

# Med-Tox Group

Strategy | Research | Documentation | Testimony

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Thomas N. Tiedt, Ph.D. | PO Box 9261, Bradenton, FL 34206 | 941-744-9397 phone/fax

September 11, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket 02N-0276**

Dear FDA:

Ephedra 'food supplement' manufacturer, marketer and distributor records revealed in litigation discovery indicate a clear and present danger, vis a vis the products themselves when used as directed as well as their abuse as likely vehicles for bioterrorism.

The intentional adding of dangerous drugs and controlled substances to food supplements typically made from poorly-defined materials from unknown and unregistered suppliers for sale to misled consumers appears to be exemplify an insidious form of bioterrorism.

Not only are hundreds-thousands of product defect reports and tens of thousands of 'secret' AERs indicated, their record keeping, product testing and quality assurance are abysmal. Ephedra pushers are in no position, nearly eight years after DSHEA passage and decades after FD&C Act passage, to responsibly or accurately assure safety from a bioterror threat.

In addition to registration and certification from company executives about appropriate monitoring of their products, ephedra pushers should also be required to register with FDA the many suppliers in their convoluted scheme to concentrate dangerous drugs and controlled substances in their food products.

Falsified registrations and certifications should be more prominently prosecuted. Certainly, the current criminal probe of Metabolife International for its false statements to federal and state government agencies is merely the tip of the iceberg. Certainly, the US Department of Justice should have the full range of the discovery documents I have reviewed.

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Trade associations defending these illegal and dangerous products should be required to register their purported inspections of ephedra product manufacturers as part of their bogus 'quality' certifications, and be investigated for RICO violations.

Retailers who prepare in any way any ephedra product should register, and certify.

My comments apply similarly to all dietary supplements, particularly those manufactured by individuals and companies with little if any 'good manufacturing' skills.

Properly, CHPA on behalf of supplement suppliers and marketers noted in its 9/4/02 comments to this docket, "...the FD&C Act also defines the term "dietary supplement," and prescribes that for most purposes, a dietary supplement shall be deemed to be a food within the meaning of this Act. Thus, it is clear that the provisions of the Act that relate to food are generally intended to cover dietary supplements as well." CHPA and other trade associations should, therefore, stop promulgating the false and illegal notion that dietary supplements need not be proven safe prior to marketing as prescribed by DSHEA.

I attach my recent invited article about DSHEA abuse, which appropriately appeared in the FDLI Update issue focused on bioterrorism (May/June 2002, [www.fdpi.org/pubs/Update/toc/2002/issue3.html](http://www.fdpi.org/pubs/Update/toc/2002/issue3.html)).

Sincerely,

A handwritten signature in black ink, appearing to be "D. H. ...", written in a cursive style.

# The Dietary Supplement Health and Education Act: Use it or Lose it

by Thomas N. Tiedt, Ph.D.

In the old days, 20 to 30 years ago, health-promoting compounds were settling into more or less discrete categories: prescription and over-the-counter (OTC) drugs, and vitamin and mineral dietary supplements. Foods, although fundamentally affecting the body's structure and function, were spared substantiation requirements except in the case of food additives. Seminal legislation in 1906, 1938, 1951, 1962, and 1976 organized and strengthened the Food and Drug Administration (FDA), and directed its mission to protecting the public from false claims and unsafe drugs, foods, additives, and supplements.

## Evolving Paradigms

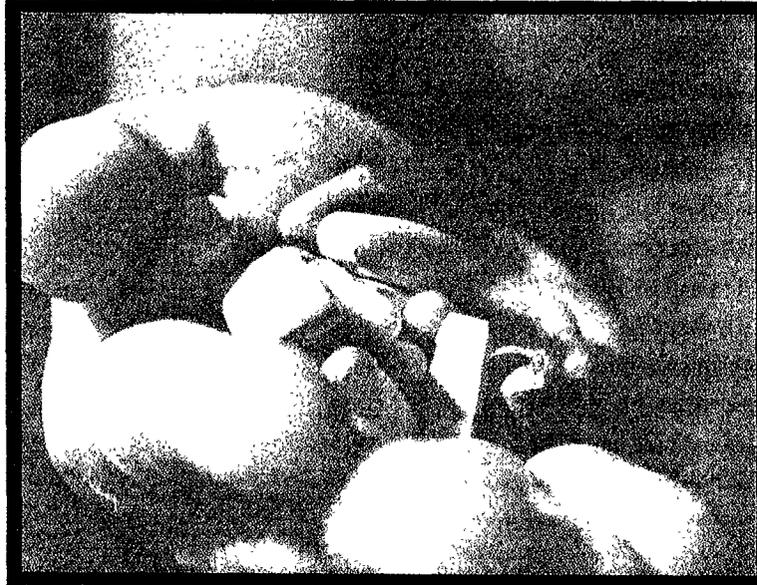
By the late 1970s, significant changes began to brew. OTC aspirin took on dramatically increased importance as new health benefits accrued with its low-dose, long-term use. The health importance of fiber and other dietary substances was more widely recognized. Ideas emerged that called for societal, rather than medical, acceptance of untested botanical substances as "naturally" safe and effective disease therapies.

