Protect your rights to natural medicine!

Robert Verkerk outlines why legal action is needed to stop regulators' abuse of power over the public's access to natural medicine in the US and Europe, where Traditional Chinese Medicine and Ayurveda are now equally threatened

Court victory in the US

The date 27 May, 2010 represents an important milestone in the protection of our right to natural health. On this day the District Court of Columbia ruled against an earlier decision by the US Food and Drug Administration (FDA) to revoke a previously approved health claim concerning the role of the mineral selenium in reducing the risk of cancer.[1]

In June, 2009, the FDA revoked the claim. They were following an agenda that was set by themselves, along with their Canadian, European and Australian counterparts, in the international forum of the Codex Alimentarius, the intergovernmental food standards body that is coordinated by two UN organs, the Food and Agricultural Organization (FAO) and the World Health Organization (WHO).

Governments have been thrashing out for some years international guidelines for health claims and the scientific requirements for substantiation of claims have been agreed. In short, the requirements are so onerous that in the case of most food constituents and plant products, insufficient data have been generated to meet the required standards for conclusive evidence.

Allowing governments to control our ability to communicate about natural health is something that small numbers of people are deeply concerned about. For millennia, verbal or written communications have been the way in which we have transferred knowledge about health-giving properties of particular food plants and botanicals, from generation to generation.

It has, of course, also been the way we've learned which ones to avoid owing to their toxicity. Some of the earliest written records go back some 5,000 years ago in China and India, representing the founding principles of two great healthcare traditions still alive today, traditional Chinese medicine (TCM) and Ayurveda, respectively. Applying a reductionist, western scientific model, based around clinical trials designed primarily to test pharmaceutical drugs, should not be the gold standard for foods and natural products.

So, what do we do if we don't like a government's decision? Action rather than just being frustrated or angry is needed to change a bad law. Civil disobedience is one option and may be helpful, although increasingly officious enforcement will soon stop most activities. Ultimately, unless unjust legislation is repaired via the courts, the slope becomes very slippery.

This is where the US district court decision, the seventh consecutive and successful challenge of this type taken by Washington-based, constitutional lawyer Jonathan Emord of Emord & Associates, is of such key importance.

The lead plaintiff was our US-based organisation, the Alliance for Natural Health USA (ANH-USA), along with Durk Pearson and Sandy Shaw, as well as a group of companies under the banner of the Coalition to End FDA and FTC Censorship.

In essence, the court ruled that it was unconstitutional to require 'conclusive' evidence for a health claim, in recognition of the fact that almost no health relationships can be proven conclusively or unequivocally. To ban our ability to communicate about the health benefits of a given natural product unless there is conclusive proof of its existence would, according to District Court Judge Ellen Huvelle, be contrary to the First Amendment and our fundamental right to free speech. Instead, the court upheld that it was sufficient for a claim to be based on 'credible', as opposed to 'conclusive', evidence. This is an important victory for common sense, rationality and, of course, justice.

Erosion of democracy

It's clear the FDA is not going to take this lying down. Most in the West forget that democracy has been increasingly eroded by government rule-making. In his book, *The Rise of Tyranny*,[2] Jonathan Emord argues that the USA has been transformed from a constitutional republic into a bureaucratic oligarchy because over 75% of all federal laws are now created by unelected heads of federal bureaucratic agencies as opposed to the elected representatives of the people.

The FDA, the Federal Trade Commission and the Environmental Protection Agency are just three of well over 100 US agencies and bureaus that have the ability to make rules without reference to the democratic process. The FDA's decision on selenium is one of thousands of such rules made each year – the vast majority pass uncontested. It is, however, refreshing to discover that, when put to the test, many of these rules are found to break the very constitution on which the society is based, one that – in the case of the USA – still values the same principles established by its Founding Fathers.

Jonathan Emord is already preparing for the inevitable response from the FDA. Being off guard in these times is simply not an option if you want to stem the tide of unjust laws affecting natural medicine.

On the other side of the pond...

In Europe, the legislative infrastructure to create unprecedented restrictions on our freedom to choose natural medicines, or our ability to communicate freely about their benefits, is already in place. These restrictions will go beyond any kind of state control over natural health experienced to date. Most Europeans are blissfully unaware of what they will endure in the coming years and, as in the USA, it is only a handful of individuals, associations and companies that seem prepared to take a stand.

Restrictions on freedom of speech over health claims have been promulgated by European law on precisely the basis that has been ruled illegal by the US District Court in the District of Columbia. The relevant law in Europe, the Nutrition and Health Claims Regulation (No 1924/2006), came into effect on 1 July, 2007. Various transition measures (specific provisions come into force incrementally) conceal, for the time being, its venom.

