as those sold in supermarkets and available years ago. The banned items include natural vitamin forms such as the mixed tocopherols (natural vitamin E), carotenoids, and methylcobalamin (B12), selenomethionine (the common form of selenium found in foods, but the list does allow inorganic selenium such as sodium selenate and sodium selenite which is known to be more toxic and deliver less beneficial results), all forms of sulphur (no MSM!), boron, vanadium, silicon, and most trace elements, the most readily absorbed and safest forms of

calcium, magnesium, zinc, chromium and molybdenum, and many chelated and plant derived forms. By 2007 the EU is planning to apply similar restrictions to other nutrient groups such as fatty acids (no more fish oils?), amino acids, fibre, and plant extracts.

ANH began its challenge against the legality of this Directive in Oct 03. They argue that the law is irrational from a scientific and economic standpoint, that it will devastate the industry – both the innovators, retailers and practitioners - and that the ban is unlawful and not necessary for the achievement of the Food Supplements Directive's stated purpose for harmonization of legislation relating to Food Supplements across the 15 EU member countries to facilitate trade in and availability of food supplements.⁶

As agreements are made via consensus within the Codex Commission, and as there is an unfair representation biased strongly towards the pharmaceuticals and the EU (the EU carries 15 votes), it is not surprising that Codex can be used as a tool to force all natural health products out of the Food Directive and into the Pharmaceutical Directive. If this occurs, then the Codex Commission has fulfilled its purpose of banning globally "The distribution of health information concerning vitamins, amino acids, minerals and other natural products for the prevention and treatment of diseases the sale of vitamins and other natural products which exceed the guidelines of this Codex commission (and) countries that fail to apply these laws will be punished by international economic sanctions."⁷

A New Definition of "First do no Harm"

Many would argue that this type of rationalization of the industry may be a good thing as we would be guaranteed the same rigorous controls applied to drugs to ensure safety, quality and efficacy of the products we buy. However, in most countries the safety and quality of natural health products is not the issue as international GMP (good manufacturing practice) standards prevail, and government agencies, such as the TGA (Therapeutic Goods Administration, Australia), have enormous powers to enforce regulations or to remove licenses as appropriate (as seen in the latest Pan Pharmaceutical recall).

Recognizing that most natural health products are of low risk, have few potent pharmacological properties and have been safely used for years, the issue has conveniently switched away from quality and safety to the efficacy of the products. Do they work? Bearing in mind that these products are regarded as safe (and the fact that most governments do not usually bother whether we waste our money or not or indeed poison ourselves with cigarettes and alcohol), governments are taking the moral high ground and adopting the ethical stance where they are concerned that indirect harm, not actual harm, may be caused by complementary therapies: "In addition to the direct health risks associated with inadequate quality control there is an indirect risk that the medicine may not be effective. This may compromise, delay or replace effective actions."⁸

In order to understand this stance we need to factor in the TGA's broadened concept of "first do no harm" which is a pre-requisite of ethical behaviour of every healthcare provider. "Harm" now includes the following:

1. Direct harm – adverse reaction, side effects, medicine interaction or encouraging withdrawal of current therapy
2. Indirect harm – delay in implementing appropriate treatment, creating unreasonable expectations that may discourage patients from accepting and dealing effectively with their health problem
3. Economic harm – encouraging expenditure on ineffective and unnecessary or unsafe medicines and therapies without providing an awareness of the unproven nature of the treatment or modality being offered might also lead to direct or

indirect harm if money is otherwise no longer available for living essentials or more-appropriate healthcare management.⁹

By translating "current therapy", "appropriate treatment", "dealing effectively," as mainstream medicine and "ineffective and unnecessary or unsafe medicines and therapies" as complementary medicine and treatment we can begin to understand that this concept of harm denies the right of the consumer to pursue their chosen therapy unless it is mainstream. However, in the same document the TGA states the primacy of the right of consumers to be able to make informed choices on matters of healthcare.

