Statement of Rep. Henry A. Waxman, Ranking Minority Member
Committee on Government Reform
Hearing on
"The Regulation of Dietary Supplements: A Review of Consumer Safeguards"

March 9, 2006

Mr. Chairman, thank you for holding this hearing today concerning what safeguards exist to protect the public from potentially dangerous dietary supplements. Most supplements are safe, but there are some on the market that pose risks. Unfortunately, the 1994 law known as the Dietary Supplement Health and Education Act, or "DSHEA," made it very difficult for FDA to provide meaningful protection against unsafe products. The problem of effective oversight has been compounded by underfunding of the Center for Food Safety and Applied Nutrition at FDA.

Today we will hear about the work of private companies that have stepped in to provide consumers with the assurance that the products that they are taking are, at a minimum, not contaminated. The companies represented here today provide a valuable service. These companies test and certify that supplements are pure and contain the ingredients listed on the label in the amounts listed on the label.

Such certification is important for pregnant women taking folic acid to minimize the risks of birth defects, who want assurance that the pill they are taking actually has folic acid in the necessary amounts, and that it does not contain anything potentially harmful, such as lead, or arsenic. For an athlete who is taking a dietary supplement product marketed as steroid-free, confirmation that the supplement does not contain steroids can mean the difference between passing a drug test and failing one.

But even where a company has certified that a dietary supplement is pure, the product is not necessarily safe and effective. That is because, unlike the review it conducts for drugs and medical devices, FDA does not conduct a pre-market review of dietary supplements to determine whether they pose a serious health hazard and the claims on the labels are true.

Understandably, consumers are confused about how dietary supplements are regulated. A 2002 Harris Poll found that 59% of consumers believed that supplements have to be approved before they can be marketed. I received a letter recently from a clinician at Johns Hopkins University who surveyed patients at three different clinics in Baltimore about their understanding of dietary supplement regulation. Over half of the people he surveyed either believed that supplements were approved by the FDA or were unsure whether the product was approved.

It seems that consumers do not understand that even when a product that has been certified as pure, the product may be ineffective and may pose health risks.

Most dietary supplement products do not pose health risks. But FDA does not have strong enough authority to take swift action to protect consumers against those products that are unsafe. Unfortunately, FDA lacks the legal authority – and political backing – it needs to protect the public.

In the case of one popular dietary supplement, ephedra, FDA amassed thousands and thousands of adverse event reports, including a number of reports of very serious injuries such as heart attack, stroke and death. Experts concluded that ephedra-containing products were likely causing serious injury and should be taken off of the market. Despite evidence of harm, it took FDA years before it took ephedra off of the market. Even now, the FDA ban on ephedra is being litigated.

What the ephedra story makes clear is that it is very difficult for FDA to protect consumers against unsafe dietary supplement products. This is why Rep. Susan Davis, Rep. Dingell, and I have introduced H.R. 3156, the Dietary Supplement Access and Awareness Act.

To those who are concerned that this bill would take away vitamin C, or would allow FDA to ban a dietary supplement on the basis of a single adverse event report, let me reassure you that this is not the case. This bill would not change the regulation of vitamins and minerals at all.

What the bill would to is to require dietary supplement companies to report to FDA adverse health consequences associated with their products. If these adverse event reports signal that there might be a problem with a supplement, FDA would have the authority to require that the company demonstrate that their product is safe. Responsible dietary supplement companies that market safe products should not find this requirement an undue burden.

The bill would also give FDA enhanced authority over dietary supplement products marketed for kids. As we learned in our investigation of steroids and sports, kids are taking supplements to try to enhance their athletic performance. It is very important that these products do not pose a significant risk to them.

I am pleased that we are also hearing today from Consumers Union, which does great work educating the public about dietary supplements through their magazine, *Consumer Reports*. And I also look forward to the testimony of our government witnesses about the work they are doing to help consumers understand which supplements are safe and which ones may not be.

I thank the witnesses for coming today and I look forward to their testimony.