The Herbal Minefield

Stephen Barrett, M.D.

Americans are now spending billions of dollars per year for capsules, tablets, bulk herbs, and herbal teas. Although many of these items are consumed for their flavor, most are probably used for supposed medicinal qualities. Sales by multilevel distributors and pharmacies amount to hundreds of millions more for products that are obviously intended for self-medication. Herbs are also marketed by naturopaths, acupuncturists, iridologists, chiropractors, and unlicensed herbalists, many of whom prescribe them for the entire gamut of health problems. Many such practitioners are not qualified to make appropriate medical diagnoses or to determine how the products they prescribe compare to proven drugs.

Herbal advocates like to point out that about half of today's medicines were derived from plants. (Digitalis, for example, was originally derived from leaves of the foxglove plant.) This statement is true but misleading. Drug products contain specified amounts of active ingredients. Herbs in their natural state can vary greatly from batch to batch and often contain chemicals that cause side effects but provide no benefit.

When potent natural substances are discovered, drug companies try to isolate and synthesize the active chemical in order to provide a reliable supply. They also attempt to make derivatives that are more potent, more predictable, and have fewer side effects. In the case of digitalis, derivatives provide a spectrum of speed and duration of action. Digitalis leaf is almost never used today because its effects are less predictable. Many herbs contain hundreds or even thousands of chemicals that have not been completely cataloged. Some of these chemicals may turn out to be useful as therapeutic agents, but others could well prove toxic.

Little Public Protection

In the United States, herbs intended for preventive or therapeutic use would be regulated as drugs under federal laws. To evade the law, these products are marketed as "foods" or "dietary supplements" without health claims on their labels. Since herbs are not regulated as drugs, no legal standards exist for their processing, harvesting, or packaging. In many cases, particularly for products with expensive raw ingredients, contents and potency are not accurately disclosed on the label. Many products marked as herbs contain no useful ingredients, and some even lack the principal ingredient for which people buy them. Surveys have found have found that the ingredients and doses of several products varied considerably from brand to brand.

• A Good Housekeeping Institute analysis of six widely available St. John's wort supplement capsules and four liquid extracts revealed a lack of consistency of the suspected active ingredients, hypericin and pseudohypericin. The study found:

- A 17-fold difference between the capsules containing the smallest amount of hypericin and those containing the largest amount, based on manufacturer's maximum recommended dosage.
- A 13-fold difference in pseudohypericin in the capsules.
- A 7-to-8-fold differential from the highest to the lowest levels of liquid extracts [1].
- A similar investigation by the *Los Angeles Times* found that 7 of 10 Dr. John's wort products contained between 75% and 135% of the labeled hypericin level, and three contained no more than about half the labeled potency [2].
- Researchers at the University of Arkansas who tested 20 supplement products containing ephedra (ma huang) found many differences in alkaloid content from product to product and between two lots of the same product. Half the products exhibited discrepancies of 20% or more between the label claim and the actual content, and one product contained no ephedra alkaloids [3]. Ephedra products are marketed as "energy boosters" and/or "thermogenic" diet aids, even though no published clinical trials substantiate that they are safe or effective for these purposes. The researchers also noted that hundreds of such products are marketed and that their number exceeds that of conventional prescription and nonprescription ephedra products, which are FDA-approved as decongestants
- The April 2000 issue of D Magazine reported that -- at its request -- a leading laboratory had tested five brands of DHEA, ginger, ginkgo biloba, ginseng, melatonin, saw palmetto, St. John's wort, and milk thistle purchased at five stores in the Dallas area. The ginger and melatonin products contained the stated amounts, but 10 of the other 30 products did not, and a few products had capsules that easily fell apart [4]
- In October 2003, the AMA Arhives of Internal Medicine reported the results of a survey of herbal products at twenty retail stores in and around Minneapolis. The chosen herbs were echinacea, St. John's wort, ginkgo biloba, garlic, saw palmetto, ginseng, goldenseal, aloe, Siberian ginseng, and valerian. The authors noted that 43% of 880 products were labeled with the ingredients and dosage that had used in published studies of the ingredients. The actual ingredients were not measured, but the survey indicated that many manufacturers failed to formulate their products to correspond with available research data. [5].

Some manufacturers are trying to develop industrywide quality-assurance standards, but possible solutions are a long way off.

