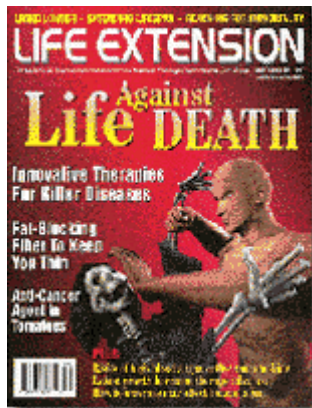


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*Point of
VIEW***Fighting For Health Freedom Worldwide:
A Report From the Battlefield**

By John Hammell



Challenges to the public's freedom to seek out and buy health care products of their own choosing are under attack around the world. The crisis is particularly acute in the U.S. and Canada.

The United States Food and Drug Administration (FDA) has just done us all a huge "favor" by openly announcing its intention to "harmonize" U.S. domestic law with the international reference standards expected to be set by the United Nation's Codex Alimentarius Commission (Codex). This represents a significant threat to free access to high-potency dietary supplements. With this announcement, consumers in the U.S. and abroad need to band together to fight back.

The FDA's announcement was posted on the agency's website, <http://www.fda.gov/ola/319.htm>. It should be viewed against the backdrop of the FDA's June 2 proposal for strict dosage limits for the herb ma huang (which contains natural ephedra), but not for synthetic ephedrine drugs. A Medline search shows no deaths attributed to ephedra/ma huang, and 57 deaths attributed to OTC drugs

containing ephedrine. This proposal is an example of the double standard the FDA is applying to the regulation of nutrients and herbs.

The FDA's harmonization efforts also can be seen in its Commission on Dietary Supplement Labels draft report, in which it advocates OTC drug status for herbs and botanicals. This report threatens to undermine the gains made through the Dietary Supplement Health and Education Act (DSHEA). While this report does not carry the force of law, it could be used as a prelude to legislation.

These FDA actions are part of an international movement. Moving with deliberate, almost glacial slowness, which makes it hard for consumers to catch on, the trans-national pharmaceutical industry is working through the Codex Committee on Nutrition and Foods for Special Dietary Use to attempt to restrict our access to dietary supplements.

AN INTERNATIONAL MOVEMENT TO RESTRICT ACCESS TO DIETARY SUPPLEMENTS

There is, for example, a German proposal that threatens to reduce consumer access to dietary supplements to no higher than recommended daily allowance levels, as well as a Canadian proposal that threatens to ban the international sale of many safe herbs.

It is through herbal products, which do not have RDAs, that the pharmaceutical industry is making its biggest takeover bid. The Canadian Codex proposal to create a negative list of herbs for the purpose of banning their sale from international commerce was first proposed at a North America/Southwest Pacific meeting in Vancouver in 1994, but it is still on the table. Mary Cheney of the Canadian Health Protection Branch (HPB) initially agreed to back off from the proposal in deference to public opinion, but later reversed her position at the Codex meeting in Bonn, Germany, last October.

Currently the HPB has a list of more than 104 herbs it intends to ban, and people all over the world had better take notice.

The German Codex proposal could be enacted by September 1998. This may seem like a long time from now, but given what we must do to stop it, it's not! In addition to the long-range threat posed by this proposal, immediate efforts are being made worldwide by drug companies to take over the natural supplement market. Consider the efforts of German pharmaceutical companies in the U.S. and Canada:

GERMAN JOINT VENTURES

Robert Yuan, Ph.D., and Jorg Grunwald, Ph.D., reported on April 15 in Genetic Engineering News, that optimistic projections for the U.S. herbal medicine market have led two major German companies, Schwabe and Madaus, to establish a joint venture in the U.S. through a well-known Utah based Vitamin-Company. Other companies, like Lichtwer Pharma and Pharmaton (a member of the Boehringer Ingelheim Group) also have subsidiaries in the U.S.

The interest by these companies is understandable. Yuan and Grunwald estimate that the global market for herbal medicines in 1996 was \$14 billion, with Europe accounting for \$7 billion, Japan \$2.4 billion and North America \$1.6 billion.

Yuan and Grunwald, who are consultants to the biotech and the herbal medicines industry respectively, confirm what I have been saying about the attempted pharmaceutical takeover of the natural products industry. They state, "The scientific data and the manufacturing quality associated with German herbal products make it likely that more American companies will enter into alliances, mergers, and acquisitions with their German counterparts as this industry continues to grow."