The report also asserts that "More and more Australians are looking for positive health and lifestyle outcomes through the use of complementary medicine. The majority of alternative medicine users appear to be doing so not so much as a result of being dissatisfied with conventional medicine but more because they find these healthcare alternatives to be more congruent with their own values, beliefs and philosophical orientations toward health and life."¹⁰

If this is the case, it is not mirrored in other countries where a recent survey conducted in the UK¹¹ to determine motivations for trying complementary and alternative medicine gave their findings. Positive motivations include: effectiveness, safety, emphasis on holism, control over treatment, good patient/therapist relationship, non-invasive nature, accessibility, and among the more negative motivations - dissatisfaction with (some aspects of) conventional health care: ineffective for certain conditions; serious adverse effects; poor doctor-patient relationship; insufficient time with doctor; long waiting lists; "high tech, low touch", rejection of science and technology, rejection of "the establishment" and desperation! This portrays a very different public attitude to the political statements made.

Efficacy – And just how are we going to measure this?

Returning to the issue of efficacy – which translates "that medicine must achieve the goals of therapy by delivering beneficial changes in actual health outcomes." (National Medicines Policy, 2000).¹ Currently sponsors of listed products (low-risk) are required to hold evidence to support indications and claims of their products. Legislation does not require the TGA to review this evidence as a) there is no criterion in law for the assessment of the evidence and b) the cost of doing so is not justified for a product that is deemed low-risk. Registered health products, which carry a higher risk, are evaluated by various complementary medicine committees who make recommendations to the TGA to the suitability of the product for inclusion into the registered list.

What evidence is required for efficacy and how is it going to be measured? Will our natural health medicines be subject to the same lengthy drug approval procedures that cost millions of dollars? Will we have to conduct clinical trials, and if so, what criteria will be imposed to assess these? How many drug interactions will have to be tested before a product is deemed safe? It is acknowledged that formulating the criteria for the evaluation process will be difficult as many complementary medicines are complex and may not conform to traditional criteria or methods of evaluation, the components responsible for their medicinal activity may not be easily identifiable, and they are rarely used in isolation but part of an integrated program. Meeting traditional data requirements for an approval process may prove impossible in the long-term.

If this is the case, is it justifiable to remove or ban products with no track record of risk, on the basis of being guilty until proven innocent? Is this really protecting our interests bearing in mind the percentage of complaints for adverse reactions in 2002 in Australia from complementary medicines was only 3% but 94% from prescription medicines and 3% from over-the-counter pharmaceutical products.¹²

However we have to accept that there is a substantial gap between the extensive use of complementary medicines and the evidence to support that use, and we have to ask ourselves why this is the case. Unlike drugs, natural health products do not attract a patent, and without patents there is no data protection or market exclusivity, hence no incentive for investors to support the complementary medicine industry as the costs involved in research to generate data needed to supply evidence may not be recouped.

So if we can't rely on philanthropic investors, how about public funding? It appears that this is not forthcoming either. "The (TGA) committee noted the apparent disparity between public funding for prescription and over-the-counter medicine research and that for complementary medicine research and the possibility of a bias against complementary research"¹³ and agreed that compared with other medicines some complementary medicines may offer lower risk and more cost-effective options for the prevention and treatment of some diseases, conditions and disorders.

Which begs the question - Will we also see the same type of disparity between approval of complementary health medicine and pharmaceutical drugs that we see with funding? Drugs are synthetic chemicals used in the treatment of serious disease or to effect changes in the normal metabolism. Drugs are clinically tested in trials before approval because of their track record in causing serious health risks for the population. Natural health products do not fall into this category, they are not used to treat serious disease, nor do they carry serious risks.

