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WAXMAN, KENNEDY, ALLEN INTRODUCE BILL TO BOOST FDA'S OVERSIGHT OF OVER-THE-COUNTER DRUGS

WASHINGTON, DC — Today Rep. Henry A. Waxman, Sen. Edward M. Kennedy, and Rep. Tom Allen introduced legislation to increase the ability of the Food and Drug Administration (FDA) to ensure the safety and effectiveness of over-the-counter (OTC) drugs.

The Non-Prescription Drug Modernization Act comes in the wake of a recent FDA advisory panel recommendation that FDA should ban OTC cough and cold medications for children under the age of six. Under current law, if FDA wants to follow its committee's recommendations, FDA would have to go through a lengthy rulemaking process that could take years to complete. Meanwhile, these drugs, for which there is scant evidence of efficacy in children under six, and, in rare cases, could cause serious harm, could continue to be marketed. The Non-Prescription Drug Modernization Act would give FDA the authority to act quickly to protect consumers from unsafe or ineffective OTC drugs, by allowing the agency to revoke authorization to market such drugs without a lengthy rulemaking.

"The pediatric cough and cold medicine debacle has shown us that FDA's authority over OTC drugs is seriously outdated," said Rep. Waxman. "When American consumers buy OTC drugs, they expect them to be safe and to actually work. If we don't get FDA the authority it needs to act quickly, Americans will continue to expose themselves to drugs that may not work, but may pose risks."

"Millions of Americans count on over the counter medicines to keep them healthy, and they deserve to have full confidence that these medicines are safe," said Sen. Kennedy. "That confidence has been shaken by recent revelations that cough and cold medicines may be unsafe for small children. Our legislation strengthens the ability of FDA to protect the health of American families when it finds safety problems with over the counter drugs."

"The basic guiding rule of medicine comes from Hippocrates: 'first, do no harm.' We now know that some widely advertised over the counter cough medicines can pose serious danger to American children." said Rep. Allen. "Our legislation will restore accountability to the process of approving and marketing the medications we give to our children. It will provide the FDA with the authority and resources it needs to protect our kids and reassure parents that the medicines marketed for children are safe and effective."

The Non-Prescription Drug Modernization Act would also give FDA the authority to regulate OTC drug advertisements. Currently, FDA regulates advertisements for prescription drugs, while the Federal Trade Commission (FTC) regulates advertisements for OTC drugs. Unlike the FDA, FTC is not a public health agency with scientific expertise — it is strictly a law enforcement agency and its enforcement activity in the area of OTC drugs has been minimal. In fact, FTC's most recent enforcement action against an OTC drug advertisement was in 1996. The Non-Prescription Drug

Modernization Act would also provide for civil monetary penalties for direct-to-consumer OTC drug advertisement violations.

The bill would also require FDA to report to Congress, after consulting with medical societies and scientists, on whether any of the current OTC drug monographs are in need of review, amendment, or repeal.

A summary and the text of the bill are available online at www.oversight.house.gov.