

Quality Control and Product Regulation The Dietary Supplement Industry

Background

The market for herbal medications and other dietary supplements in the U.S. is a multibillion dollar industry. Sales skyrocketed five-fold between 1996 and 1999.

The number of Americans who say that they had used an herbal medication increased from 2.5% to 12.1% during this period.

The DSHEA Act

Part of this growth was fueled by the Dietary Supplement and Health Education Act (DSHEA) which was passed by Congress in 1994.

Key components of the DSHEA Act:

- Products that occur naturally can go to market without testing of safety or efficacy.
- FDA and FTC have no role in evaluating labeling claims, as long as no specific disease is named (“promote healthy joints” is OK, but “treat arthritis” is not).
- Products can be banned, but burden is on the FDA to show that a product is unsafe.

Reliability of Labels

In the more than 10 years since DSHEA was written, a huge industry has emerged which is riddled with poor quality products. Though some products contain what they claim, many have significantly more or less than what is stated on the label, and some may have dangerous contaminants.

DSHEA did give FDA authority to regulate product quality, but the FDA has been slow to act on this due to the complexity of the undertaking, budgetary constraints within the FDA as a whole, and largely behind the scenes resistance from a powerful industry lobby which is concerned about overbearing new regulations.

Standardization Issues

Standardization of herbal medicine extracts is a complex undertaking. This is partly because our knowledge of the active components in a given plant is often sketchy, but also because of the great variability in the plants themselves.

Factors that affect the variability of plant extracts include:

- What part of the plant was used (roots, stems, leaves, flowers)?
- Which species or strain of plant was used?
- What time of year was the plant harvested?
- What extraction process was used?

FDA Begins to Act - Good Manufacturing Practices

Standards and reliability requirements are coming in the form of Current Good Manufacturing Practices (CGMP's). These outline requirements for physical plants, quality control procedures, and testing of products. The FDA will have the authority to bar products which do not meet these requirements or have labels that misrepresent their contents.

Independent non-profit organizations such as U.S. Pharmacopeia (USP) will be publishing even more detailed product-specific quality standards that will complement the FDA standards and be voluntary. Products are expected soon which will bear the USP seal, indicating that they have been tested and approved by USP.

A draft proposal of these requirements was presented by the FDA in March 2003 with implementation planned over the next 2-4 years.

The impact on the industry over the coming years is likely to be profound:

- Many small manufacturers will probably go out of business.
- Costs to producers and customers will probably increase.
- Product reliability will likely improve.

A for-profit company named ConsumerLab.com has been performing quality testing on specific brands since 1999 . Information about specific products is available from their website (www.consumerlab.com). Manufacturer's who pass testing can pay to have their product listed in the free area of the Website. A full online listing of all products which passed testing is available for a yearly subscription fee of \$24. Lists of products from the free area or from the for-pay area can be printed and handed to patients.

Key References

1. Morris CA, et al. Internet marketing of herbal products. *JAMA*. 2003;290(11):1505-9.
2. Garrard J, et al. Variations in product choices of frequently purchased herbs: caveat emptor. *Arch Intern Med*. 2003;163:2290-5.
3. Larimore WL, et al. Quality assessment programs for dietary supplements. *Ann Pharmacother*. 2003 Jun;37(6):893-8.
4. FDA Proposes Labeling and Manufacturing Standards For All Dietary Supplements, March 7, 2003. <http://www.fda.gov/bbs/topics/NEWS/dietarysupp/factsheet.html>.
5. USP's Dietary Supplement Verification Program. Accessed May 19, 2004. <http://www.uspverified.org>.