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REPORT

Europe Threatening To Ban Dietary Supplements
International Assistance Needed To
Stop Draconian EU Vitamin Laws

By John C. Hammell, President
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<http://www.iahf.com>



Poster for the Health Freedom Movement

Currently under consideration in Europe is legislation that will severely limit a consumer's right to choose and use supplements. This restrictive legislation is the first major step towards the adoption of global standards for the regulation of dietary supplements, as is being worked on at the UN's Codex Alimentarius Commission. Since the U.S. is part of this process and is a member of the World Trade Organization, the U.S. could be forced to harmonize its vitamin laws with these new, highly restrictive international standards.

In an effort to stop this punitive legislation, the Alliance for Natural Health (ANH), an organization based in England, is planning to file an emergency lawsuit on behalf of consumers, vitamin companies and health food stores to overturn the European Union (EU) Food Supplements Directive, which became law on June 10, 2002. The Food Supplements Directive (FSD), currently concerns itself only with vitamins and minerals. However, by the year 2007 the European Union (EU) will be obliged to provide detailed proposals to expand the law to cover all other types of nutrients. Eventually this will force vitamin companies to reformulate their most important supplements. Although the 13 key vitamins would be permitted, the Directive excludes the most bioavailable forms of vitamin complexes. For example, The Food Supplement Directive bans any chelated or other organically complexed mineral forms such as selenomethionine. Additionally, it will only allow the alpha-tocopherols of Vitamin E but excludes the complete tocopherol range as found in nature (including the gamma-tocopherols), which are far more effective as antioxidants than the simpler alpha-tocopherol group. Research has proven that many vitamins and minerals are most bioavailable when in the forms found in nature. Unless the

current Directive is overturned, many Life Extension products will be banned, and the Foundation will be forced to either cease selling particular products in Europe or will be forced to reformulate their scientifically-balanced products.

Replacing them would be vitamins that are less bio-available, potentially more toxic and better suited to the pharmaceutical industry affiliated supplement companies. In other cases, entire minerals such as boron, sulphur and vanadium would have to be removed as they would not be allowed under the new EU law. If this law is not overturned in July 2003 then it will become the national law of all European Union member states including England, Ireland, Netherlands and Sweden, which currently have liberal vitamin laws similar to those of the United States. Along with the Food Supplements Directive, is the additional threat of the Traditional Herbal Medicinal Products Directive which would impose medicinal law on herbs and other so-called borderline supplements. Both of these Directives would severely limit any chance for individuals to oversee their health as they so choose.

TAKING IT TO THE STREETS

On June 15th, the UK-based Health Freedom Movement (HFM) (<http://www.healthfreedommovement.com>), a consortium of more than 700 health freedom organizations, will be holding a street march and health freedom rally in central London in opposition to England harmonizing their vitamin law to the Food Supplements Directive. The march will go from Hyde Park to Trafalgar Square. Lynne McTaggart of HFM told me in an interview that she hopes to carry a message to the government and to the EU that the FSD is totally unacceptable. She also hopes to generate donations for the Alliance for Natural Health, a non-profit organization seeking ways to change, reshape or revoke laws affecting dietary supplement consumers, practitioners and manufacturers in Europe. As publisher of What Doctors Don't Tell You (<http://www.wddty.co.co.uk>), the UK's leading alternative medical newsletter, McTaggart, who is in constant contact with alternative practitioners, supplement manufacturers and consumers, is painfully aware of what is at stake with this pending legislation. She wants American vitamin companies and consumers to be aware that, "will we, along with future generations be deprived of access to the most innovative dietary supplements currently on the market including many of the Life Extension Foundation's products? Will the Foundation be forced to reformulate Life Extension Mix by removing all the most bio-available, effective and natural-state nutrients? Will the Foundation be blocked from selling life-saving products due to future harmonization to a grossly restrictive international standard? We stand at a crossroad—the fate of this global industry is literally in all of our hands right now. We sink, or swim, together. This is the battle for The Dietary Supplement Health and Education Act (DSHEA) all over again, but this time on a world stage." We can be negatively impacted here via the mechanisms of globalization unless we actively assist our international allies. Those who think DSHEA posed the ultimate bulwark against the Pharma Cartel are sadly mistaken.



