

FDA Redefines "Safety" of Dietary Supplements

The FDA has commissioned the Institute of Medicine (IOM) of the National Academies to develop a framework for the evaluation of the safety of dietary supplement ingredients for the Food and Drug Administration (FDA). Because this Framework is designed to increase the FDA's efficiency in compiling "scientific" (as per FDA definition) safety information on dietary supplement ingredients, it will increase the FDA's effectiveness in overcoming public support for access to dietary supplements. Also, parallels between this Framework and international agreements will set us up for harmonization of our domestic dietary supplement market with international law. The comment period for the Framework ends Sept. **, 2002. The IOM has completed a preliminary draft entitled, The Proposed Framework for Evaluating the Safety of Dietary Supplement Ingredients. The final draft will include six critical evaluations, or "monographs," on individual dietary supplement ingredients.

Ignorance is not bliss

Unless an overwhelming volume of comments are received during the comment period, consumers will lose all basis for contesting the Framework in court. The FDA is using every available technique for withholding information about this Framework:

- 1) The authors of this Framework are immune from the Freedom of Information Act because the National Academies are not part of the government.
- 2) The comment period ends before the final implementation is available.
- 3) Of the draft now available, only the first page of each chapter (13 pages out of 155) is posted on the Internet for comments. Up to eight pages of each chapter appear as OCR text, with the following instruction: "Do not use for reproduction, copying, pasting, or reading-exclusively for search engines."

What's missing?

Because of the wide range of supplements on the market, the FDA cannot evaluate them all at once, much as it would like to: "In an ideal situation, FDA would be able to immediately undertake a full safety evaluation for every supplement ingredient." The 13 pages available provide minimal information on how supplements will be prioritized:

- 1) Benefit to consumers: "First and foremost, it is important to note that this framework focuses on how to consider the safety of dietary supplement ingredients rather than offering guidance on how to consider their benefits and role in health.¹ In other words, even the most beneficial ingredients can be redefined as prescription drugs.
- 2) Widespread use: "...this framework...reflects a public health perspective that a supplement ingredient used by more individuals warrants greater attention, given similar concerns."²
- 3) Interactions with available pharmaceutical drugs The Framework includes the following statement under the heading: "THE COMMITTEE'S TASK:" "To monitor the continually evolving patterns of dietary supplement use and potential interactions with other consumed substances,... (presumably including pharmaceutical drugs)"
- 4) Similarity to available pharmaceutical drugs Not specifically mentioned in the selected pages.
- 5) Dosage restrictions based on "Risk Assessment Models": Existing risk assessment models--commissioned by the FDA and prepared by the National Academies of Science--are not specifically mentioned in the selected pages. The dosages they propose as maximum safe dosages are only sufficient to prevent the symptoms of scurvy and other forms of extreme malnutrition.
- 6) Restrictions imposed in other countries: Not specifically mentioned in the selected pages.

Other evidence of bias

The introduction includes the following statement: "Vitamin mineral supplement use by the U.S. population has been a growing trend... This is despite research-based dietary recommendations supporting the position that the best nutrition strategy for optimal health and reducing the risk of chronic disease is to obtain adequate nutrients from a wide variety of foods."³

Unfortunately, most Americans cannot afford quality and variety of food necessary to obtain adequate nutrition from food alone. As far back as 1969, the An amendment to the 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.

For more information:

See <http://www.iahf.com> What's New section- Questions for Yetley and L.Robert Lake.(U.S.) Senate's Select Committee on Nutrition and Human Needs was concerned about inadequate nutrition and diet-related illness and deaths.

How safe is safe?

To qualify as safe, supplements will be required to be safer than (prescription or over-the-counter) drugs, safer than food (except organic produce), and safer than tap water. Furthermore, in the past, FDA has removed restricted access to supplements on spurious grounds (such as natural L-tryptophan and kava kava), and there's no indication that this will change. The main difference will be that consumers will be more helpless to overturn FDA decisions.

Prototype ingredients selected

The Institute of Medicine, a branch of the National Academy of Sciences, has already selected the first six dietary supplement ingredients to be reviewed as a demonstration of the effectiveness of this framework: chaparral, chromium picolinate, glucosamine, melatonin, saw palmetto, and shark cartilage. 12

Information from industry

During the evaluation process, the FDA will review all available data, including data obtained from manufacturers. For the first six ingredients to be evaluated, "...the timeliness of this project requires that industry and other stakeholders volunteer data within one month after the time the dietary supplement ingredients under consideration are announced."⁹

Potential Regulatory Actions

Once an ingredient has been evaluated, the FDA may more easily justify the kinds of actions it has already taken to restrict access to some dietary supplements.¹⁰

They may advise manufacturers of possible contamination, notify health care professionals of possible drug interactions or safety concerns, warn consumers to discontinue use, or even request voluntary recall by manufacturers and distributors.

Concerns based on context

- The (EU) Food Supplements Directive.¹⁵
- The (EU) Traditional Herbal Medicinal Products Directive
- The (EU) Novel Foods Directive
- The Sanitary Phytosanitary agreement (SPS)
- The World Trade Organization
- The North American Free Trade Agreement (NAFTA)
- (N..AA)
- Germany, dietary supplements are produced only by pharmaceutical companies and sold only in drugstores, with prescriptions required for all but minimal-dosage formulations.¹⁴
- Codex Alimentarius
- Pharmaceutical companies are buying out as many producers of dietary supplements as possible.
- Although the proposed framework is designed to appear scientifically objective, the history of the FDA shows consistent partiality in favor of pharmaceuticals and against dietary supplements.

With very few exceptions as part of a legislative continuum... over time language of the law changes gradually for better or worse... it takes constant vigilance to protect our health freedom.

-Suzanne Harris JD, The Law Loft

(See FDA endnotes

1. Proposed Framework for Evaluating the Safety of Dietary Supplements-For Comment," © 2002 by the National Academy Press, p. 99, <http://www.nap.edu>.
2. Proposed Framework... p. 99
3. Proposed Framework... p.13
4. Proposed Framework... p. 39
5. Proposed Framework... p. 39
6. Proposed Framework... p. 39
7. Proposed Framework... p. 77
8. Proposed Framework... p. 1
9. Proposed Framework... p. 103, See also:
"FDA: Friend or Foe," The Patients' Voice, Patients for Alternative Medicine, Spring, 2001
10. Proposed Framework... p. 138
11. Proposed Framework... p. 47
12. Proposed Framework... p. 103, See also:
"Institute of Medicine to evaluate supplements," CNN.com./health, July 24, 2002, <http://www.cnn.com/health>; and Mitchell, Steve; "FDA Congress to look at supplement safety," United Press International, July 29, 2002, <http://www.upi.com>
13. "Good Manufacturing Practices for Dietary Supplements," The Patients' Voice, Patients for Alternative Medicine, Spring, 2001; See also: It Couldn't Happen Here?-Just Watch What's Happening!," The Patients' Voice, Patients for Alternative Medicine, Summer, 2001
14. Graham, Gray; CODEX-German Standards Are Not the Answer, The Patients' Voice, Patients for Alternative Medicine, Winter, 2001
15. "EU Vitamin Directive Update," The Patients' Voice, Patients for Alternative Medicine, Spring, 2002

16. Paul, Ron, M.D., R-TX. and Peter DeFazio, D-OR; "Don't Regulate Supplements!" The Patients' Voice, Patients for Alternative Medicine, Spring, 2002