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**RE: Perspectives on Herbal Medicines; American Botanical Council Responds**

De Smet P. Herbal remedies. *The New England Journal of Medicine* 2002;347:2046–2056.

Marcus DM, Grollman AP. Botanical medicines—the need for new regulations. *The New England Journal of Medicine* 2002;347:2073–2076.

Straus SE. Herbal medicines—what's in the bottle? *The New England Journal of Medicine* 2002;347:1997–1998.

American Botanical Council. American Botanical Council calls for expert herb advisory panel: herbal science group clarifies herbal regulation issues [Press Release] [www.herbalgram.org](http://www.herbalgram.org) 2002 Dec 18.

Brody J. Herbal remedies: natural does not mean safe. *The New York Times* 2003 Feb 4.

A trio of articles published in *The New England Journal of Medicine (NEJM)* discusses the current state of the herbal medicines industry and the pressing need for new regulations to protect consumers. In the first article, Peter De Smet, Pharm.D., Ph.D. of the Scientific Institute of Dutch Pharmacists reports that the popularity of herbal medicines soared during the 1990s. By 1997, U.S. consumers were spending \$5.1 billion in out-of-pocket expenses for these products. Current regulations in the United States classify herbal products as dietary supplements, which do not need to meet the standards for drugs but instead fall under the 1994 Dietary Supplement and Health Education Act (DSHEA). According to De Smet, this means that "herbal products may be produced without the assurance of compliance [with] standards for Good Manufacturing Practice (although such standards are being developed), and they are marketed without prior approval of their efficacy and safety by the Food and Drug Administration [FDA]."

The manufacturer does not need to submit data on safety or efficacy before putting the product on the market, De Smet explains. If the safety of a product is later questioned due to reports of adverse effects, the burden of proof falls on the FDA to prove that the product is unsafe. The manufacturer is expected to make only truthful claims on the product label and to possess evidence supporting these claims. According to De Smet, under DSHEA, manufacturers are not told what constitutes sufficient evidence. Manufacturers cannot claim that their products prevent or treat diseases, but can only say that the products affect the structure or function of body systems. However, consumers may not understand this subtle distinction. In addition, pamphlets and other advertisements placed near the product at the point of sale may suggest that the product can effectively treat or prevent disease, De Smet notes.

According to the author, in order to protect the public regulations of herbal medicines must address three main issues: safety, quality, and efficacy. Regarding safety, he says, "contrary to popular belief, the use of herbal remedies can pose serious health risks." These products can cause direct adverse effects and can also interact with other drugs, sometimes in unexpected and harmful ways. Also, De Smet explains, "there is an indirect risk that an herbal remedy without demonstrated efficacy may compromise, delay, or replace an effective form of conventional treatment." Adverse effects can develop gradually over time and may be incorrectly attributed to the underlying disease. An example of this is when a patient develops hepatitis from the bile-duct remedy celandine.

Regarding efficacy, very few herbal products have ever been appropriately tested in randomized, controlled clinical trials, according to De Smet. Such studies are costly, and manufacturers are not required to conduct them. Animal studies and anecdotal reports may suggest a benefit, but these types of data cannot substitute for, or predict, the results of well-designed clinical trials. Finally, the quality of herbal medicines is directly related to their safety and efficacy. A high-quality product is free of contaminants, contains consistent amounts of the active ingredients, and is clearly and accurately labeled with the names and quantities of the active ingredients, the recommended dosage, and storage information. A major problem with herbal products is that herbs are complex mixtures of many potentially active ingredients. Sometimes the active constituent has not even been identified, and natural variations in the composition of botanical materials can make standardization very difficult. De Smet also reviews the available data on safety and efficacy for several specific herbs.

After describing the current state of the herbal medicine industry, De Smet concludes with several recommendations. He tells clinicians that they must strike a difficult balance when talking with patients about herbal remedies. They should recognize the strong appeal of herbal products and should discuss the topic in a nonjudgmental way. It is crucial that patients reveal their use of herbal remedies so that clinicians can evaluate and explain the risks of drug interactions and adverse effects, as well as any available data on potential benefits. To do so, clinicians must stay informed and up-to-date about research on herbal medicines.

