STATEMENT OF REPRESENTATIVE HENRY A. WAXMAN
COMMITTEE ON GOVERNMENT REFORM
HEARING ON EPHEDRA AND FDA'S DIETARY SUPPLEMENT ADVERSE EVENT REPORTING SYSTEM
Thursday, May 27, 1999

Mr. Chairman, today's hearing raises important questions about the regulation of dietary supplements.

The Food and Drug Administration (FDA) is supposed to ensure the safety and effectiveness of an enormous range of health products, including supplements. To do this, it is essential that manufacturers report deaths and other "adverse events" to FDA. This is the rule that applies in the case of drugs and medical devices.

But the public will be surprised to learn that manufacturing of dietary supplements are exempt from this most basic public health protection.

When Congress enacted the Dietary Supplement Health and Education Act of 1993, we severely limited FDA's authority over supplements. FDA may not approve supplements before they are marketed. And FDA is held to the very high threshold of demonstrating a "significant or unreasonable risk of illness or injury" before it can remove an unsafe supplement from the market. This is a higher threshold than for foods, drugs, or medical devices.

This means it is up to the supplement industry to ensure that the products that they are marketing are safe. But here, too, we have restricted the FDA. We require all drug and medical device companies to report any adverse events they learn of which are associated with their products. But not supplement companies. Instead, we rely on a wholly voluntary system of reporting.

This system is not adequate to protect public health. There are many unavoidable problems with a voluntary reporting system, not least of which is the possibility that manufacturers become aware of problems with products and choose not to share this information with the FDA. I am interested in learning from today's witnesses how reliable the current system has been, and how the system can be strengthened.

I want to commend the Chairman for his balanced approach in putting this hearing together. He has graciously - and appropriately - agreed to allow three minority witnesses to testify. As a result, we have witnesses here today who can tell both sides of the story, including witnesses who have lost family members because of ephedra products. I look forward to hearing their stories, and to hearing what they have to say, from first-hand experience, about the need for a strong monitoring system, especially for dietary supplement that do not have to undergo pre-market testing for safety.

Let me make a final comment about the FDA's regulation of ephedra. Ephedra is practically a

molecular twin to methamphetamine, or speed. The Drug Enforcement Agency (DEA) has already restricted its availability. And in response to hundreds of adverse events relating to ephedra supplements, including several deaths, the FDA proposed to limit the amount of ephedra permitted in supplement doses and to require labeling to fully inform consumers about their risks.

These proposals seem sensible. Despite the industry's claims, there is no ephedra ban. No one is going to burst into your home to take away your ephedra. Instead, the regulation appears to contain minimal, common sense health safeguards.

There is a lot of misinformation about ephedra. That is why I found Dr. Tim Johnson's comments this morning on Good Morning America to be so helpful. I would like to play his comments for the Committee. I think he cuts through a lot of the false claims and provides a balanced analysis.

I hope we can approach this issue with the same kind of objectivity Dr. Johnson displayed. I welcome our witnesses and look forward to their testimony.

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