The <u>Dietary Supplement Health and Education Act of 1994</u> included herbal products in its definition of "dietary supplements," even though herbs have little or no nutritional value. (The bill was spearheaded by the health-food industry in order to weaken FDA regulation of its products.) Herbal or other botanical ingredients include processed or unprocessed plant parts (bark, leaves, flowers, fruits, and stems) as well as extracts and essential oils. They are available as teas, powders, tablets, capsules, and elixirs, and may be marketed as single substances or combined with other herbs, vitamins, minerals, amino acids, or non-nutrient ingredients. Products containing multiple herbal ingredients

may produce adverse effects that are impossible to predict. A 1999 survey by Prevention magazine's found that 12% of herbal remedy users reported adverse reactions [6]

The manufacture of prescription and over-the-counter drugs is closely regulated by the FDA, But herbal products are not [7]. Even the fact that an herb is known to be toxic does not ensure its removal from the marketplace. When the FDA concludes that an herb is dangerous, it usually issues a warning rather than a ban. A few years ago, the FDA Center for Food Safety and Applied Nutrition maintained a database of reports the FDA has received of adverse events associated with the use of dietary supplements and herbal products. However, the database is no longer posted because the FDA could not be certain that the reported problems were caused by the products or occurred for other reasons.

Much Unreliable Information

To make a rational decision about an herbal product, it would be necessary to know what it contains, whether it is safe, and whether it has been demonstrated to be as good or better than pharmaceutical products available for the same purpose. For most herbal ingredients this information is incomplete or unavailable. Even worse, most published information about herbs is unreliable. The late Varro E. Tyler, Ph.D., former dean of the Purdue University School of Pharmacy and a leading authority on pharmacognosy (the science of medicines from natural sources), observed:

More misinformation about the safety and efficacy of herbs is reaching the public currently than at any previous time, including the turn-of-the-century heyday of patent medicines. The literature promoting herbs includes pamphlets, magazine articles, and books ranging in quality from cheaply printed flyers to elaborately produced studies in fine bindings with attractive illustrations. Practically all of these writings recommend large numbers of herbs for treatment based on hearsay, folklore, and tradition. The only criterion that seems to be avoided in these publications is scientific evidence. Some writings are so comprehensive and indiscriminate that they seem to recommend everything for anything. Even deadly poisonous herbs are sometimes touted as remedies, based on some outdated report or a misunderstanding of the facts. Particularly insidious is the myth that there is something almost magical about herbal drugs that prevents them, in their natural state, from harming people [8].

Two of Tyler's books (*The Honest Herbal* and *Herbs of Choice*) summarize what is known about many commonly used herbs, as do several recently published guidebooks for professionals. However, for most substances, not enough is known to make well-informed decisions about their use. The American Botanical Council, which markets many science-based herbal guidebooks, includes several unreliable books in its otherwise valuable catalog. In 1996, <u>I asked the council's executive director Mark Blumenthal to purge the catalog of books that contain highly irresponsible or quack advice</u>. When he refused, I made a similar request to Tyler, who was a member of the Council's 7-person board of trustees. But the books I complained about remained in the catalog, and several other quacky ones were added.

A study published in 2002 found that many sites located by searching for "herbs" and "cancer cure" contained illegal claims. [9] Dr. Stephen Barrett advises consumers to ignore advice from anyone who has a financial interest in the sale of dietary supplements, herbs, or homeopathic products.

Researchers from Harvard have evaluated claims made on 443 Web sites located by searching for information about eight widely used herbal supplements (ginkgo biloba, St John's wort, echinacea, ginseng, garlic, saw palmetto, kava kava, and valerian root). [10]. The researchers concluded:

- Among 443 sites, 338 (76%) were retail sites either selling product or directly linked to a vendor.
- 273 (81%) of the 338 retail Web sites made 1 or more health claims, with 149 (55%) claiming to treat, prevent, diagnose, or cure specific diseases.
- More than half (153/292; 52%) of sites with a health claim omitted the legally required standard federal disclaimer.
- Nonretail sites were more likely than retail sites to include literature references, but only 52 (12%) of the 443 Web sites provided referenced information without a link to a distributor or vendor.
- Consumers may be misled by vendors' claims that herbal products can treat, prevent, diagnose, or cure specific diseases, despite regulations prohibiting such statements. Physicians should be aware of this widespread and easily accessible information.
- More effective regulation is required to put this class of therapeutics on the same evidence-based footing as other medicinal products.

The involvement of drug companies into the herbal marketplace may improve standardization of dosage for a few products. And public and professional interest in herbs is likely to stimulate more research. However, with safe and effective medicines available, treatment with herbs rarely makes sense, and many of the conditions for which herbs are recommended are not suitable for self-treatment.

Reliable Information Sources

- The <u>Natural Medicines Comprehensive Database</u> is available <u>online</u> and in print [11] for \$92 per year (or \$132 for both versions). The online version is updated daily, while the print version is updated several times a year. A <u>recent review</u> has noted that the 1999 book covered 964 herbs and dietary supplements, of which only 15% had been proven safe and only 11% had been proven effective for the indications for which they are used [12]. The July 2000 edition covers over 1,000 substances. <u>Each month</u>, <u>Quackwatch posts one monograph from this database</u>.
- <u>AboutHerbs</u>: This Memorial Sloan-Kettering Cancer Center (MSKCC) database has more than 300 entries about herbs, dietary supplements, and "alternative" cancer treatments. Each item provides details about constituents, adverse effects, interactions, and potential benefits or problems. "Professional" and consumer versions are provided, but most of the professional information is readily

understandable by laypersons. The articles have less information than their counterparts in the Natural Medicines database, but they are researched and written quite well.