The next *NEJM* article is by Donald Marcus, M.D. of Baylor College of Medicine and Arthur Grollman, M.D. of the State University of New York. They provide additional perspective on the need for new regulations of the herbal (botanical) medicine industry. They discuss issues including adulteration of botanical products, lack of standardization, the potential for herb-drug interactions, and failures in the reporting of adverse events. According to the authors, when manufacturers learn of adverse events that may be related to their products, they are not required to keep any records of them, investigate them, or report them to the FDA. In addition, most adverse events go unrecognized, or if recognized they still go unreported. "Only 10% of serious adverse effects associated with the use of prescription drugs are ultimately reported to the FDA," the authors note. "Less than 1 percent of adverse events caused by dietary supplements, including herbs, are reported to FDA. Only a fraction of these are adequately investigated," they add.

Marcus and Grollman conclude that the regulation of the herbal medicine industry is inadequate and outline six legislative proposals that would better protect consumers while still allowing them access to such products. These proposals for reform include requirements that manufacturers obtain premarketing safety approval from the FDA, show that they are using good manufacturing practices, and report all adverse events promptly to the FDA. "Manufacturers of supplements should assume and bear full responsibility for ensuring the safety of their products," Marcus and Grollman say. They call for "vigorous and concerted action" to inform Congress and the public about the urgent need for new legal safeguards and the need for funding to put the safeguards into effect. They add that strong opposition to their proposal from the herbal industry is likely.

Additional views and perspective are provided in the third *NEJM* article, by Stephen Straus, M.D. of the National Center for Complementary and Alternative Medicine (NCCAM). Straus refers to the burgeoning use of herbal medicines as a "public health experiment that much of academic medicine has failed to acknowledge until recently." He agrees with De Smet, Marcus, and Grollman that there are "serious problems with the overall quality, safety, and efficacy of herbal products." Straus also points out that "what is on the label may not be what is in the bottle." He illustrates this point with a figure showing that the amounts of active ingredients actually in certain ginseng products ranged from 11.9% to 327.7% of the amounts indicated on the labels. Straus calls for additional research on the healing potential of herbs, tempered by a focus on improved quality of both research data and herbal products themselves. He characterizes the mission of NCCAM as building a "research enterprise that subjects complementary and alternative medicine to open-minded, hypothesis-driven investigation." Straus adds that some people consider these efforts to be pointless, but the majority has been very supportive of the center's work.

The American Botanical Council (ABC) responded to this set of *NEJM* articles in a press release dated December 18, 2002. Mark Blumenthal, Founder and Executive Director of ABC, comments that "many of the issues raised in the article [by Marcus and Grollman] and the proposals are not really new, and, in some cases, may not be feasible." Blumenthal notes that for many years ABC has recommended that a special expert committee be convened to assess the safety and efficacy of herbs sold in the U.S. In response to this proposal by ABC and other testimony, two White House Commissions have recommended establishment of

an expert advisory panel for evaluating herbal products. Blumenthal also notes that in 1998 ABC translated and published *The Complete German Commission E Monographs* to provide the American public with accurate information about the responsible use of many herbs that are considered medicines in Germany.

Blumenthal calls on the FDA to "fully enforce the existing laws and regulations," noting that "many experts believe that FDA has adequate authority to protect the public." However, Blumenthal also notes that the FDA has been slow to accomplish certain key goals, such as releasing new Good Manufacturing Practices designed for dietary supplements and responding to manufacturers' petitions requesting over-the-counter drug status for certain herbs. Other Western countries have made more progress than the United States in regulating herbal products to improve safety, quality, and efficacy; their achievements may prove instructive to the United States, Blumenthal adds.

Finally, in a *New York Times* article entitled "Herbal remedies: natural does not mean safe," Jane Brody alerts consumers to the risks of using herbal products while acknowledging that not all of these products are dangerous. Brody reviews the *NEJM* articles for her readers, highlighting the points of greatest interest and importance to consumers.

The article begins with the hypothetical example of a woman with high blood pressure who is urged by a friend to go see an herbalist. The woman does so and purchases a bag of herbal remedies that she knows nothing about. She does not discuss the herbs with her physician. "Are they safe? Are they pure? What drug effects do they have? And what side effects? Will they interact badly with her prescriptions and cause her blood pressure to plunge dangerously low?" asks Brody. The author goes on to warn readers that herbal products remain unregulated and do not have to meet the same standards as drugs do for safety and purity. Herbal medicines may be contaminated with toxic metals, pesticides, plant chemicals, and microorganisms that may cause disease.

Although some products have been tested in clinical trials and are made by reputable manufacturers, "reports of disastrous effects abound," Brody says. According to the author, the situation is even worse than it appears, because these reports of side effects and adverse reactions are just a small fraction of the effects that actually occur; most go unreported. Brody concludes that until herbal medicines are properly regulated to protect consumers, the old adage applies: "let the buyer beware."

—Christina Chase, MS, RD

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