But by 2012 it will be a different

story. At this time, all generic health claims will be banned unless they are specifically approved. Approved by who, you ask? Yet again, it is an unelected bureaucratic agency, in this case the European Food Safety Authority (EFSA), based in Parma, northern Italy, that holds all the cards. The EFSA, of course, provides its 'scientific opinions', but it is then the unelected European Commission that enforces the law.

And how do we know that EFSA's opinions will be problematic? Because it has already provided nearly 1,000 of 4,500 opinions and, in the case of most plant-derived nutrients and phytochemicals – the sort that are invaluable tools in nutritional and herbal medicine – most have been negative.

On completion of EFSA's evaluations, which require conclusive evidence of a causal relationship between a food or food constituent and a particular health benefit, no health claim will be able to be made – in any medium – unless it has been specifically allowed.

Simple claims rejected

To give an idea of how EFSA is evaluating claims, glucosamine, the shellfish-derived polysaccharide millions use to help support joint health, has not been successful in gaining approval, despite a series of high-quality trials demonstrating its beneficial effect.

Probiotic ('healthy') bacteria have been similarly unsuccessful for any kind of claim, including improvement of intestinal function and health. Quite simply, the authorities seem to be ignoring the base principle that if it is not possible to prove a health relationship conclusively, it does not mean that it does not exist.

A key question in Europe is whether elements of the food or natural products industry will have the courage to take a complaint to the European courts. Ironically, with the European Commiss-ion set to ban so many claims including terms like 'superfruit' because it says it is not possible to qualify what it means and it may mislead consumers, this is a law that is as unpopular with most of the large food corporations as it is with smaller, healthfood interests.

But so far, there is little evidence that major corporations will take the EC and EFSA to task. Perhaps, as representatives of the global food oligopoly, they are too deeply linked with governments to oppose them on this issue? Big Food and Big Pharma have had a long history of working very closely with governments and keeping people healthy through the use of natural products has never been part of their agenda. Why should things change now?

Come 2011 or 2012, perhaps a small consortium of interests will decide that enough is enough. The only significant limiting factor to a legal action on this or related issues is funding. If corporations are not going to step up to the plate and if insufficient numbers of consumers know that their donations toward a legal action could alter the course of history, perhaps it will take a forward-looking philanthropist to back at least the initial action. So far none is available, so if any reader is interested to help fund one or more strategic legal actions, please contact the Alliance for Natural Health (see below).

EU threatens great eastern healthcare traditions

In 2004, a European law known as the Traditional Herbal Medicinal Products Directive (THMPD) was passed. It has 7-year transition phase so will not be fully implemented until 1 April, 2011. At that point, thousands of products associated with two of the longest standing, healthcare traditions in the world, TCM and Ayurveda, will effectively be banned.

These products have been sold safety in the EU often for decades or more, being used both by people of European and non-European descent. The bans will occur not because there is any evidence of lack of safety of these products, but simply because it is not possible, for eligibility, technical or financial reasons, to have the products registered in accordance with the requirements of the THMPD scheme.

We at ANH-Intl have already announced our intention to challenge the THMPD.[3,4] We aim to do so initially in the High Court in London in order to gain a reference to the European Court of Justice (ECJ). Rather than trying to invalidate the directive itself, we intend is to use the challenge to force amendment of the THMPD so that it is amenable to the non-European traditions for which it was intended, rather than it acting as a barrier to them.

We also will be seeking clarification of the food supplement regime for botanicals to prevent European member state governments from legislating against them. The ANH is one of very few non-commercial organisations representing natural health interests that has previously and successfully taken a case to the ECJ (on vitamin and mineral food supplements).[5]

With the support of key interests in two very large nations (China and India) that represent one-third of the world's population, the decision of the European Court will determine whether justice in Europe is truly fair, or whether it exists largely to foster European protectionism. As with the recent selenium case in the US, to rule in favour of the latter would be to offer judgment contrary to fundamental human rights maintained under the European constitution. This suggests reasonable grounds for optimism in a judicial review.

Conclusion

It is becoming increasingly clear that the juggernaut of internationally conceived legislation that works counter to our ability to practise and communicate about natural health has been gaining momentum the world over. Nowhere is the legislative framework so highly developed to constrain and restrict natural health as it is in Europe.

The European model has been agreed by the governments of the USA, Canada and Australia. Most other governments seem wiling to follow this lead. The European regulatory model must therefore be seen as the blueprint that is intended to be enacted in all countries, being helped along by intergovernmental processes both formal (eg. Codex Alimentarius) and informal (ie. 'back room deals').

To end where this article began, it is also apparent that concerted efforts to change the direction of the juggernaut are well worth the effort. I believe that it is incumbent on those of us who can see the problems to do something about it. We must now be proactive, not just reactive. We owe this not only to the millennia of our co-evolution with our natural environment – but also to future generations. ✪

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