Veteran health freedom advocate Clinton Ray Miller (left) and Bonnie Miller advise ANH Attorney David Hinde on defending vitamin access world wide.

Summary of key European legislation affecting dietary supplements

	Food Supplements Directive (FSD)	Pharmaceuticals Directive (PD)	Traditional Herbal Medicinal Products Directive (THMPD)
Status	Passed into EU law 10 June 2002	First Reading 23 October 2002	First Reading 21 November 2002
Impact	Limits ingredients (nutrient sources) and maximum dosages. Framework structure; only applies to vitamins and minerals at present, will cover other nutrients in future. Full impact will not be felt until 2005 - 2009. Is likely to omit 285 nutrient sources that are currently used in Europe. Improved prospects for trade between European countries.	All dietary supplements that are not controlled under FSD will be controlled under PD. A drugs regime would therefore apply and this would not be affordable for many non-pharmaceutical-owned supplement manufacturers.	A derogation of PD which allows fast-track legislation for eligible herbal products. The number of products caught will ultimately depend on PD definition of a medicine. Allows for improved labelling and quality control of medicinal herbs.
Potential for improvements to Directive	Can affect implementation in EU member states through national authorities. Can influence maximum permitted levels of nutrients. Consider challenging entire legality of directive.	Can alter the definition of a medicine, as well as scope of directive, to ensure that most dietary supplements cannot fall under PD. Can positively exclude non-medicinal food supplements, herbs and cosmetics.	First Reading amendments allow for combinations of herbs and nutrients, but make ineligible herbs that have less than 10 years use in EU. Can promote amendments for Second Reading which allow traditional (e.g. 30-year) use from outside the EU with evidence from a competent authority.
Summary of ANH achievements in 2002	Mounted Brussels and UK-based campaign which helped to almost block FSD's passage through Second (final) Reading in EU Parliament.	Lobbied to ensure tabling of critical amendments on definition of a medicine, scope of directive and exclusions. All amendments successfully voted for at First Reading.	Lobbied to help ensure major amendments were supported. Key amendment on non-EU traditional use was lost in pre-First Reading vote but successfully re-tabled by European Liberal Democrats at First Reading plenary. Although it again failed, it can be re-tabled at Second Reading.

Source: Alliance for Natural Health Newsletter, March 2003.

Recently I spoke at the Vitality Vitamin Trade Show in England before a group of alternative medical practitioners and consumers who form the backbone of the growing European health freedom movement. My concern is that these latest directives threaten to force the creation of a draconian vitamin standard at the UN's Codex Alimentarius Commission. What is especially troubling is that

due to America's membership in the World Trade Organization, the United States could be forced to harmonize its vitamin laws to this emerging restrictive international standard.

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I was extremely fortunate to be joined by veteran health freedom lobbyist Clinton Ray Miller in England to fight for our rights with regard to health and supplements. At 81 years, Clinton would not have left the comfort of his Statesville, North Carolina home if he did not believe that we were up against critical challenges. At the conference, I informed my audience that the Food and Drug Administration (FDA) under a guise of "fully implementing the Dietary Supplement Health and Education Act" has contracted the National Academy of Science to prepare a report and draft "safety monographs" for several of the top selling, most effective dietary supplements: saw palmetto, chaparral, chromium picolinate, melatonin, DHEA and shark cartilage. This analysis will eventually be applied to all dietary supplement nutrients under a three-stage process, which in its final stage is very similar to the stringent evaluation process for pharmaceuticals referred to as a "critical safety evaluation." In time, the FDA wants all supplement ingredients to go through this third, most onerous route, as well as any new ingredients, regardless of how closely related it is to other well-known, safe ingredients.

