

## **Legislative Alert!!! Dietary Supplement and Education Act of 1994 (DSHEA) is at an extreme risk!!!!**

**The "Dietary Supplement Safety" Act (S.722)** would amend the Federal Food, Drug and Cosmetic Act to require manufactures of dietary supplements to submit to the Food and Drug Administration (FDA) to report on adverse experiences with dietary supplements, and for other purposes. [1] This act would “protect” your access to all nutritional safe supplements by requiring them to go through their approval process first. “Millions of Americans use dietary supplements, and we owe it to them to ensure that they are getting the products they’re paying for,” stated Secretary Thompson.[2] This Act would allow the FDA to dismantle the Dietary Supplement Health and Education Act (DSHEA).The hard\_won natural health freedoms ensured by the DSHEA of 1994 would be overturned! Using the adverse media attention, this bill was triggered by the alleged ephedra\_related death of Baltimore Orioles pitching prospect Steve Becheler, ephedra as a lever, the FDA, the Department for Health and Human Services (HHS) Secretary Tommy G. Thompson and at the request of U.S. Senator Dick Durbin (D\_IL), has reopened the comment period on the DSHEA legislation until June 15, 2003.

### **What is DSHEA?**

SB 784, The Dietary Supplement Health and Education Act of 1994 (DSHEA, or the Act) was enacted by Congress following the largest volume of response/debate on record from the public concerning the importance of dietary supplements in promoting health, the need for consumers to have access to accurate information about supplements, and controversy over the FDA regulatory approach to this product category. Signing DSHEA into law on October 25, 1994, President Clinton said:

After several years of intense efforts, manufacturers, experts in nutrition, and legislators, acting in a conscientious alliance with consumers at the grassroots level, have moved successfully to bring common sense to the treatment of dietary supplements under regulation and law. . . [3] DSHEA amends the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) to alter the way dietary supplements are regulated and labeled. . . . [4]

### **What has changed sense this study on the importance of the public having access to dietary supplements for health?**

In July 1976, Dr. D. Mark Hegsted, Harvard School of Public Health, Senate Select Committee on Nutrition and Human Needs, stated, “I wish to stress that there is a great deal of evidence, . . .that the major causes of death and disability in the United States are related to the diet we eat . . .” This clearly indicates the need for dietary supplements that have been proven safe and effective. The laws relating to protecting consumers from dangerous foods have existed for decades and also apply to supplements . With dietary supplements proven to be safe and effective why has the FDA habitually ignored the dangerous side effects of prescribe drugs and better safe guard the public’s safety from them ?

### **Good Manufacturing Practices (GMP):**

DSHEA of 1994 defines "dietary supplements" as a separate regulatory category. [5] DSHEA also created an NIH Office of Dietary Supplements and directed the President to appoint a Commission on Dietary Supplement Labels to recommend ways to implement the act . The Food, Drug, and Cosmetic Act defines "drug" as any article (except devices) "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or function of the body." [4] These words permit the FDA to stop the marketing of products with unsubstantiated "drug" claims on their labels.. [6] Following the DSHEA act, on November 20, 1995 representatives of the dietary supplement industry submitted an outline for CGMP (current good manufacturing practices) regulations for dietary supplements and dietary supplement ingredients to the FDA.

At the time of enactment October 24, 1994, Congress considered, .” . . improving the health status of United States Citizens ranks at the top of national priorities of the Federal government to ensure public health and safety . . . and required the FDA to establish GMPs for the supplement industry. The FDA is in an adversarial role of trying to put supplements into a "dangerous" category with GMPs that are close to drug standards and “harmonize them to CODEX/ European Union Vitamin Directive” standards. The FDA recommends the following revision: “All labels should bear a statement that a supplement should be taken on the advice of a nutritionist, a dietician, or a medical doctor.” [7] The Journal of American Medical Association conquers with the FDA, “If dietary supplements have or promote such biological activity, they should be considered to be active drugs . . .”[8] This falls just short of requiring prescriptions for all dietary supplements. This dangerous loophole in the DSHEA law allows the FDA to ban any product over “safety” concerns following the letter of the law not the intent which exempts dietary supplements from harmonization with international law and prohibits regulating them as drugs. The FDA’s citing DSHEA reference to GMP as justification for applying QW&A ICH “Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients to Food Supplements.” [9] This move has prompted Emord and Associates, P.C. to submit lengthily comments to the FDA on behalf of Pure Encapsulations, Inc; Dirk Person and Sandy Shaw, Trace Minerals Research, LLC and American Nutrition Corporation. (To read the brief the law firm’s website at: [emord.com/public.com](http://emord.com/public.com) Could this be why the FDA isn’t “really” concerned about consumers? Why has it taken almost 8 years to come up with a new GMPs proposal finalized March 13, 2003? By contrast, the supplement industry only took 13 months to create an effective plan to self regulate themselves by substantiating label dosage claims to food manufacturing GMPs.

