

Statement of the Honorable Orrin G. Hatch
Senate Special Committee on Aging Hearing
“Dietary Supplements: What Seniors Need to Know”
May 26, 2010

Mr. Chairman, the issue before the Committee today is extremely important to my home state of Utah and my fellow Utahns. I want all Americans, including senior citizens, to have the best and most accurate information about the dietary supplements they use.

False health claims about these products – on the Internet, in newspaper ads or on product labels are illegal today. So is selling contaminated dietary supplements. Companies engaging in these types of activities are breaking the law and, therefore, should be taken off the market immediately. That power is granted through current law, so amending that law is not necessary. What is necessary is providing the Food and Drug Administration (FDA) the funding it needs to properly enforce and implement current law.

As an original author of the 1994 Dietary Supplement Health Education Act (DSHEA) and the Nonprescription Drug Consumer Protection Act of 2006, I feel it is important for Committee members to understand the history behind these laws.

Senator Tom Harkin and I were the lead sponsors of both bills, which enjoyed strong bipartisan support. In fact, DSHEA passed the Senate twice by unanimous consent and the House of Representatives once by unanimous consent.

DSHEA established a statutory framework for the FDA so that dietary supplements are regulated as foods. The law grandfathered U.S. dietary supplements already on the market at the time of its enactment because these products had a history of safe use.

DSHEA also includes a strong safety standard so that potentially harmful products could be removed from the market. Through DSHEA, the FDA has an *imminent hazard* authority it may use to immediately remove an unsafe product from the market.

The law also requires manufacturers to submit marketing safety information to the FDA about any new ingredients not previously marketed. This information must be submitted to the FDA 75 days prior to putting a product on the market.

Another key provision authorized issuance of good manufacturing practice (GMP) standards so that FDA inspectors could ensure products are being manufactured in compliance with the law.

One of my biggest frustrations was that once DSHEA was signed into law, it took the FDA many years to implement the GMP standards.

Today, these GMP standards apply to large- and medium-size manufacturers and, in a few weeks, will apply to small manufacturers.

Finally, DSHEA required that all ingredients on dietary supplements be listed on the label and that any claims made must be truthful and not misleading. Misleading claims or labels are a violation of the law, and the FDA should take products with misleading claims and labels off the market. Period!

Some have argued that dietary supplements should be subject to pre-market approval, but let me explain why this is not done. Most dietary supplements have been used safely for years and raise no concerns warranting the time and resources necessary for pre-market review.

The entire time Senator Harkin and I were writing this legislation, not one member of Congress raised any concerns about the grandfather clause.

In addition, the FDA has not been able to find the resources to even enforce the current law. As Chairman of the Appropriations Subcommittee which funds the FDA, you are well aware of this issue.

Therefore, it is clear to me that FDA has much higher priorities than dietary supplements. Moreover, the FDA has not asked for additional funding for supplement enforcement – which I believe is an indicator these products are not the safety concern some would argue from the cases highlighted at this hearing.

The Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 mandated a system to provide the government with information about serious adverse events (AERs) associated with the use of two FDA-regulated products – dietary supplements and over-the-counter drugs. This law requires manufacturers, packers or distributors of these products to provide to the FDA, within 15 business days, any reports of serious AERs.

It also is important to note that previous FDA commissioners – Dr. Jane Henney, Dr. Mark McClellan, Dr. Lester Crawford and Dr. Andy von Eschenbach – have all stated in Senate hearings and in my meetings with them that, through DSHEA, they had the power necessary to regulate dietary supplements. Moreover, current FDA Commissioner Dr. Margaret Hamburg has assured me that she will work with me to ensure these laws are enforced.

To ensure that these laws are properly enforced, Senator Harkin and I introduced the Dietary Supplement Full Implementation and Enforcement Act of 2010.

This legislation requires the Secretary of Health and Human Services (HHS) to submit annual reports to Congress regarding HHS' activities on dietary supplements. It directs the FDA to issue its new dietary ingredient (NDI) guidance, as recommended by the General Accountability Office, within 180 days and requires the FDA to notify the Drug Enforcement Agency if it finds that a new dietary ingredient being evaluated contains an anabolic steroid.

This bill is supported by the Major League Baseball Players Association, the NFL Players Association, the Natural Products Association, the United Natural Products Alliance, Council for Responsible Nutrition,

American Herbal Products Association and the Consumer Health Care Products Association. I urge Members of the Committee to seriously consider supporting our bill.

Mr. Chairman, before I close, I want to emphasize that a vast majority of the dietary supplement industry are providing consumers not only with safe products but also accurate information about their use. They, too, want bad actor companies off the market.

So, as Chairman of the Agriculture Appropriations Subcommittee, please work with me, Mr. Chairman, to ensure that the FDA has the money to enforce existing laws. That should be this Committee's first goal. And, we should not be talking about changing current law and instead focus on enforcing current law. Hopefully, today's hearing will begin these discussions.

Thank you Mr. Chairman.