Take the drug Thalidomide which was responsible for one of the most horrific "accidents" in medical history. This drug was never approved in the USA as there was insufficient proof of its safety in humans. However, it was approved in Canada and the UK. It was soon banned worldwide when it was discovered that it caused tragic birth defects. The drug affected more than 10,000 children worldwide who were born with gross deformities after their mothers took the drug during pregnancy. After a long legal battle the drug manufacturer was forced to pay compensation. The burden was left to the consumers to take the company to court - not our regulatory "protectors." Furthermore, as the drug manufacturers refused to accept legal liability in the settlement, a pathway was left open to exploit the patent for the drug to re-enter the marketplace in the future, of which it has recently done. At issue is who accepts the responsibility for consumer protection in the pharmaceutical category - the pharmaceuticals who produce the drugs or the regulatory bodies which set the rules and regulations and give the drug approval? Both parties can wriggle and make statements such as correlative evidence is not proof (in simple terms this means that just because a higher incidence of specific symptoms or even death is noted in a population taking a specific drug than in the community at large, this does not constitute sufficient evidence or proof that the drug is the causative agent). We have an interesting twist to "first do no harm." By contrast we see an entirely different interpretation placed on complementary medicine where a widespread ban on these products may occur not through scientific evidence of harm, but not enough scientific evidence to prove they either work or don't cause harm.

This is the way things are going in our move towards harmonization. Our natural health products will be classified as drugs unless consumers take moves to protect their health freedom. The outcome would establish the adoption of stringent laws preventing the use of any food, herb, or supplement that has physiological benefits. In some cases this will be achieved by requiring food, herb or supplement manufacturers or growers to an uneconomic compliance framework similar to the same requirements as for medical drugs before consumers could use them. From experiences to date this would have the effect of either making the existing product either too expensive for the average consumer, forcing the total withdrawal of the food/product from the market-place and in extreme cases even banning consumers from growing their own produce or herbs. We are already seeing the removal of nutritional supplements from the market, and those that remain have maximum limits known to be of little or no therapeutic value; there are already reports of

police raids on members of the community growing their own herbs to use as teas – what will it be next – the humble apple and carrot juice?

A Market Ripe for the Plucking

So why is this all happening now? There are two reasons – the market is ripe and technology exists to exploit it. To understand this we need to know how much the industry is worth and how many people use it. According to figures supplied by a research report organized by the WHO and Geneva Foundation for Medical Education and Research ¹⁴ it is estimated that the complementary health industry is worth: \$US2.7 billion in the US; \$US2.3 billion in the UK; and \$US1.0 billion in Canada. It is estimated that between 40% and 90% of the entire world population use complementary medicine. Cultures that are more dependent on traditional medicine include in India and Africa, while elsewhere in countries such as China, Latin America, Chile and Colombia, traditional medicines are still used widely. In the developed countries 90% of the German, 75% of the French, 70% of the Canadian, 46% of the UK and 48% of the Australian populations have all used complementary medicine at least once in their lifetimes. Furthermore, in Australia the personal expenditure of complementary medicine is twice the patient expenditure on pharmaceutical medicines; in the UK, during the year of 1998, 90% of the £450million was met by out-of-pocket expenditure,¹⁵ and in Malaysia the estimated outlay on complementary medicine (\$US500,000) outstripped that of modern medicine (\$US300,000).

Given these statistics, it is far from the minds of governments and pharmaceuticals to destroy the complementary medicine industry; no, they want to replace it, control it and if necessary, regulate natural products out of existence to secure investment. Their ethical stance on natural substances that have been safely and effectively used by millions of people for thousands of years, with little to no track record of harm (unlike pharmaceutical drugs) can be summed up by the words of Professor Ivor Ralph Edwards, Director of Drug Monitoring for the Collaborating Centre (USA) "About 80 percent of all therapies in use in many countries are made from herbs according to tradition and experience, and most of these are multi-molecule herbal medicines that previously could not be standardized into pharmaceutical versions. As a result, it was previously impossible to clinically establish whether or not they perform as intended and some may even cause harm if used incorrectly."¹⁶

