STATEMENT OF CONGRESSMAN HENRY A. WAXMAN

HEARING ON DIETARY SUPPLEMENTS

Thursday, March 25, 1999

Mr. Chairman, I have a number of remarks I want to make about the topic of dietary supplements, but before I do, I want to welcome FDA Commissioner Henney.

Commissioner Henney was sworn in only a few months ago, and I understand that this is the first time that she has appeared before our Committee. As her written testimony indicates, she has identified five priorities for FDA, including enhancing the agency's science base, protecting the nation's food and blood supply, and reducing teen smoking. These are essential priorities for improving and protecting the health of the American people. It is crucial that we in Congress work with Commissioner Henney in achieving these priorities.

Today's hearing addresses an issue that I have been involved in for years: dietary supplements. Five years ago, I worked with Senator Hatch and my colleagues on the Commerce Committee in crafting the Dietary Supplement Health and Education Act of 1994. Since I was intimately involved in the negotiations that produced the legislation, I think I'm in a good position to address the topic of this hearing: "Dietary Supplement and Health Education Act: Is the FDA Trying to Change the Intent of Congress?" It is clear to me that FDA is doing a good job implementing a complex, challenging, and sometimes deliberately ambiguous law.

The law we enacted in 1994 was a series of compromises. DSHEA allowed makers of supplements to market their products without having to demonstrate that they are safe or effective, but at the same time it authorized FDA to remove products that are later proven to be dangerous from the market. It allowed manufacturers to claim that dietary supplements will benefit the structure or function of the body, but at the same time it prohibited manufacturers from making unproven claims that supplements will cure diseases. Our hope was that the law would balance the goal of providing consumers with wide access to dietary supplements and the goal of protecting consumers from

dangerous or ineffective products.

Today we will hear arguments that Congress did not intend for FDA to have an active role in protecting the consumer from dangerous products being sold as dietary supplements. We will also hear that FDA's recent efforts to protect the consumer are inappropriate and heavy-handed intervention. This is simply erroneous.

When we passed DSHEA, we knew that many dietary supplements, such as minerals and vitamins, can play an important role in promoting health. But we also knew that without proper regulation, dietary supplements can sometimes be lethal. We knew about L-tryptophan, a product that was marketed in the 1980s as a sleep aid. L-tryptophan was linked to EMS, a painful, debilitating, and sometimes fatal disease. At least 1500 people were struck with this disease and at least 38 people died from it before the FDA issued regulations banning L-tryptophan.

Events since enactment of DSHEA have confirmed the need for an active FDA. Sometimes it seems like there is a new article about the dangers of dietary supplements every month. For example, in 1997, the Washington Post reported about the dangers of Nature's Nutrition Formula One which contained a dietary supplement called ephedra. Products like Nature's Nutrition Formula One and other products containing ephedra like herbal ecstasy and herbal fen-phen are marketed for weight loss, energy boost, and "natural high." But in fact, according to the Washington Post, these products have been linked to at least 38 deaths. FDA also received hundreds of reports of other adverse events associated with products containing ephedra. These adverse events include increased blood pressure, chest pains, insomnia, heart attack, stroke, psychoses, and seizure.

More recently, in March 1998, FDA warned consumers against "Sleeping Buddha," a product being marketed as a dietary supplement but which actually contains a prescription-strength drug ingredient, Estazolam, which is known to have serious side effects, including potential damage to a fetus if consumed by a pregnant woman. Earlier this year, FDA issued a warning against dietary supplements containing GBL, a substance marketed as a performance enhancer. When GBL is taken orally, it is

converted in the body to GHB, a potent and unapproved drug. GBL has been associated with at least 55 incidents of adverse health effects, including seizures, vomiting, comas, and death. Five of the reported victims were children under 18 years old.

These are not the only products that have caused problems. For example, certain teas with plant-derived laxatives have been associated with the deaths of four young women. And as Commissioner Henney states in her testimony, some dietary supplements containing the ingredient plantain were actually contaminated with digitalis, a powerful stimulant which can cause nausea, vomiting, dizziness, headache, confusion, low-blood pressure, vision trouble, and abnormal heart rate and heart rhythm.

I do not recite these examples in order to alarm the public or criticize the dietary supplement industry. There are many important and effective dietary supplements on the market. No one disputes the importance of calcium to maintaining healthy bones, or the link between folic acid and the prevention of certain birth defects. Consumers need to learn about these products.

My point is that we need an active and vigilant FDA to help us weed out the dangerous dietary supplements and identify the safe and effective ones. The answer isn't to attack FDA every time the agency takes even baby steps toward regulating dietary supplements. The answer isn't to criticize the agency for failing to adhere to the intent of Congress when, in fact, the agency is trying its best to implement a complex and ambiguous law. Instead, the answer is to establish a regulatory framework for dietary supplements at FDA that appropriately balances the interests of consumer access and public health. This position is supported by a variety of consumer groups, including the American Dietetic Association, which represents nearly 70,000 food and nutrition professionals. At this time, Mr. Chairman, I ask that the statement of the American Dietetic Association be entered into the record.

If I have learned one thing about dietary supplements over the years, it is that we also need to reduce the mistrust and polarization that has surrounded this issue for far too long. I believe that Commissioner Henney understands this. And I look forward to learning her ideas -- and those of the

other witnesses -- about dietary supplements.