“We must acknowledge that herbal supplements are drugs and should be regulated as such.”

The FDA Should Tightly Regulate Herbal Supplements

Joe Dobrin

In the following viewpoint, Joe Dobrin argues that the U.S. Food and Drug Administration (FDA) should impose strict regulations upon herbal supplements. Because some of these supplements have proven dangerous, Dobrin maintains that the FDA needs to ensure the public of the purity and safety of all herbal products. In order to do this, Dobrin states, the FDA must have the enforcement powers to regulate herbal supplements in the same manner that it regulates other drugs.

As you read, consider the following questions:

1. As Dobrin relates, what have been the dangerous properties of yohimbine and androstenedione?
2. What does Dobrin claim are the two reasons that regulatory enforcement of supplements is currently ineffectual?

Joe Dobrin, “A Call to Pharms: The Need for Tighter FDA Regulation of the Neutraceutical Industry,” Mount Sinai Journal of Medicine, vol. 73, no. 2, March 2006, pp. 565–66. Copyright © 2006 Mount Sinai Journal of Medicine. This material is used by permission of John Wiley & Sons, Inc.
3. What “loophole” in the FDA regulatory guidelines does Dobrin say supplement makers exploit in marketing their products?

Beverly Hames sought a natural remedy for her persistent backaches. She visited an acupuncturist, who gave her a list of Chinese herbal preparations, some of which contained aristolochic acid. Two years later her kidneys began to fail. She ultimately received a kidney transplant and must now take anti-rejection medication for the rest of her life. Only later did she learn that the sale of aristolochic acid has been banned in several European countries due to its carcinogenic properties and its association with kidney failure. The Food and Drug Administration (FDA) issued a consumer warning in 2001, but the product remains on the market in the U.S.

Unfortunately, Ms. Hames’ experience, cited in the May 2004 edition of Consumer Reports, is not unique. Many people take herbal supplements (also known as “neutraceuticals”) under the mistaken impression that they are safer than regulated pharmaceuticals because herbal remedies are “natural” and don’t contain “chemicals.” The herbal supplement industry exploits this ignorance by implying that substances derived from plants are safer than chemicals synthesized in a lab. In fact, however, the active ingredients in herbal supplements are chemicals.

Dangerous Substances

Although most herbal supplements are benign, some of these chemicals induce dangerous reactions in the human body. Aristolochic acid is far from the only chemical in herbal supplements currently on the market that has been associated with serious morbidity. The sexual stimulant yohimbine has been associated with heart and lung disease. The muscle-enhancing steroid androstenedione (andro), made famous by the baseball slugger Mark McGwire, increases cancer risk and decreases HDL (good) cholesterol. And kava, commonly found