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REP. WAXMAN AND REP. MARKEY INTRODUCE COUNTERPART TO ENZI-KENNEDY DRUG SAFETY BILL

WASHINGTON, DC – Today Representatives Henry A. Waxman (D-CA) and Edward J. Markey (D-MA), two senior members of the Energy and Commerce Committee, announced the introduction of H.R. 1561, the House counterpart to the Enzi-Kennedy Enhancing Drug Safety and Innovation Act of 2007 (S. 484). H.R. 1561 builds on the Senate drug safety bill to further increase FDA's post-market drug safety authority, provide greater FDA transparency, and enhance the mandatory clinical trial database created in the Enzi-Kennedy bill.

"We need only look to recent high-profile post-market safety problems, like Vioxx, to know that our drug safety system is in desperate need of some serious improvements," Rep. Waxman said. "We also cannot continue to allow drug companies to cherry-pick and distort the clinical trial information on which physicians rely about which drugs work and the risks those drugs pose. The Enzi-Kennedy bill is a significant step forward in addressing these concerns. Our legislation goes even further in giving FDA the full complement of tools it needs to protect our citizens from unsafe products."

"In the wake of Vioxx, Paxil, Ketek and other drug scandals, Congress needs to act now to improve drug safety at FDA," Rep. Markey said. "I am proud to cosponsor this legislation with Representative Waxman, who has long been a leader on reforming the FDA. As the Congress moves forward with the reauthorization of the Prescription Drug User Fee Act, I hope to build on this broad package of reforms to further ensure a culture of scientific integrity and transparency within the FDA and enhance the role of the drug safety experts who work in the office of drug surveillance and epidemiology within the FDA."

Rep. Waxman and Rep. Markey's legislation makes several important improvements to the Enzi-Kennedy legislation, including:

- Gives the FDA enhanced tools to ensure post-market drug safety through the "Risk Evaluation and Mitigation Strategy" (REMS) process, including: (1) increasing the possible moratorium on direct-to-consumer advertising from two years to three years; (2) adopting the IOM recommendation that the FDA place a symbol on the packaging of a product to let consumers know that the drug is new to the marketplace; and (3) requiring a review of drug products after they have been on the market for 7 years (the average time it takes to detect most side effects);

- Increases the transparency of the REMS review process and creates a public record of any disputes brought before the Drug Safety Oversight Board;

- Enhances FDA's enforcement authority by giving the FDA the ability to impose civil monetary penalties if drug companies fail to comply with any requirements relating to drugs in the Federal Food, Drug, and Cosmetic Act and increasing the amount of those civil penalties;

- Provides for a balance between funding from user fees and federal dollars in FDA's drug safety budget by authorizing $25 million for each of fiscal years 2008 through 2012 in addition to other funds available for carrying out Title I activities;

- Requires the FDA to report to Congress on its efforts to integrate the expertise of the Office of Surveillance and Epidemiology (formerly Office of Drug Safety) into the Agency's approval, labeling, and post-approval safety decisions; and

- Strengthens the clinical trials registry and results databases to include more information on more trials (including medical devices), and gives the Secretary the added ability to impose civil monetary penalties for non-compliance.

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