Fatefully, FDA proposed in the *Federal Register*, on August 4, 1987, a monumental policy shift (i.e., allowing

health messages for foods and supplements without prior FDA approval—as long as the claims were truthful, not misleading and supported by scientific evidence), a standard that calls for far less proof of safety/effectiveness than that needed for a new drug application or food additives. Claims for dietary supplement products needed only to be consistent with generally

recognized medical and nutritional principles.

An explosion of false claims and harmful health products ensued, particularly newly marketed "dietary supplements" from unconventional low-budget companies that seemed to disregard science and medicine in their business models. Poorly designed and manufactured "health"



products sped to market—largely without medical or legal support—to treat and cure virtually every actual and perceived disease. Few of these products were nutritional or beneficial.

In February 1990, FDA attempted to rescind its well-meaning new policy, proposing instead to require prior approval procedures similar to those for foods and drugs. The dangerous milieu of false claims and untested formulas, however, had stirred enactment of the Nutrition Labeling and Education Act of 1990 (NLEA), which required prior health claim approval by FDA. As mandated by NLEA, FDA proposed food and dietary supplement health claim regulations (November 1991), but the new-age super-growth business had become a significant player in the formation of

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*Dr. Tiedt is a drug and dietary supplement consultant and Director of Med-Tox Group, Longboat Key, FL.*

policy. The ensuing Dietary Supplement Act of 1992 (DSA) placed a moratorium on the application of NLEA requirements to dietary supplements. FDA, in June 1993, proposed subjecting supplements to the requirements of foods *vis à vis* FDA's prior approval for health claims. By June 1994, FDA had promulgated its final rule.

## Changing of the Guard

FDA's rule for supplements was short-lived. The Dietary Supplement Health and Education Act (DSHEA) was enacted in October 1994, emerging from a vigorous blend of integrative, alternative, and counterculture medicine; consumer confusion; and unprecedented lobbying. DSHEA effectively voided FDA's final regulations. At industry's request, marketers—not FDA—would carry profoundly expanded responsibilities, including new legal burdens of ensuring safety and claim substantiation. DSHEA required that FDA generally would have to use the courts to act against an unsafe or unproven dietary supplement. A societal preference for deregulation was complicated when an enigmatic DSHEA provision expanded the definition of "dietary supplements" to include undefined botanicals (as long as they were dietary ingredients and not merely botanical sources of drugs).

DSHEA opened an even bigger Pandora's box than FDA's 1987 policy shift. Certainly, new science and market opportunities for supplements could benefit both public health and business. Sales for supplements now top \$16 billion annually. DSHEA confusion, however, nurtured illicit and harmful exploitation by hundreds of unqualified supplement marketers with unsupportable homemade combinations. Promoting drugs as food supplements seemingly enables marketers to bypass the research and quality controls that consumers assume are applied to all manufacturers. Hundreds of useless, and possibly harmful, supplements now

exist, and they jeopardize both sound supplement development and consumer confidence.

## Supplement Headaches

Contrary to DSHEA provisions, supplements often contain nutrients and pharmaceuticals that are concentrated and/or manipulated to help meet product performance claims, which more often than not are disease claims. In addition, vaguely defined formulas can contain presumably unintended ingredients (e.g., pesticides, heavy metals, prohibited animal parts, and denatured ingredients intended to be

pharmacologically inactive). Undefined plant ingredients typically are derived from China, whose exports notoriously test positive for unsafe contaminants. OTC drugs, prescription drugs, and controlled substances often are added at some stage in the processing of the supplement. Raw materials for purported dietary supplements are also, in some cases, being diverted to illegal drug manufacture.

