Find way to focus on dietary supplement safety, experts say

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A former principal deputy commissioner of the U.S. Food and Drug Administration is proposing a solution to the current gridlock over the regulation of dietary supplements: Focus less on whether these vitamins, minerals and herbal extracts actually do what they claim and instead take important steps to improve their safety.

Joshua M. Sharfstein, MD, associate dean for public health practice and training at the Johns Hopkins Bloomberg School of Public Health, and Akshay Kapoor, MSPH, a recent graduate of the school, argue that the market for dietary supplements is riddled with unsafe products that may be spiked with pharmaceuticals, poorly manufactured or absent the stated ingredients.

Yet despite hundreds of recalls and outbreaks associated with death and disability, federal law on supplements has not shifted to strengthen oversight and protect the integrity of the market. What's keeping progress from being made, Sharfstein and Kapoor say, is an ongoing dispute over whether the products work. Manufacturers and many consumers think they do. Many public health officials and doctors think they don't. Calling a truce on these questions of efficacy, Sharfstein and Kapoor argue, can bring people together to improve safety.

Their paper appears Nov. 2 in the journal *Drug Testing and Analysis*.

"The key equation in drug regulation is benefit versus risk. That is, do the potential benefits from using the drug outweigh the potential risks?"

Sharfstein says. "This framework, however, has led to gridlock for dietary supplements. An alternative framework is access with safety. That is, can we find a way ensure that dietary supplements are safe for consumers to take?"

Surveys have shown that Americans want assurance that their supplements will be safe, but they want to make their own decisions about whether they are effective.

Sharfstein says that many manufacturers would likely support stronger safety controls if they were not tied with greater scrutiny of claims about the products. These perspectives open a door to compromise that advances safety and protects public health, Sharfstein and Kapoor say.

A recent study in the New England Journal of Medicine estimated 23,000 emergency department visits in the United States every year can be attributed to adverse events related to dietary supplements. Roughly 100 million Americans purchase supplements each year, including calcium for osteoporosis and multivitamins for general health as well as supplements for sexual dysfunction, joint health and weight loss. U.S. sales of dietary supplements reached an estimated $36.7 billion last year, according to the National Institutes of Health.

Federal law allows manufacturers to make many types of claims, though they are not permitted to make claims about treating or preventing specific diseases such as diabetes, cancer or heart disease. The FDA's authority over dietary supplements is limited by federal law and has left the agency unable to protect consumers effectively, Sharfstein says.

The FDA also has limited capabilities when it comes to overseeing manufacturing standards for supplements. There are by most estimates at least 15,000 domestic and international manufacturers of supplements sold in the United States, with most of the raw materials originating

overseas. Across all of these manufacturers, FDA conducts just 400 inspections of their facilities a year, the researchers say. The agency finds significant deficiencies in about two-thirds of all the inspections it conducts, with most facilities cited for multiple, serious violations.

Hundreds of times a year, FDA recalls dietary supplements that contain pharmaceuticals. Examples include tainted sexual enhancement products that contained prescription erectile dysfunction drugs sildenafil (Viagra) and tadalafil (Cialis); weight-loss products containing banned pharmaceuticals; and sports supplements that contain antihistamines and anabolic steroids. However, research has shown that recalled supplements are still available for sale and that efforts by FDA to keep tainted products from reaching the market in the first place have not been successful.

Sharfstein and Kapoor say progress on safety can proceed in three phases. The first would be a requirement for manufacturers to register each dietary supplement product with the FDA and greater authority for the FDA to require more detailed disclaimers on products so the public better understands the nature of the agency's oversight. Requiring registration of supplements would give the FDA the opportunity to deny manufacturers that have poor track records the ability to sell new supplements.

A second phase would have the FDA establish standard manufacturing procedures accompanied by a standard laboratory technique to characterize each product sold, making manipulation and adulteration of products more difficult.

The third phase would give the FDA enhanced authority to strengthen surveillance of potential adverse effects with the authority to suspend sales during an agency review when there is sufficient concern and to remove ingredients that pose a significant risk. Such a standard would be

far more effective than the current approach, which sets an unreasonably high standard for action, Sharfstein says.

"Stories in the media about bad outcomes associated with some supplements are gaining traction and the behavior of some manufacturers could tarnish the image and reputation of the entire industry," Sharfstein says. "It's time we actually made progress and we're going to have to find a path to do it. We need to think about safety first."

More information: "Breaking the Gridlock: Regulation of Dietary Supplements in the United States" was written by Akshay Kapoor and Joshua M. Sharfstein.

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