Interest Increases in Plants as Medicine

Relatively recent technological developments have allowed improved screening of plants for potentially beneficial chemical compounds. Both public and private sectors have responded by beginning natural-products drug research. Markets for herbal remedies have also expanded, driven by increasing interest in health and alternative medicines.

The natural-plant-products industries are very diverse. It is estimated that about 50 percent of natural plant products are used in food-related industries, including medicinal infusions and unlicensed herbal remedies (dietary supplements). Another 25 percent are used in cosmetics, 20 percent in medicinal applications (ointments, creams, oils, etc.), and 5 percent for miscellaneous uses, such as insecticides and fungicides (1). Such diversity often results in various plants being used by multiple, and often unrelated, industries--for example, dietary supplements and cosmetics.

Medical Treatment Uses Plant Products

Plants are an important part of human medical treatment and health care. The World Health Organization estimates that 70 to 80 percent of the world's population relies mainly on traditional forms of medicine, of which plants are a major part. Plants also play a significant role in modern medicine. Approximately 25 percent of all prescriptions dispensed in the United States contain plant extracts or active ingredients obtained from, or patterned after, plant materials. With the worldwide prescription pharmaceutical industry assessed at roughly $150 billion, James Duke, an economic botanist with USDA, has estimated the current world market for plant-containing pharmaceuticals to be about $30 billion. Other estimates have suggested that U.S. medicinal plant imports alone could be worth over $1 billion annually.

In recent decades, there has been limited interest in research on plants for potential pharmaceutical uses. Prior to the mid-1980's, methods for screening plants were relatively slow, and only a handful of drugs made it to market from several decades of research. However, recent bioassay screening technology is faster, more thorough, and more economical than before. This helped lead to a new 5-year research program at the National Cancer Institute (NCI) in 1987, which was renewed in 1991 for another 5 years at an estimated cost of $3.8 million. In addition, several major pharmaceutical companies, specialized plant-research companies, universities, and botanical gardens have begun extensive natural-products research.

It may be years before the full economic impact of these programs is known. Discovery of useful natural compounds is only the first step. After finding a useful compound, organizations must find sources of raw materials (or alternatives such as semisynthesis or synthesis) to create large quantities of the product for extensive testing. NCI's Gordon Cragg estimates that preclinical tests, followed by clinical trials and approval by the U.S. Food and Drug Administration (FDA) may take as many as 15 years before a drug is ready for market. The cost incurred by the researching companies is tremendous, perhaps as much as $230 to $500 million in just proving a drug safe and effective to meet FDA standards. In addition, the companies generally seek patent protection, which can be a difficult task in itself, to ensure a return on investment.

Alternative Markets for Medicinal Plant Materials Expand

The costs of prescription pharmaceutical research make it difficult, if not impossible, for smaller organizations to undertake. However, the recent growth in natural food products and herbs as medicinal plants (marketed as dietary supplements) has created economic opportunities for individuals and organizations of all sizes. Steven Foster, an herb industry expert, has identified three primary markets for medicinal plants in the United States: pharmaceuticals, health and natural foods, and exports. European markets have potential, particularly Germany. In that country, herb products are manufactured according to recognized standards and allowed as treatments so long as they have no proven detrimental side effects. European phytomedicinal sales reached $2.2 billion in 1990, and have a projected annual growth of 10 percent (2).

Use statistics on natural plant products, other than for food or flavoring, are unavailable. For example, USDA Agricultural Marketing Service data on herbs are limited, and reflect only herbs used for food or flavoring. USDA Foreign Agricultural Service data on bulk dried herbs, spices, and essential oils cover only import trade at point of origin. These figures do not give any indication as to what products the herbs, spices, and oils will be used to create. They may end up in spice racks, dietary supplements, cosmetics, or personal-care items.

Because of the lack of statistics, estimating the size and growth rate of the alternative markets for medicinal plants

is a difficult task. However, the recent growth in the health food industry is probably a good indicator of overall expansion. As reported in the June 1994 *Natural Foods Merchandiser*, the volume of sales in health-food chains reached $822 million in 1993, up 23 percent from 1992. Health-food chains are defined as chains with at least 150 stores that focus mostly on vitamins, supplements, and herbs. Much of this increase can be attributed to surging sales of herbs and dietary supplements, which often include herbs, essential oils, and other plant materials. One industry expert has placed the retail value of herb products and homeopathic remedies at over $1 billion.

One of the most popular and high-valued herbs in both domestic and international markets is ginseng, a medicinal herb for which some statistics do exist. According to U.S. Fish and Wildlife Service data, nearly 1.4 million pounds of certified, cultivated ginseng were produced in the United States in 1993, mostly in Wisconsin. That same year, approximately 110,000 pounds of certified wild ginseng were collected in the United States, with large amounts coming from the Appalachian Mountain region. Ginseng prices vary greatly, depending on quality and type. American Ginseng generally sells for more than Asian Ginseng, and wild ginseng more than cultivated. U.S. Department of Commerce trade data show that nearly $80 million worth of ginseng was exported in 1993.

Growing retail sales of herbal products is evidence that many Americans are beginning to use herbal remedies as alternatives to common over-the-counter drugs. The most common uses for herbal remedies are as cold/flu medicines, laxatives, diuretics, antacids, stress reducers, and sleep aids. Interest in Chinese herbs is growing as Americans and Europeans learn about traditional Chinese medicine. One California herb-and-spice company has noticed dramatic increases in sales of ginkgo leaf and dong quai root, while maintaining solid sales of domestically grown herbs, such as echinacea and goldenseal. Other top selling herbs for various companies include chamomile flower, psyllium seed husk and powder, peppermint, licorice, and ginger (4).