With the market in place, the health industry has been waiting for the ripening of a technology that will enable industry to patent new products based on natural medicines. Natural products cannot be patented, but what can be patented is the technology that isolates and measures the bioactivity of each active compound of a natural health product and then replicates this in a laboratory. In the industry this is known as PharmaPrinting or the production of pharmaceutical versions of natural health products that are standardized and clinically tested as a pharmaceutical for government approval.¹⁷ We now have patents in the making (or possibly approved by now) for pharmaceutical versions of Mistletoe, Saw Palmetto, Echinacea, Ginkgo, St.John's Wort, and Valerian.

What are the costs involved in PharmaPrinting a botanical drug? The initial cost is approximately \$US0.5 million (this cost includes validating manufacturing under Good Manufacturing Practice guidelines and filing for patent protection), and the clinical trials between \$US6.5 million – \$US21.5 million.¹⁷ The total process takes between four and five years to complete. But unless market exclusivity is assured, investors will not invest. In order to guarantee market exclusivity, the removal or banning of the natural product is essential. If they are able to ban the use of natural health products under the guise of protecting consumers from themselves and the well-publicized unscrupulous natural health industry rogues, then it provides multi-nationals with the potential to acquire a royalty to

be paid each and every time a patient or consumer uses one of their replacement products.

The estimates on the size of this market potential vary dramatically making it almost impossible to define the actual revenue that they are trying to acquire, but currently if you consider the entire natural, holistic, alternative market, including the use of foods (like juicing for health benefits) and factor in the existing healthcare market (last year in the US alone this was worth \$US1.5 trillion) – that is the magnitude in scale of the market that a small number of multi-nationals are trying to corner and control. If we factor in genetically modified foods we have quite an ugly scenario. As many of our natural foods are increasingly producing “side-effects” and allergic reactions (which may be fatal in some cases) in a significant number of the population, I have to ask what the future holds for us regarding legislation on our food: will the offending compounds be isolated and replaced by new genetically modified foods, and if so, will our natural foods be banned as unsafe with global regulations to enforce legislation and the use of GM foods? Or will we be allowed to revert to sustainable organic farming practices, a clean food chain, and enjoy a diet that has sustained the human population for thousands, if not millions, of years? In a millisecond of time, we have managed to devastate the environment to a point where it may no longer be sustainable, and we are watching the increasing toll of cancer, heart disease, and diabetes – the so-called affluent diseases – on human life. The most worrying aspect is that history shows us how powerful chemical companies appear to enjoy thirty years grace in which to market a product that has previously been found to have toxic effects on the environment and despite the catalogue of environmental disasters (DDT, dioxins, PCBs, PVCs) that have taken such a human toll, the companies responsible have been able to avoid true accountability on the basis that correlative evidence is inadmissible. In the meantime we, and our children, carry the cost and the burden.

Do you care enough?

Within the next decade most people will may not be able to afford medical treatment. A report from the US indicates that due to the rising costs of new patented drugs and procedures that the industry is expected to account for 17% of the US gross domestic product by the year 2012 leaving those consumers, who already pay the equivalent of their annual mortgage on full healthcare insurance, unable to absorb these rising costs.¹⁸ How much of our disposable income does this industry want, especially if it corners the alternative sector as well.

Do you care now? Will you care if you become locked into a system where you may not be able to afford healthcare and are impotent to rectify it? Will you care if you are robbed of the tools with which to handle your own health? You probably will.

Looking to the immediate future the changes we may face within the next few years will impact various sectors of our community:

- Manufacturers who supply the raw materials may bear the brunt and those for whom it isn't cost-effective to provide the dossiers and the funding for approval may sell out to the pharmaceuticals.
- Companies that formulate the products, if the raw materials are not approved, will be unable to produce and supply their products, and they may sell out to the pharmaceuticals.
- Distributors of products that are banned for over-the-counter sale (dosages exceed the upper limit) may be able to continue with existing products (providing they are not banned) or new products, providing they supply to a practitioner market.
- Those who have built businesses through network marketing and sell to the general consumer will find that both the restrictions on dosage and the banning of

some of the more bio-available nutrients will limit the range of their stock and be the death of the exclusivity factor that their brand may have offered in the past.