- <u>Herbal Medicines (2nd edition)</u>, which contains 148 herbal monographs, can be ordered at a discount through Quackwatch.
- The <u>Professional's Handbook of Complementary & Alternative Medicines</u>, which covers about 300 herbs and other substances, can be ordered from Amazon Books.
- <u>ConsumerLab.com</u>: Does product evaluations, including laboratory tests of ingredient levels.

Reviews of Books to Avoid

- <u>Chicken Soup & Other Folk Remedies</u> (Joan and Lydia Wilen)
- <u>The Complete German Commission E Monographs</u> (Klein and Riggins)
- <u>The Complete Medicinal Herbal (Ody)</u>
- Earl Mindell's Herb Bible (Mindell)
- <u>The English Physician (Nicholas Culpeper)</u>
- Natural Healing with Herbs (Santillo)
- <u>PDR for Herbal Medicines</u> (Fleming)

References

- 1. Good Housekeeping Institute. New Good Housekeeping Institute study finds drastic discrepancy in potencies of popular herbal supplement. News release, Consumer Safety Symposium on Dietary Supplements and Herbs, New York City, March 3, 1998.
- 2. Monmaney T. Labels' potency claims often inaccurate, analysis finds. Spot check of products finds widely varying levels of key ingredient. But some firms object to testing method and defend their brands' quality. Los Angeles Times, Aug 31, 1998.
- 3. Gurley BJ and others. <u>Content versus label claims in ephedra-containing dietary</u> <u>supplements</u>. American Journal of Health-System Pharmacists 57:963-969, 2000. [PDF]
- 4. Roffman GE. <u>Herbal remedy ripoffs</u>. D Magazine, April 2000.
- 5. Garrard S and others. <u>Variations in product choices of frequently purchased herbs:</u> <u>Caveat emptor. Archives of Internal Medicine</u> 163:2290-2295, 2003.
- 6. Survey of Consumer Use of Dietary Supplements. Emmaus, PA: Rodale Press, 1999.
- 7. <u>Hasegawa GR. Uncertain quality of dietary supplements: History repeated</u>. American Journal of Health-System Pharmacists 57:951 2000.
- 8. Tyler VE. The overselling of herbs. In Barrett S, Jarvis T, editors: The Health Robbers: A Close Look at Quackery in America. Amherst, NY: Prometheus Books, 1993.
- 9. Bonakdar RA. <u>Herbal cancer cures on the Web: Noncompliance with the Dietary</u> <u>Supplement Health and Education Act.</u> Family Medicine 34:522-527, 2002.

- Morris CA, Avorn J. <u>Internet marketing of herbal products</u>. JAMA 290:1505-1509, 2003.
- 11. Jellin JM, Batz F, Hitchens K, editors. <u>Natural Medicines Comprehensive</u> <u>Database</u>. Stockton, CA: Therapeutic Research Faculty, 1999.
- 12. Marty AT. <u>Natural Medicines Comprehensive Database</u> (book review). JAMA 283:2992-2993, 2000.

Reader Response (2/14/00)

You, sir, are the quack. How could you even think of saying, "With safe and effective medicines available, treatment with herbs rarely makes sense."? The correct statement would be: "With all those dangerous drugs available, with all those terrible side effects, treatment with herbs is the only choice." All pharmaceuticals are toxic to the human body. Over 150,000 hospital patients die every year from taking the prescribed dosage of a drug prescribed to them by their doctor. Drugs have their place -- in emergencies only -- or when a condition has become so bad that the patient is willing to deal with the side effects in order to treat the main problem. Modern "medicine" is more of a scam than herbal medicine could ever be. If people with health problems would stay away from drug stores and spend more time in health food stores, people would live longer, stay healthier, and have a better quality of life. Talk to the men who take blood pressure "medicine" and can no longer get an erection. Talk to the relatives of the men who died from taking viagra. Drugs only address the symptoms, herbs address the cause. Drugs simply mask the symptoms, herbs assist in the healing.

I have a B.S. in education from Indiana State University, have been studying natural medicine for 17 years, and have been working as a health food store manager and nutritional consultant for 7 years. My disdain for pharmaceutical industry is the result of hearing the horror stories of my customers about the side effects of the drugs they have used. Many of the herb shop customers of today are people who have had bad experiences with prescription drugs and/or doctors who won't listen to or work with them. In a way i am thankful for the drug industry, because they drive many people into health food stores. I don't mean to imply that there is no place for drugs, because there definitely is a place for them. However drugs should be the last resort.