

Dietary Supplements: How Family Physicians Can Address Safety Concerns by Working with the FDA

NORMAN S. MARKS, MD, MHA
*U.S. Food and Drug Administration (Retired),
Silver Spring, Maryland*

The nation's physicians rely on the U.S. Food and Drug Administration (FDA)—the first consumer health protection agency created following the Pure Food and Drug Act of 1906—to safeguard all medical products prescribed for our patients. However, the FDA continues to have only limited oversight of more than 85,000 dietary supplements of uncertain effectiveness or safety, often used by patients without their family physician's knowledge.

That is why it was troubling to hear of the death of a healthy 18-year-old Ohio student attributed to an acute cardiac arrhythmia from an unintentional overdose of caffeine.^{1,2} The student athlete ingested about 1 teaspoon of a powdered caffeine product to enhance exercise performance, inadvertently consuming the equivalent of more than 30 cups of strongly brewed coffee in a single dose. Members of Congress and a respected food safety group, the Center for Science in the Public Interest, have called for FDA action to ban all bulk caffeine products sold directly to patients.^{3,4} In December 2014, the FDA announced that it was looking into this product safety issue and working on next steps.⁵ Since then, it has issued warning letters to several powdered caffeine manufacturers and updated its dietary supplements web page to include information on safety concerns for powdered caffeine products.⁶

Caffeine is regulated by the FDA as a food additive, dietary supplement, and drug, and it remains available for sale online in formulations that are dangerous because of the inability of our patients to determine a safe dose without a measuring scale. Promoted widely for its noticeable ergogenic effect during high-intensity exercise (e.g., weight training), powdered caffeine is used by

adolescent athletes in the hope of enhancing workout performance.⁷⁻⁹ The 100- to 300-g containers sold online for \$20 or less include 10 to 30 lethal doses of powdered caffeine.

Your patients are likely using some type of dietary supplement, whether they tell you or not. More than one-half of U.S. adults consume a dietary supplement daily, with use growing steadily over the past decade.¹⁰ Many supplements that claim to enhance specific elements of health (e.g., stamina, sexual performance, bone joint health, mental acuity) are found to be ineffective for the purported benefit or found to be toxic, harmful, or even deadly.^{11,12}

Few patients or physicians understand that the FDA does not have the authority under current law to approve or monitor dietary supplements in the same rigorous fashion as its postmarket surveillance of prescription drugs.¹³ In contrast, consider the antihypertensive medication that you prescribed today. The FDA can assure you and your patient that the drug dispensed by the pharmacy is of the quality, security, and integrity expected in the United States—safe when used as specified in the prescribing information approved by the FDA.

The Dietary Supplement Health and Education Act (DSHEA) of 1994 made supplement manufacturers responsible for ensuring that their products are safe, essentially using an honor system. The supplement that your patient is taking under DSHEA is presumed to be safe and effective; manufacturers do not need FDA approval before selling their product. The FDA mainly depends on physicians and patients to recognize and report unexpected safety issues. This must occur before any steps can be taken to evaluate the safety signal, create a risk mitigation plan, warn the public of newly discovered safety concerns, and, if risk mitigation fails, remove the supplement from the market.¹⁴

Under authority recently granted by Congress, the FDA can now require dietary supplement manufacturers to report a serious adverse event when they become aware

of it. Unfortunately, no active surveillance is required by the manufacturer,¹⁵ and it is estimated that the FDA receives reports for less than 1% of all serious adverse events associated with dietary supplement use.^{16,17}

Under these constraints and faced with limited resources, the FDA has implemented a program that monitors products pulled from store shelves or sold online with claims for weight loss, improved sexual performance, and muscle growth. The agency is identifying many products that are sold with claims to be supplements but that instead have been adulterated with undeclared prescription drug ingredients, including corticosteroids, phosphodiesterase type 5 inhibitors, or sibutramine.¹⁸ Serious drug-drug interactions leading to hypertension or hepatic or cardiac toxicity have been documented.^{19,20}

What can a physician do to support and protect patients from harm if they choose to use readily available dietary supplements? Don't expect a change in law or regulation anytime soon that would permit the type of monitoring we count on from the FDA to keep our prescription and over-the-counter medications safe. Instead, the FDA will continue to rely on primary care physicians to counsel and educate patients about supplement use. In recent years, excellent science-based information, including quick health professional references and patient fact sheets, has become easily accessible online from federal agencies and private sources.²¹⁻²⁴ Most importantly, the FDA needs the active support of physicians in identifying and voluntarily reporting suspected serious adverse events or product quality concerns to MedWatch, the FDA reporting program (<http://www.fda.gov/Safety/MedWatch/>). These reports can then trigger the investigation, evaluation, and risk mitigation actions that can avert future patient harm from dietary supplement use.

Address correspondence to Norman S. Marks, MD, MHA, at normmarks@gmail.com. Reprints are not available from the author.

Author disclosure: No relevant financial affiliations.

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