BOX 8.3 The Herbal Supplement Industry

The lack of regulation of the prosperous supplement industry provides a stark reminder of why reasonable regulations are needed for food and medicines. The supplement industry produced about $32 billion in revenue in 2012 and is projecting an increase to $60 billion in 2021.[60]

Dietary supplements now account for almost 20% of drug-related liver injuries that turn up in hospitals, up from just 7% a decade ago.[61] Many adults combine prescription drugs and supplements in ways that can lead to serious side effects.[62]

"It's really the Wild West," said Dr. Herbert L. Bonkovsky, Director of the Liver, Digestive and Metabolic Disorders Laboratory at Carolinas HealthCare System in Charlotte, NC. "When people buy these dietary supplements, it's anybody's guess as to what they're getting."

Americans spend an estimated $32 billion on dietary supplements every year, attracted by unproven claims that various pills and powders will help them lose weight, build muscle,

and fight off everything from colds to chronic illnesses.[63] About half of Americans use dietary supplements, and most of them take more than one product at a time.

The supplement business is largely unregulated. In recent years, critics of the industry have called for measures that would force companies to prove that their products are safe, genuine, and made in accordance with strict manufacturing standards before they reach the market.

But a Federal law enacted in 1994, the Dietary Supplement Health and Education Act, prevents the US Food and Drug Administration (FDA) from approving or evaluating most supplements before they are sold.[64] Usually, the agency must wait until consumers are harmed before officials can remove products from stores. Because the supplement industry operates on the honor system, studies show the market has been flooded with products that are adulterated, mislabeled, or packaged in dosages that have not been studied for safety.

The FDA estimates that 70% of dietary supplement companies are not following basic quality control standards that would help prevent adulteration of their products. Of about 55,000 supplements that are sold in the United States, only 170 (about 0.3%) have been studied closely enough to determine their common side effects, according to Dr. Paul A. Offit, the Chief of Infectious Diseases at the Children's Hospital of Philadelphia and an expert on dietary supplements.[65]

"When a product is regulated, you know the benefits and the risks and you can make an informed decision about whether or not to take it," he said. "With supplements, you don't have efficacy data and you don't have safety data, so it's just a black box."

A second trend emerged when Dr. Victor Navarro and his colleagues studied 85 patients with liver injuries linked to herbal pills and powders. Two-thirds were middle-aged women, on average 48 years old, who often used the supplements to lose weight or increase energy. Almost a dozen of those patients required liver transplantation, and three died.[61]

It was not always clear what the underlying causes of injury were in those cases, in part because patients frequently combined multiple supplements and used products with up to 30 ingredients, said Dr. Herbert Bonkovsky, an investigator with the network. One product that patients used frequently was green tea extract, which contains catechins, a group of potent antioxidants that reputedly increase metabolism. The extracts are often marketed as fat burners, and catechins are often added to weight-loss products and energy boosters. Most green tea pills are highly concentrated, containing many times the amount of catechins found in a single cup of green tea, noted Dr. Bonkovsky. In high doses, catechins can be toxic to the liver, and a small percentage of people appear to be particularly susceptible.

But liver injuries attributed to herbal supplements are more likely to be severe and to result in liver transplantation, according to Dr. Navarro. Unlike prescription drugs,

which are tightly regulated, dietary supplements typically carry no information about side effects. Consumers assume they have been studied and tested, but that is rarely the case. "There is this belief that if something is natural, then it must be safe and it must be good," he said.

There are a number of salesmen who have taken advantage of the absence of regulation. For example, Joseph Mercola, who markets a variety of controversial dietary supplements on his website, has been warned by the FDA to stop making illegal claims regarding his products' ability to detect, prevent, and treat diseases.[66,67] The medical watchdog site *Quackwatch* has criticized Mercola for making "unsubstantiated claims [that] clash with those of leading medical and public health organizations and many unsubstantiated recommendations for dietary supplements."[38] Ironically, Mercola has demanded more testing of crops made from genetic engineering despite the fact that genetically engineered crops are the most highly regulated crops on the market. Mercola has been the subject of criticism from the business, regulatory, medical, and scientific communities. A 2006 *BusinessWeek* editorial criticized Mercola's marketing practices as "relying on slick promotion, clever use of information, and scare tactics."[68]

Consumers deserve regulation of products that are potentially harmful, such as supplements, not ones that pose little danger, such as genetically engineered crops.