### **Why did this happen?**

“An amendment to SB 830, FDA Modernization Act of 1997 was supposed to exempt dietary supplements from harmonization, but the FDA is ignoring the amendment, and Congress is allowing them to ignore it. Congress whitewashed the Codex oversight hearing on March 20, 2001. The will of the people and the will of Congress was clearly expressed via Senator Hatch in his statement in the Conference Report on this legislation, but the FDA has found a loophole in the legal language of this amendment. By stealth international pharmaceutical companies are moving toward the European Union (EU) Vitamin Directive through the United Nations (UN) and the World Trade Organization (WTO). This “process” will harmonize all vitamins, minerals and herbs into a drug prescription category. The EU Vitamin Directive used unscientific “upper limits” for safety in order to justify moving these nutrients to a drug category. It will also eliminate most sources of these products by making the regulations so expensive only the giant drug companies will be able to clear and sell them. See [iahf.com](http://iahf.com) - Questions for Yetley and L.Robert Lake. [11]

**Editor’s note:** When President Clinton signed SB 830 into law, The FDA Modernization Act he stated, “ I am pleased to sign into law SB 830, Food and Drug Administration Modernization Act of 1997. This bipartisan legislation culminates several years of work by my Administration and the Congress on steps to streamline and rationalize the process by which the FDA approves new drugs and medical devices, while ensuring that these products are safe.” Is this why this amendment is being ignored so dietary supplements can be moved into a prescription drug category and “harmonized” with EU Directive/CODEX?

#### **Who would benefit from the proposed amendments to DSHEA?**

Your health and right to natural therapies or the pharmaceutical companies who profit from disease? If the FDA ratifies the legislative changes they are seeking, alternatives/dietary supplements will be restricted leaving unsafe, ineffective and expensive patented drugs. Consequently, the multi\_billion dollar pharmaceutical "business with disease" will continue to grow requiring a prescription for your nutritional supplements. Dr. Matthias Rath sums it up well, “Therefore, the pharmaceutical industry fights the eradication of any disease at all costs. The pharmaceutical industry itself is the main obstacle, why today’s most widespread diseases are further expanding, including heart attacks, strokes, cancer, high blood pressure, diabetes, osteoporosis and many others. Pharmaceutical drugs are not intended to cure diseases. According to health insures, over 24,000 pharmaceutical drugs are currently marketed and prescribed without any proven therapeutic value.” (AOK Magazine, 4/98). [12] John Le Carre former employee of the British Foreign Office knows the politics of big business very well. In his book, “The Constant Gardner, focuses on the corrupt nature of the pharmaceutical industry.” In an inter view on the subject Le Carre state, “ Big Pharma is engaged in the deliberate seduction of the medical profession, country by country, worldwide. it is spending a fortune on influencing, hiring and purchasing academic judgement to a point where, in a few years’ time, if Big Pharma continues unchecked on is present happy path, unbought medical opinion will be hard to find.” [13] To help sway media, public opinion and congressional votes into their direction multinational pharmaceutical companies have been highly successful in hiring lobbying firms who work for parties with conflicting interests. Independent supplement companies and consumers need to know Parry Romani, Deconcini and Symms - the DC lobbying firm hired by NNFA - also represent multinational pharmaceutical companies. The lobbyist web site is: [lobbycongress.com/?](http://lobbycongress.com/?) See also Open Secrets website [openscretres.org/politicians/index.asp](http://openscretres.org/politicians/index.asp) and [openscretres.org/politicians/index.asp](http://openscretres.org/politicians/index.asp) **individual contributors (including individuals employed by pharmaceutical firms) at: [opensecrets.org/indivs/org-win/indivsprofile.exe?S6UT00063](http://opensecrets.org/indivs/org-win/indivsprofile.exe?S6UT00063)**. Follow the money of international pharmaceutical companies: Pfizer, \$29.6 billion sales for 2000 at: [pfizer.com/main.html](http://pfizer.com/main.html), Aventis, \$1.12 billion in sales for 2000 (formerly Hoechst, part of IG Farben) at: [aventis.com/main/](http://aventis.com/main/), Shering Plough, over \$9 million in sales for 2000 at: [sch-plough.com/](http://sch-plough.com/), Pharmacia, over \$18 million is sales in 2000 (merger of Pharmacia & Upjohn with Monsanto Company and its G.D. Seale unit) at: [pharma.com](http://pharma.com). Wat, Watson Pharmaceuticals \$812 million in sales in 2000 at: [watsonpharm.com/](http://watsonpharm.com/) and [pfizer.com/main.html](http://pfizer.com/main.html)