According to the April 1997 issue of Whole Foods magazine, Madaus AG is currently funding a \$300,000-plus double-blind study of Echinacea at Bastyr University in Seattle, Wash. This aggressive investment in an herb currently available from many dietary supplement companies is likely geared towards selling Echinacea as a drug in North America.

This speculation is further supported by the fact that the Utah Natural Products Alliance, the National Nutritional Foods Association, and the American Herbal Product Association all signed a memo sent to the FDA's Dietary Supplement Label Commission, in which they support the creation of an over-the-counter drug category for herbs and botanicals.

THE CANADIAN BATTLE FOR HEALTH FREEDOM

On January 8, Zoltan Rona, M.D. of Toronto ordered three bottles of DHEA capsules from the Life Extension Foundation and was disappointed to receive the following reply from The Foundation.

"I regret to inform you that we can no longer ship DHEA into Canada. The Gov't there stops every package to insure that the product is not passing customs. If they find any DHEA, they have warned us that they will deny all shipments from LEF into Canada and that they may arrest the person ordering the product. I'm sorry for any inconvenience."

The Canadian Health Protection Branch, which regulates foods as "drugs," not only blocked Dr. Rona from receiving DHEA from the States, but also blocked him from receiving vitamin E, zinc, and natural formulas such as Cognitex, which have a "pharmacological effect" (the HPB says this about cayenne pepper, or any other food in Canada the moment it becomes encapsulated). [Editor's Note: The Life Extension Foundation continues to be able to ship all its products successfully to all Canadian customers other than Dr. Rona, except for DHEA.]

ADDING INSULT TO INJURY

The HPB also is stopping Dr. Rona from getting these products because the Foundation hasn't yielded to its \$10-\$20,000 Drug Identification Number application fee, and the fact that Dr. Rona (as a distributor) hasn't paid a "site licensing" fee of thousands of dollars to have an HPB inspector inspecting Life Extension's manufacturing facility.

Adding insult to injury, Dr. Rona also would have to pay a \$500 to \$1,500 a year maintenance fee as a distributor for the DIN numbers on each imported product, and these costs would have to be passed on to his patients. These fees soon will drive many small Canadian manufacturers and distributors out of business unless Toronto-based Freedom of Choice in Health Care is successful with two soon-to-be-filed lawsuits seeking injunctions.

Under Phase 3 of "Cost Recovery," the HPB proposes collecting 1.5 percent of annual sales from vitamin manufacturers in order to make up for funding that was cut from its budget by Health Canada. This would not have an adverse effect on large vitamin firms owned by pharmaceutical companies, but it threatens to destroy numerous small to mid-sized manufacturers and distributors.

Under the Canadian Financial Administration Act, federal agencies such as HPB are allowed to charge flat fees to regulate industry for some of the services they perform. However the moment they charge on a percentage basis of annual sales they cross a legal boundary by charging an illegal tax, one which was never debated and approved by the Canadian Parliament after a careful review of the financial impact of such a move.

A CONFRONTATION IN CANADA

In March, I traveled to Canada, ignoring threats that I'd be arrested by the Royal Canadian Mounted Police if I set foot on

Canadian soil. At the Vancouver airport, Canadian customs detoured me into the bowels of the airport, where I was forced through several checkpoints, asked a million questions, and given the "fine toothed comb" routine for an hour and a half. The empty threat to have me arrested was issued by the publisher of a Canadian vitamin trade publication because I had angrily turned my back on the fake grass roots "astroturf" organization, the Canadian Coalition for Health Freedom, after realizing that the organization was controlled by pharmaceutically connected Vitamin-Companies, which are trying to sweep their smaller competitors off a cliff.

The CCHF had succeeded in blocking me from the podium at a public forum in Vancouver at which I had been scheduled to speak. They were fearful I would expose their pharmaceutical ties, and threatened to withdraw their financial support for the event if I was allowed to speak. So the Health Action Network Society was forced to drop me from the program.

With a sigh of relief I finally cleared customs, and met Debbie Anderson, the British Columbia coordinator of Freedom of Choice in Health Care (FCHC), a genuine grass roots health freedom group. FCHC favors a "food are not drugs" amendment and has just filed two lawsuits against the Health Protection Branch, in time to block phase 3 of HPB's Cost Recovery program from going into effect.

