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Reps. Davis, Waxman, and Dingell Introduce Legislation to Protect Consumers From Dietary Supplements that Pose a Risk to Health and Safety

WASHINGTON — In response to growing concerns about the potential dangers posed by ephedra and other dietary supplements, Reps. Susan A. Davis, Henry A. Waxman, and John D. Dingell introduced legislation increasing the Food and Drug Administration's authority to protect consumer health.

This legislation enables FDA to monitor the health risks of dietary supplements and take appropriate action if problems develop. Current law proved inadequate when one manufacturer of ephedra-containing products spent years denying the existence of nearly 2,000 reports of significant adverse events related to ephedra, including three deaths, 20 heart attacks, and 24 strokes. During this time, FDA was unable to learn about these adverse events or investigate the manufacturer.

"With dietary supplements, the FDA's hands are tied when it comes to protecting the health of consumers and, more importantly, our children," said Rep. Davis. "This legislation is carefully crafted to carve out dietary supplements that are safe and effective, yet it weeds out dietary supplements that cause significant health risks. It will give the FDA tools it needs to do its job."

"While most dietary supplements are safe, there are some that pose serious health risks," said Rep. Waxman. "The FDA must have the authority to investigate manufacturers and take action against them when necessary to protect consumers' health. It is shocking that a dietary supplement company withheld information for years about illnesses and deaths that may have been due to its product while it continued to make millions of dollars a year selling that product. This bill will give FDA the authority to prevent a similar occurrence in the future."

"This bill is a good beginning. It will let the FDA go after the worst charlatans — those scofflaws and frauds that Congress all but invited to prey upon the public in 1994," said Rep. John D. Dingell, Ranking Member of the Committee on Energy and Commerce. "Responsible consumers and producers should support this targeted and very necessary legislation."

The legislation introduced today will not have any impact on the regulation of vitamins and minerals, which are specifically excluded from the bill. For dietary supplements that contain herbs, amino acids, and other botanicals, the bill will ensure that FDA has basic information about who makes them and the products' ingredients. It also requires dietary supplement manufacturers to provide FDA with information about all adverse events so that the agency can spot warning signs and investigate if necessary.

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The bill further allows FDA to prohibit sales to minors of supplements that may cause significant harm to children. Finally, the bill allows FDA to demand safety information from a manufacturer if FDA has evidence that a particular supplement may pose serious risks.

Recent attention has focused on dietary supplements containing steroids. Bills to address those products have been introduced in both the House and the Senate. However, steroid-containing supplements are not the only potentially dangerous products on the market. According to FDA, aristolochic acid is associated with kidney disease and some cancers; experts warn that usnic acid can cause liver toxicity. These ingredients are in supplements and they are available even to children. The legislation Reps. Davis, Waxman, and Dingell are introducing today takes a comprehensive approach to supplement safety in order to help protect against all potentially risky products.

This legislation will both protect consumers from those few dietary supplements that pose a real risk to health and preserve access to safe dietary supplements.