This latest move on the part of the FDA immediately grabbed the attention of Dr. Robert Verkerk and attorney David Hinde of the UK-based Alliance for Natural Health. They immediately recognized that the impact of the FDA plan was more or less identical to that of the proposed EU legislation. The U.S. and EU legislation might look rather different from the outside, but the impact on our freedom to manage our own health would be identical. Both systems are set to kill innovation in the non-pharmaceutically-aligned sector of the dietary supplement industry, leaving it open only to the drug companies themselves. The FDA program is clearly an effort to set the USA up for harmonization of its dietary supplement laws to a grossly restrictive emerging international standard. As pointed out by attorney Suzanne Harris of the Law Loft in Missouri, the UN's International Conference on Drug Regulatory Authorities (ICDRA) has been coordinating the actions of the world's "Fads," and there is plenty of evidence on the web in official documents to prove this.

With the Journal of the American Medical Association's recent editorial calling for the repeal of DSHEA, and Illinois Senator Dick Durbin having just introduced S.722 Dietary Supplement Safety Act of 2003 for this purpose, I have no doubt that the Alliance for Natural Health is absolutely right in drawing parallels between the proposed EU, U.S. and other international laws.

I firmly believe that all of the vitamin trade associations worldwide are controlled from the top-down by pharmaceutical interests. For this reason, the estimated 20% of the supplement industry that are manufacturing the most innovative products must come to the aid of consumers by backing the Alliance for Natural Health's lawsuit, which must be filed by July!

Even more troubling is the establishment of controlled opposition groups established by the pharmaceutical industry around the world. These shadow groups only appear to go through the motions of fighting back, and all too often consumers and vitamin companies get manipulated into joining them without understanding their real agenda.

An example of a controlled opposition group is the International Alliance of Dietary Supplement Associations (IADSA) (see <http://iadsa-exposed.tripod.com>).

IADSA has UN NGO (non-governmental organization) status to represent the supplement industry at Codex meetings in Germany. Its chairman is Randy Dennin, an employee of Pfizer, the largest pharmaceutical company in the world. IADSA's agenda was made transparent during its interactions with a member trade association: NNFA New Zealand (National Nutritional Foods Association of New Zealand). You can view JPEG files of correspondence between NNFA New Zealand and IADSA at the above mentioned website. These documents show that IADSA was unwilling to assist New Zealand in its effort to defend its very liberal, food-based dietary supplement laws from harmonization to Australia's far more stringent pharmaceutical regulations under which consumers have far less access to products. When NNFA New Zealand raised the issue of conflict of interest, and questioned IADSA's true intentions to defend health freedom, IADSA kicked them out from their association.

International Advocates for Health Freedom (IAHF) ally Ron Law from New Zealand attempted to get IADSA's Simon Pettman to issue a press release defending the herb kava when it came under global media attack. But Pettman refused, even when Mr. Law provided him with expert risk analysis data showing the comparative safety of kava.

Pettman publicly declared his desire that the EU Food Supplements Directive be passed into law along with a finalized Codex vitamin standard. These positions are highly contradictory because of the impact the passage of the EU FSD threatens to have at Codex, especially after 2004 when the EU expands by ten more countries, none of which will dare to go against an EU Directive.

If in fact, the anti-vitamin standard passes at Codex, the U.S. would be obligated under international law to adhere to it, given that they are members of the WTO and signatories of the Sanitary Phytosanitary Measures Agreement. The FDA Modernization Act of 1997 was amended to specifically exclude dietary supplements from the harmonization language. This makes it illegal for the FDA to take any action that would allow us to participate in a restrictive international standard. However, the FDA has stated to me in writing that they intend to ignore the will of the people, and the will of Congress. Congress whitewashed an oversight hearing on March 20, 2001 in which the effects of Codex on the U.S. would have most likely emerged. IADSA member Karl Reidel testified at this hearing that events in Europe pose "no threat" to American law. Just 10 days later, on 30 March 2001, Reidel's co-chair on NNFA's International Committee, as well as IADSA's Chair, Randy Dennin, both chaired a meeting in Capetown, South Africa titled "Toward A Global Regulatory Model." IADSA is clearly concerned with maintaining the interests of its predominant membership, which are pharmaceutically affiliated supplement companies and big food interests such as vitamin trade associations like EHPM (European Health Product Manufacturers Association) and ERNA (European Responsible Nutrition Alliance). These happen to be key associations that Pettman consults with via European Advisory Services (EAS), his consulting firm in Brussels. While going through the motions of "defending" the industry, IADSA appears to be actually helping the pharmaceutical interests, which dominate it, to get control of the supplement industry by helping to usher in a global regulatory model, which drives numerous products off the shelves.