Industry experts note the increasing importance of quality products, particularly organically grown herbs. Many supplement producers are looking for quality herbs to produce their formulas, which may boost domestic growers' chances to compete with imports. Many herbs are currently imported due to lower labor costs in producing countries, but as the demand for high quality and organic products grows, so to do the chances for domestic producers with highly skilled labor and ideal growing conditions, such as greenhouses. Foster suggests that farmers interested in growing medicinal plants must first do extensive research on particular commodity markets and production practices.

The Supplements Industry Now Subject to Regulation

In October, Congress passed and the President signed the Dietary Supplement Health Education Act of 1994. For the first time, dietary supplements are legally defined as vitamins, minerals, herbs, etc., intended to supplement the diet by increasing dietary intake, but not intended or represented as a conventional food or sole item of a meal or diet. This definition excludes ingredients that fit the definition of a food additive (flavoring, seasoning, etc.) or a drug.

Other major aspects of the act:

- Authorize FDA to remove a supplement from the market if it is found unsafe. The burden of proof rests with FDA.

- Authorize FDA to promulgate new good-manufacturing-practice regulations, which will be used to ensure quality products.

- Disallow direct health claims on product labels without FDA approval, but permit truthful and nonmisleading claims on how ingredients affect the body's structure or function so long as the statement is registered with the Secretary of Health and Human Services, and the following disclaimer is on the label: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." If this provision is not followed, FDA can remove the product from the market.

- Allow third party information to be made available in the store where a product is sold so long as it is truthful and nonmisleading, independent of a specific manufacturer or product, and displayed separately.

- Create a 2-year commission to evaluate a more effective health-claims approval process.

- Create a new Office of Dietary Supplements within the National Institutes of Health (NIH) for the purpose of further exploring the potential role of dietary supplements in improving health care.

Alternative Medicines and Phytochemicals Are Hot Research Topics

The Federal government is interested in alternative medicines as well. NIH now has an Office of Alternative Medicine (OAM), which conducts and sponsors research on medical practices and interventions that do not have significant documentation of safety and effectiveness in the United States, are not generally taught in medical schools,

or are generally not reimbursable by insurance companies. OAM will hold regular meetings with FDA in order to "enroll its cooperation in reevaluating the interpretation of current rules and regulations governing device, herb, and homeopathic-drug research and use" (3). Currently, OAM has issued two grants of about $30,000 each for research on Chinese herbs and their effectiveness in treating common warts and hot flashes.

OAM believes that pharmaceutical companies also may be interested in studying traditional herbal formulas, even though they may not be proprietary. If a formula was proven safe and effective and approved by FDA, the company submitting the research could possibly receive a new-drug exclusivity award that could last 3 to 5 years. During this time the company would have exclusive rights to market the formula as a drug, giving it an opportunity to receive a return on its research investment. As stated earlier, many pharmaceutical companies are indeed screening natural plant products for new drugs, but much of this research is focused on tropical plants and not necessarily on herbal remedies.

Many phytochemicals (compounds that exist in plants) have been shown to have various effects on human health, ranging from toxic to nutritionally beneficial. Scientists have begun isolating these chemicals and studying their properties. NCI's Designer Foods Program is currently working on identifying, isolating, and quantifying beneficial chemicals in foods. [Charles Plummer, (202) 219-0009]

1. Anjaria, J.V. "Herbal Drugs: Potential for Industry and Cash." *New Crops for Food and Industry*. Chapman and Hall, Ltd., London, 1989.

2. Foster, Steven. "Medicinal Plant Production: Breaking into the Marketplace." *Classic Botanical Reprints*, Volume III. American Botanical Council, Austin TX, 1992.

3. National Institutes of Health, Office of Alternative Medicine. *Functional Description of OAM*, fascimille fact sheet, April 20, 1994.

4. Peterson, Natasha. "Medicinals Expected to Lead Herbal Sales Surge." *Natural Foods Merchandiser*, Vol. 15, No. 6, New Hope Communications, Boulder, CO, June 1994.

Guayule Research Continues

Current research and recent studies on the hypoallergenic nature of guayule latex show promising results for the future demand of guayule latex products. Prior clinical tests have shown that patients who have severe reactions to Hevea latex did not react to latex derived from guayule. The results of these studies have been verified in the laboratory by Katrina Cornish and Deborah Siler, researchers with USDA's Agricultural Research Service (ARS). Their research concludes that even highly purified Hevea rubber still reacts strongly with certain antibodies, indicating that highly purified Hevea latex would not necessarily prevent allergic reactions in individuals who have already developed an allergy to Hevea.

Recent estimates indicate that as many as 17 million Americans may be affected by Hevea allergy, and this number is likely to climb as more people come in contact with latex products. Reactions can range from mild irritation to life-threatening. People with type-1 allergies to Hevea can still be affected by highly purified Hevea products, which opens the market to products such as guayule latex.

ARS is investigating commercialization opportunities for guayule latex. Small-scale processing trials of guayule latex have been successful, and guayule test plots have been grown in Arizona, Texas, and California. It is believed that even a small share of the U.S. latex glove market would be enough to make it economically feasible to produce guayule for its hypoallergenic latex, even at current yields. ARS has applied for a patent on latex rubber from guayule.