With little or no funding to implement DSHEA, FDA's minimal enforcement activity produces daily media accounts of lack of supplement regulation and scientific support. Virtually untested herbal medicines, with fundamentally new formulas and health claims, raise new issues of liability and concerns about the need for new cautions in product labeling and in the advertising of mature drug products as well as supplements. As consumers are convinced by advertisements and the internet to self-medicate, increasingly combining approved drugs and unapproved supplements, adverse interactions are, predictably, increasing (e.g., toxic synergies and interference with absorption or effectiveness). Consumer confidence in dietary supplements is eroding.

Private lawsuits against supplement marketers are increasing in the form of class actions for false advertising

**"Contrary to DSHEA provisions, supplements often contain nutrients and pharmaceuticals that are concentrated and/or manipulated to help meet product performance claims, which more often than not are disease claims."**

and misconduct noted under Securities and Exchange Commission requirements, as well as in lawsuits seeking compensatory and punitive damages for adverse health events from defective products.

The opportunities afforded by DSHEA are being squandered. DSHEA called for greater marketer responsibility, more consumer education, and better dietary supplements, but little progress has been made in those areas. Like the illicit supplements that were spurred by FDA's 1987 policy shift, few post-DSHEA supplements are intended to be nutritional. Hoped-for innovation has been stifled due to the absence of legal and regulatory protections for responsible marketers to develop proprietary, well-founded supplements.

The use of the ancient medicinal component, ephedra, as a dietary substance illustrates the abuse of DSHEA on many levels. With virtually nothing spent on research and development (R&D), and with label warnings mostly focused on contra-indicated drugs, adulterated ephedra is being combined with synergistic stimulant drugs. Its "dietary" use is based on a patented ephedrine/caffeine prescription drug product approved only in Europe. Like other botanical stimulants, ephedra contains a controlled substance and is used to make other controlled substances (e.g., methamphetamine). Used by 57% of high-school students for stimulant purposes,<sup>1</sup> and by many to mistreat obesity and other diseases, ephedra is banned or contraindicated by the military, foreign governments, leading sports organizations, and both professional and government health organizations. Ephedra has no nutritional use. Accordingly, the supplement industry believes that even the dietary use of a safer form of ephedra's principle stimulant (racemic ephedrine) is illegal; its representatives testified before Congress, in March 2001, against dietary ephedra. Despite these efforts, ephedra sales keep growing and currently have reached over \$1 billion annually.

Some marketers have been jailed for selling supplements with ephedrine, or for using supplements to treat AIDS and cancer. It is unclear how many deaths will occur until the

situation attracts criminal investigations and/or congressional hearings into hazardous supplements, ineffective enforcement, and alleged encouragement of illegal drug claims by some trade associations.

## Solutions Are Taking Shape

Recent DSHEA-inspired movements show great promise. Some supplement makers are seeking a quality certification process. Third-party testing is revealing the problems of low and excess potency—an especially important pharmacodynamic consideration in view of the therapeutic claims being made. Glucosamine is being discussed as both a supplement

and a drug, and the product arguably has some musculoskeletal benefits. Trace minerals, anti-oxidants, and excipient improvements are serving as catalysts for the development of new products and the study of new health benefits. FDA is clarifying acceptable structure/function claims and unacceptable disease claims in letters to industry. And, an industry alliance has been formed to help deliver the "E" in DSHEA—education.

Much is at stake with dietary supplement development as envisioned by DSHEA. Nutrition is one of the pillars of life, and properly developed botanical sources of nutrients (and new drugs) might provide profound new health benefits. On the other hand, consuming unproven therapeutic supplements without medical support or standard

quality controls likely will pose new safety and labeling challenges, especially for FDA-approved products.

It is time to decide to implement DSHEA intensely; otherwise, the Act seems to be on a sure path to amendment or repeal. Congressional action will stir innovation and law enforcement, and can renew confidence in dietary supplements. Clearly, dietary supplement R&D and subsequent product marketing are weighty responsibilities. ▲

<sup>1</sup> Dan Morain, *Youths' Use of Supplements Decried*, L.A. TIMES, Jan. 15, 2002, at B7 (surveys show one million people between the ages of 12 and 17 have used such products, and that 57% of college athletes who use supplements report starting when they were in high school).