Despite being barred from the public forum podium, I popped out of the crowd at a microphone that had been placed for audience participation and exposed the Canadian Coalition's pharmaceutical ties. At the same time, I urged the standing-room-only crowd to instead back Freedom of Choice in Health Care as the true grass-roots organization that stands firm on principles through their efforts to sue the HPB and to pass a "foods are not drugs" amendment. You could have heard a pin drop as I explained to the crowd that in Norway and Australia, health freedom already had been destroyed by the same process now underway in Canada, while identical takeover campaigns were unfolding in New Zealand, South Africa and many other countries as part of Codex harmonization. I warned the audience not to back the third category ("neither foods nor drugs") being pushed by the Canadian Coalition for Health Freedom, arguing that it favored only the large, pharmaceutically connected Vitamin-Companies.

I related the story of John Hansen in Norway, whose vitamin distribution company had been driven out of business by NONA, the Norwegian vitamin trade association, which has been taken over by pharmaceutical interests, and discussed how he had been pursued by undercover agents for selling Vitamin-C above the 200-mg limit.

Because a lot of Canadians had traveled long distances to hear me speak, many were disappointed and angered that I had been barred from the podium. A woman named Inga passed out flyers to the crowd so they could hear me speak the next day at her church. The following day, Inga's church was packed, and the response to my talk was highly enthusiastic.

CONCERNS IN THE U.S.

In the United States, the situation is just as bad. Most Americans don't grasp the fact that we did not win a victory with the passage of the Dietary Supplement Health and Education Act. This legislation ultimately favors large, pharmaceutically owned or connected companies over small companies.

According to attorney Milton Bass and lobbyist Clinton Miller, DSHEA gave a huge weapon to the FDA by allowing them to create new good manufacturing practices (GMPs) for dietary supplements, and by shifting the burden of proof on health claims from the FDA to the manufacturer. In addition, DSHEA created a presidentially appointed "Dietary Supplement Label Commission," which is dominated by pharmaceutical interests.

The Commission On Dietary Supplement Labels was supposed to take two years to study how truthful claims would be allowed for dietary supplements, which the bill was originally supposed to allow upon passage, and which are protected commercial free speech under the First Amendment to the U.S. Constitution. As stated earlier, rather than call for an expansion of claims made under DSHEA, the Commission has proposed the creation of an over the counter drug category for herbs and botanicals, and proposes to restrict sales of the herb ma huang. This push for an OTC drug category threatens to spur a legislative push that could gut DSHEA. It should be strongly opposed by consumers.

According to The Reader's Digest Family Guide to Natural Medicine, "For thousands of years, practitioners of Chinese medicine have relied on ma huang tea to treat asthma, flu and even arthritis." Two decades ago Danish investigators found it is effective for weight loss. Since then millions of consumers have used ephedra/ma huang to lose weight safely.

But, in a move to protect manufacturers of such expensive and dangerous prescription weight-loss drugs as dexfenflouramine, FDA Deputy Associate Commissioner William Shultz, a long time opponent of the dietary supplement industry, said these limits "...would essentially prohibit any ephedrine supplement from being used as a weight loss product" (AP 5/2/97). The Commission's draft report attacks ephedra before the comments period on ephedra products has even concluded, illustrating just how biased it is against the dietary supplement industry.

Unless it is extended, the comments period for the Commission's draft report ends August 4, 1997 You can fax your requests for

an extension to Ken Fisher, Executive Director of the Commission on Dietary Supplement Labels at 202-205-0463. You can obtain a copy of the draft report by calling the Commission's Response Center at 301-650-0382.

The FDA has announced its intention to base new good manufacturing practices for dietary supplements on the same "Hazard Analysis Critical Control Point" system used in pharmaceutical manufacturing, threatening to drive many small Vitamin-Companies from the market via bureaucratic overkill. Final Rules could be issued this summer. The FDA's usual pattern in releasing anything that would anger dietary supplement consumers is to issue the new rules in August, when many people are on vacation, and when Congress is recessed, hoping that people won't pay attention.

