

Joshua M. Sharfstein, M.D. -- Council for Responsible Nutrition Annual Symposium for the Dietary Supplement Industry

Remarks of Joshua M. Sharfstein, M.D.
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at

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Thank you for the opportunity to speak with you today. I have been on the job for about six months, and each day brings new experiences ... as well as a new and deeper understanding of the span of the agency and the scale of its challenges.

FDA-regulated products touch the lives of every American multiple times a day – from our toothpaste in the morning to most of our breakfast, lunch, and dinner... to the medications, vitamins, and other supplements we rely on for our health.

Personally, I rely on a supplement – lactase enzyme -- almost every day to help digest dairy products. I decided to try this supplement after talking to a cousin of mine ... at my wedding.

My just-married wife was skeptical. She was even a little reluctant to let me run out to a pharmacy before heading to the airport. But in what proved to be a good sign for our future together, she let me anyway ... and I was able, on our honeymoon, to have ice cream for the first time in more than 15 years.

The reach of FDA is vast – and the responsibility is tremendous. FDA oversees products representing about 20 cents of every dollar spent by U.S. consumers – more than 2 trillion dollars worth.

FDA's mission is to protect the public health ... keeping the public from harm while supporting innovation and quality in a wide range of products.

This is an enormous challenge. And it is one we cannot meet alone.

Companies are primarily responsible with providing consumers with quality and safe products. The FDA's job is to set science-based standards and provide effective oversight and enforcement.

This shared responsibility is true for drugs, devices, cosmetics, vaccines, foods ... and for vitamins and other supplements.

In recent years, we have made important strides in dietary supplement safety.

Each step is a step that FDA and the industry have taken together.

For example, we have worked together to implement new provisions mandating reporting of serious adverse events. Implementation of these provisions will help the agency identify unsafe products ... warn the public about them ... and remove them from the market.

We also worked together to develop dietary supplement current good manufacturing practice requirements. These requirements will enhance the quality of the products provided to consumers.

I thank the Council for Responsible Nutrition and all of the companies who participated in these regulatory processes for their input and help. The public is counting on a safe supply of supplements, and these actions are important steps in this direction.

But we are not there yet.

There are products marketed as dietary supplements today that pose serious risks to consumers – in some cases, life-threatening risks. Addressing this problem is critical for consumer health and for consumer confidence in the dietary supplement industry.

One of FDA's biggest concerns is the problem of dietary supplements spiked with potentially dangerous pharmaceuticals. Exhibit A is anabolic steroids. Online, in gyms, and in stores, products sold as dietary supplements can contain steroids ... steroids that threaten the health of athletes young and old, professional and amateur. Risks include serious liver injury, kidney failure, and serious psychiatric changes.

The steroid problem is the most high profile safety issue facing the nation's supplement supply. Recently, at a hearing before the Senate Judiciary Committee, the chief executive officer of the U.S. Anti-Doping agency testified that elite athletes are "testing positive for banned drugs because they were taking products that were either accidentally contaminated or purposefully spiked by manufacturers with designer steroids, stimulants, or other drugs."

He also said that "the more we have learned about the prevalence of these dangerous drugs in allegedly 'healthy' products, the clearer it has become that this problem extends well beyond elite level athletes and is impacting an ever-increasing number of American consumers."

And he told the story of Jareem Gunter, a college student who took a product marketed as "100% legal to sell." The product contained steroids. Jareem suffered acute liver failure and almost died.

The problem of steroids in the nation's supply of dietary supplements has been recognized by your industry's leadership. The acting CEO of the Natural Products Association recently explained to the press that the dietary supplement industry is being "victimized by a guerrilla-style criminal drug peddling operation."

The result is not just damage to individuals but damage to the entire industry. People can hear these stories and believe that the entire supply of supplements is tainted.

How can we fix this problem?

Let's start with the obvious. Companies must follow and FDA must enforce the existing law.

With respect to steroids, we have committed substantial resources to finding illegal products and taking action. Recently, after an extensive investigation, FDA executed a criminal search warrant and issued a warning letter against American Cellular Laboratories. FDA also recently executed a criminal search warrant at Bodybuilding.com and seized over 60 dietary supplements containing steroids. In 2008, FDA acted to seize \$1.3 million in illegal synthetic steroid supplements.

This summer, FDA also issued a public warning calling on consumers to "stop using body building products represented as containing steroids or steroid-like substances."

We intend to continue this aggressive enforcement and education. But given the scale of the problem, these steps alone will not be enough.

What else can be done?

Recently, the American Herbal Products Association suggested to FDA that the solution to steroids was to use the same strategy we are using to fight fraud related to H1N1 influenza. However, there are significant legal barriers to applying this same strategy to supplements.