- Retailers will not be happy to see the size of their stock diminish, but if something comes along to replace it – then this may suffice.
- Practitioners may still have access to certain products, but again many products may be banned. It will make it extremely difficult for practitioners to do their job without the tools of their trade. The TGA have also raised questions as to the professional ethics of practitioners who prescribe and dispense products, indicating that commercial incentive could bring bias in product choice. It is possible that chemists may be required to undertake this role of dispensing all natural health products. Practitioners who genuinely supplement their income from profits made on products will have no choice other than to raise their fees.
- Consumers for whom the medical industry can give no hope and who are getting good results with their chosen natural therapy, will be devastated.
- Consumers may not tolerate the inflated prices of previously low-cost, safe products. We have already experienced this inflation when tryptophan, a common amino acid, became a “drug” – the price nearly doubled. Many products will become prescription-only and this will incur the additional cost of a consultation.
- Some consumers will oppose the legislation on ethical grounds, but many may not care at all.

What is certain is that the full force hasn't hit yet because these changes are being phased in. By the time we wake up it would take an unlikely event, such as mass consumer outrage to reverse legislation in a single country and even if this were to occur it's likely that the country in question would evoke retribution from the WTO through trade sanctions. However, consumers have never been so well organized due to the internet and we may well see this battle being strong enough to generate the world's first global consumer rejection of international policy.

If you feel concerned about these issues there are many ways you can support these efforts. You may write, join or set up your own e-petition to Members of Parliament. Fundamentally, the issue is simple and I have listed a few important points that you may like to consider when making your representation:

- We feel that natural health products have a long track record of safety, they are not dangerous and therefore should not be banned
- We wish to see the high standards of manufacture maintained
- We wish to maintain the current listing and registration of products on the ARTG (Australian Register of Therapeutic Goods), which currently lists around 16,000 products, and encourage the Agency to broaden their lists to include products which are currently available from other countries which have equally stringent regulations, such as the USA.
- Any new compliance framework should be economic and not unduly onerous for low to medium risk products.
- Public funding should be made available for research into Complementary Medicine as it is for pharmaceuticals
- The burden of proof should lie within the government to produce evidence to show lack of safety of any Natural Health Product before its removal from the market. We are not making the statement “Innocent Until Proven Guilty” as the compounds used in formulations are already rigorously controlled before approval, and in the case of herbs, have been used for thousands of years to no ill-effect. Legislation which bans or removes Complementary Health Products upon any other basis can only raise the question of collusion with multi-nationals.

If you wish to make a financial contribution to the Alliance for Natural Health then this is a good way forward. This group is legally challenging the EU on its Pharmaceuticals Directive, its Food Supplements Directive, its Traditional Herbal Medicinal Products Directive, Health Claims Regulations and Codex Alimentarius. You may feel that Europe is

very far away but what happens in Europe at a legislative level paves the way for the rest of the world. By addressing these issues through the European Courts we stand the best chance of legally halting the process, negotiating fair terms and most importantly, preserve our access to natural health products in their natural state. If you wish to make a donation then please go to their website <http://www.alliance-natural-health.org/>

In Australia you may like to join and make financial contributions to the Natural Health Care Alliance <http://www.nhca.com.au> This group's primary aim is to speak with a united voice for natural therapies, to lobby at governmental level and respond to industry needs. "The primary goal is to bring together Natural Healthcare / Complementary Medicine under a common banner to take the positive story to the media, politicians and regulators, and to protect the valuable contribution we ALL make to the healthcare of Australians." This group needs our support.

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Other useful sites include:

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