PATENTS OUT OF CONTROL

There is trouble elsewhere. PharmaPrint Inc. of Irvine, CA, became the first company to get a patent on a complex herbal molecule, and it has announced the intention to patent many of the world's most popular herbs, as well as to license pharmaceutical companies to use its patented technology. Regulators such as Schultz are helping the company by trying to take natural substances off the market so they can't compete with the patented versions. The World Health Organization backs PharmaPrint, and this does not bode well for consumers.

According to the Rural Advancement Foundation International, patenting is out of control. RAFI documents the patenting of human genes, umbilical cord cells and human cell lines, as well as herbs such as kava, barbasco and others. They correctly state that exclusive monopoly patents related to the processes and formula of life are contrary to a country's moral sense. On its website (<http://www.rafi.ca/misc/courtrips.html>), the group discusses the fact that under Article (27)2 of GATT, the international trade agreement, countries have the right to deny "immoral" patents, and that patents can be repealed by invoking this section.

IAHF HELPING CONSUMERS FIGHT BACK WORLDWIDE

I started International Advocates for Health Freedom to promote freedom of choice in health care worldwide. Americans need to realize that we can't stop Codex by lobbying Congress. With the exception of a handful of people, such as Rep. Ron Paul (R-Texas), who introduced the American Sovereignty Restoration Act of 1997, which would get us out of the United Nations, we can't rely on Congress to assist us. They have already sold out by signing NAFTA and GATT, through which Codex derives its power via the phytosanitary measures and technical barriers on trade sections.

Since the U.S. Congress can't stop Codex, we must reach out to health freedom fighters around the world. IAHF is currently assisting health freedom groups in the U.S., Canada, the U.K., the Netherlands, Spain, South Africa, Australia, Iceland, New Zealand, and a growing number of other countries.

My articles, public speaking, Internet web site, and fax-on-demand triggered the awareness of the Codex threat in Canada, and it greatly encouraged me to see a spirited health freedom rally in Vancouver prior to the election on June 2. Several seats in Parliament were won by candidates who rallied to the health freedom cause. David Dingwall, the Health Minister who strongly supported the HPB's attacks on the natural products industry, was ousted in that election.

With assistance from IAHF, Freedom of Choice in Health Care in Toronto has just filed its lawsuit against the HPB, and the HPB has backed off on implementing the third phase of cost recovery. I was able to provide FCHC with key information, fund-raising support, and networking, without which the lawsuit couldn't have been filed in time, and am consulting on several similar efforts worldwide.

A battle similar to Canada's is underway in South Africa. I've been able to assist Stuart Thomson there by providing intel data from other countries. His group is called PHARMA-PACT, which stands for People's Health Alliance Rejecting Medical Authoritarianism, Prejudice, and Conspiratorial Tyranny. PHARMAPACT is mounting constitutional and legal challenges to the authority of South Africa's Medicine Control Council, which operates much like the HPB in Canada. Thomson's house has been shot at, and his phone lines have been tapped.

IAHF is working in a similar fashion with Janice Priest in New Zealand, John Lesso in Australia, Einar Thorsteinn in Iceland, Ron Birkhead in Norway, Vance Lanneman in Jamaica, Major Gordon Smith in the U.K., Suzanne Harris and Patrick Von Mauck in the U.S., Debbie Anderson, Marilyn Nelson and numerous other Canadians as well as other health freedom fighters around the world.

Consumers of natural products and small Vitamin-Companies worldwide now have a vehicle through which to fight for freedom of choice in healthcare. Please contact us.

JOIN DR. JULIAN WHITAKER IN SUPPORT OF INTERNATIONAL ADVOCATES FOR HEALTH FREEDOM!

Consumers, Vitamin-Companies, Distributors, Alternative M.D.s, Healers & Health Food Stores:

Your generous donations and consulting fees will assist me to:

- Continue researching and writing articles such as this one.
- Hire a staff to assist me in my efforts to serve you.
- Continue to travel to help unite health freedom fighters worldwide.
- Build a better website, a better fax-on-demand server, and have more time for research, radio shows, public speaking, networking and organizing.

John, thanks for assisting us to defend our health freedom!

Enclosed is my donation of:

()\$25. , ()\$50., ()\$75., ()\$100., ()\$200,

My best gift of \$_____.

(checks payable to International Advocates for Health Freedom).

To hire me as a consultant, please call, fax, or e-mail to discuss your needs.

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