For H1N1 fraud, FDA can act against products as soon as we identify unlawful claims related to H1N1. So far, we have taken steps to halt the distribution of more than 120 products making illegal claims about preventing or treating H1N1.

For many claims that appear on dietary supplements containing steroids, however, we usually cannot take action based on these claims alone. The claim of enhancing muscle bulk is not necessarily ground for action, because we may not have evidence that the claim is false or misleading.

As a result, to take action, we must often demonstrate that steroid ingredients are present in these supplements.

This is more complicated than checking the ingredient list. Each steroid ingredient can have numerous different names, many of which are obscure, chemical names. Some may be nicknames given to the compound by the manufacturer. These products are frequently mislabeled. Frequently, the agency will send the product to the lab for analysis. This is a highly technical, expensive, and time-consuming undertaking.

We must develop new tools and approaches to succeed.

An important step is to develop all the tools DSHEA gives us for improving the safety and quality of dietary supplements.

One such tool is the agency's ability to review new dietary ingredients, or NDIs. An NDI is a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994.

Although DSHEA excludes from premarket notification "grandfathered" dietary ingredients that were marketed before DSHEA became law, dietary supplements that contain new dietary ingredients must submit a 75-day pre-market notification to FDA. This provides FDA a chance to review the safety of the supplement that contains the new dietary ingredient before consumers can use the product.

Dietary supplements containing new dietary ingredients for which this notification is not provided are illegally marketed.

So far, we have been hampered by the fact that no verified list of grandfathered ingredients exists.

But here's what we can do. We can set out guidance explaining how to demonstrate that a product is in fact grandfathered in. Then, when we see concerning products we do not believe were marketed prior to October 15, 1994 on the market, we can ask companies to provide evidence of prior marketing ... or to voluntarily pull the product until an NDI premarket notification is filed.

For this approach to work as well as possible, we must also provide clear standards and prompt review for new ingredients. This will allow us to support legitimate products ... while acting to remove risky ingredients quickly from the market.

We will have to work together to make such a system work effectively. This will not solve the problem of undeclared ingredients. But it will be further our joint interest in keeping unsafe products off the shelves.

Another tool under existing law is the dietary supplement GMP regulation. Issuance of such a regulation was specifically authorized by Congress. Implementation of cGMPs across the industry is an important step in assuring the quality of dietary supplements, and the industry's cooperation here has been critical. FDA is committed to extending these protections across all companies producing vitamins and other supplements.

Effective cGMPs will stop some of the contamination of products in the market ... and will help consumers be assured that the products they intend to purchase are the ones they are actually getting.

Another tool in FDA's arsenal for protecting the public health is post market surveillance of dietary supplements. FDA, as you know, does not review your products for safety prior to marketing. As a result, evaluation of adverse event reports is one of FDA's main tools in

identifying potentially life threatening toxicities. Your continued effort in providing complete and well documented serious adverse event reports, with vigorous follow-up, will greatly assist FDA in protecting consumers from further harm.

Our work together on new dietary ingredients, cGMPs, and serious adverse event reporting will be helpful in addressing the safety challenges facing the supplement industry. But I cannot tell you yet how helpful. A key part of a public health strategy is assessment and reevaluation. As we move forward, we must keep in close communication about the progress we are making. And both FDA and industry should be open to other ideas as well.

We are also thinking about the future.

In the past two years, we have seen contamination of a drug – heparin – leading to a number of deaths and the disruption of clinical medicine around the country. We have seen melamine poisoning of pet food in the United States and infant formula in China. And we have seen numerous over-the-counter medications poisoned with diethylene glycol in developing countries.

What keeps Dr. Hamburg and me up at night should worry you as well – the safety of the supply chain in an increasingly globalized world.

There are criminals out there who will dilute your ingredients with dangerous additives --- from melamine to diethylene glycol to lead and arsenic. There are criminals who might claim to sell you one chemical and actually provide another.

Because you are ultimately responsible for the product you put on the market and its impact on consumers, every company in the supplement industry should be responsible for where you are purchasing their ingredients. When you find problems, you should notify the FDA, so we can take action to prevent these ingredients from being sold by other companies in your industry.

I very much enjoyed meeting last week with the leadership of the American Herbal Products Association, the Natural Products Association, the Consumer Healthcare Products Association, and the Council for Responsible Nutrition. We agreed on many topics, including the need to collaborate on solutions to the challenges facing the industry and FDA ... to improve consumer health and consumer confidence.

I see this visit today and our continuing discussions as important steps in that process.

Thank you very much. And I look forward to your questions.