

Supplements (Continued from p. 11)

the NDI," or "to put forward comprehensive safety information."¹⁵ Some dietary ingredients identified by the FDA as "new," have been marketed as herbal supplements and/or teas for decades.¹⁶

Post-market warnings

The FDA is much quicker to issue warnings related to dietary supplements than to drugs. To issue a warning, all they have to prove is that one or more individuals who took a specific supplement suffered side-effects, regardless of other health problems.

KavaKava is just one example. The FDA advisory (March 2002) associating Kava with liver damage, implied that there were no other possible causes of liver damage.¹⁷ KavaKava may yet be banned due to international pressure.

Conflicts of Interest

Red yeast rice extract—"In banning red yeast rice extract, the court upheld a strict interpretation of DSHEA, the Dietary Supplement Health Education Act of 1994, which says that once a substance has been approved as a prescription drug, it cannot be marketed subsequently as a dietary supplement even if it is completely natural and derived from food."¹⁸

Under this interpretation, it is theoretically possible for pharmaceutical companies to get the FDA to ban every beneficial herbal product by identifying its most potent ingredient, creating a synthetic form, and getting FDA approval of the synthetic form as a new drug.

In its ban on the supplements containing the natural herb ephedra, the FDA refers to them as "dietary supplements containing ephedrine alkaloids".¹⁹ Ephedrine is a synthetic form of ephedra.

The example of the 2002 L-tryptophan ban is more subtle. It was considered safe until a genetically-engineered batch from Japan caused several deaths because of production shortcuts.²⁰ The increased market for serotonin-reuptake inhibitors, such as Prozac, may be presumed to be coincidental.

Advertising and Publicity

Subtle distortion of news reports undermines confidence in dietary supplements, as Owen Fonorow explained: "Any seller that can generate 'news' articles advantageous to its image, products or services, almost 'at will,' truly has an ... marketing advantage. First, such an approach is not likely to cost much; but more important, are more likely to accept the message and to believe it. The FDA limits the amount of factual information on the benefits of supplements both on labels and in advertising. Supplement producers can be penalized for making unauthorized claims.

Negative publicity against dietary supplements is published with impunity. One example of this is a recent meta-analysis of vitamin E published on The Annals of Internal Medicine Web site.²¹ A meta-analysis is a survey of published studies. As in any other survey, the may be distorted by the design of the study.

The meta-analysis concluded that vitamin E at over 400 IU increased the risk of death. Most of the subjects in the 19 selected studies were elderly and/or chronically ill. In the selection process, "all studies reporting fewer than 10 deaths" were excluded.²²

Furthermore, "most of the studies were done on supplements of single source vitamin E, usually alpha-tocopherol"—which can be produced synthetically.²³ According to Dr Robert Verkerk, executive director for Alliance for Natural Health, alpha-tocopherol can reduce the body's absorption of other forms of vitamin E.²⁴

Our only hope

A victory in European courts for the Alliance of Natural Health is our best hope for defeating Codex. The thrust of the ANH campaign is 1) that vitamins, minerals and other micronutrients not be classified as drugs and 2) that individual countries be permitted to set nutritional standards for supplements for domestic consumption independent of the larger body—whether the European Union or the World Trade Association.

Endnotes

1 "The Codex Nutrition Committee Supplement Guidelines Final," *Health Supreme*, Nov. 2, 2004
www.codexalimentarius.net/web/index

2 Wilson, John S. and Tsunehiro Otsuki; "Global Trade and Food Supply: Winners and Losers in a Fragmented System,"
<http://econ.worldbank.org>