THE GOOD NEWS

The good news is that the UK's Alliance for Natural Health (<http://www.alliance-natural-health.org>) is a first-rate health freedom organization composed principally of scientists and lawyers, well up to the task of spearheading the fight. The organization is ably led by Robert Verkerk, PhD, (Executive Director) and assisted by David Hinde LLB Solicitor (Legal Director).

This scientist/attorney leadership team is heavily backed up by a crackerjack scientific advisory panel, a top flight public affairs team in Brussels, the best EU law firm in Britain and a host of alternative medical practitioners including all of the top complementary practitioner associations in the UK (e.g. British Complimentary Medical Association, the Complementary Medical Association, the Institute of Complimentary Medicine, the British Association of Nutritional Therapists; the Guild of Complimentary Practitioners). The Alliance for Natural Health also has support from a growing number of key innovative European and international manufacturers and distributors.

WHAT YOU CAN DO

Check out ANH's website <http://www.alliance-natural-health.org> where you will find their detailed strategy, which deals with the FSD and the other Directives. Consider joining organizations that are fighting for your freedom. ANH is doing an excellent job and should be supported in every way possible. Along with the lawsuit to overturn the EU Food Supplements Directive, ANH must keep lobbying in the EU against the Traditional Herbal Medicines Directive and for amendments to the Pharmaceuticals Directive. You can e-mail Robert Verkerk or David Hinde for further information at info@alliance-natural-health.org.

International Advocates for Health Freedom (IAHF) is a consulting firm to the dietary supplement industry on legislative matters. IAHF also provides a valuable service to vitamin consumers by calling attention to threats to our access, which are currently being covered up by controlled opposition groups such as IADSA, and other pharmaceutically dominated vitamin trade associations worldwide. Unless we take this battle to the world stage, the USA's vitamin laws will be forcibly harmonized to a grossly restrictive international standard.

Your financial assistance is urgently needed to support the efforts to overturn the European Directive and file the necessary lawsuits to protect your freedom. Time is of the essence as the lawsuit must be filed by July 2003. Vitamin companies and consumers interested in supporting the work of IAHF can contact me directly at 800-333-2553 (North America) and 540-961-0476 international or at <http://www.iahf.com>. Donations can be sent to: IAHF, P.O. Box 10632 Blacksburg, VA 24062, USA.

For further information on this global issue, you may read the full version of this document at www.iahf.com/anh_lawsuit.html. Additionally, this site posts the latest news on the international fight for freedom in health care.

As we go to press, we have some sobering news from Australia, which clearly illustrates that this industry is under full scale global Pharma attack right now: over 1300 dietary supplement product lines have just been banned by the Australian TGA (Therapeutic Goods Administration) due to a recall under highly suspicious circumstances. Thus 80% of the stock of Australian health food stores has just been pulled from the shelves and the media is exhorting consumers to stop taking their dietary supplements. Within six months, a high percentage of Australia's 5,000 health food stores could easily be forced into bankruptcy. With the U.S. FDA on the verge of coming out with new Good Manufacturing Practice Regulations (GMP) for dietary supplements that show every sign of violating the letter of the law as put forth by the Dietary Supplement Health and Education Act of 1994 (which calls for the FDA to promulgate food based GMP), the FDA is in fact attempting to come out with regulations that are stricter than pharmaceutical GMP in an effort to set the U.S. industry up for the same sort of destruction that is occurring in Australia. Could this be why Randy Dennin of Pfizer is trying so hard to get New Zealand and the rest of the world to harmonize to Australia and to the EU? Is this why IADSA appears to only be going through the motions of fighting back?



John Hammell, (center holding flyer) at Vitality Vitamin Trade Show, London, UK

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