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ONE HUNDRED TENTH CONGRESS

# Congress of the United States

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2157 RAYBURN HOUSE OFFICE BUILDING

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MAJORITY (202) 225-5051  
FACSIMILE (202) 225-4784  
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**FOR IMMEDIATE RELEASE**  
January 23, 2008

**FOR MORE INFORMATION, CONTACT:**  
Karen Lightfoot (Waxman): (202) 225-5051  
Melissa Wagoner (Kennedy): (202) 224-2633  
Erica Chabot (Leahy): (202) 224-2154

### **MEMBERS OF CONGRESS QUESTION FDA PROPOSAL DESIGNED TO CREATE LIABILITY SHIELD FOR DRUG AND DEVICE COMPANIES**

**WASHINGTON, DC** — Today Representatives Henry A. Waxman, John D. Dingell, Frank Pallone, Jr., Rosa L. DeLauro, and Edward Markey, and Senators Edward M. Kennedy, Patrick J. Leahy, and Christopher J. Dodd, questioned the basis for a new Food and Drug Administration (FDA) proposal that was apparently designed to shield pharmaceutical and device companies from liability for injuries sustained by American consumers as a result of unsafe products.

“We are concerned that the intent of this proposal is to protect companies in the pharmaceutical and device industry from being held liable for marketing products they know are unsafe,” said the members in a letter to FDA Commissioner von Eschenbach. “Such a policy change comes at the expense of consumers and violates the mission of the FDA.”

FDA’s proposed rule would amend the regulations that permit companies to promptly update their drug and device labels with new safety information without waiting for FDA approval. These regulations serve the vitally important public health function of ensuring that patients and healthcare providers are made aware of safety risks associated with their medical products at the earliest possible moment.

Given that FDA failed to identify a public health basis for why this lengthy proposal was necessary at this point in time, the letter’s authors ask FDA to answer questions justifying the expenditure of the agency’s limited resources on this effort.