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Van Hollen, Braley Introduce Patient Safety and Drug Labeling Improvement Act
Bill Would Ensure All Prescription Drugs Have Accurate Labels and Up-to-Date Warnings

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Today Congressman Chris Van Hollen (D-MD) and Congressman Bruce Braley (D-IA) announced the introduction of the Patient Safety and Drug Labeling Improvement Act, legislation to ensure that all prescription drug manufacturers can revise their labels to provide accurate, up-to-date warnings to consumers. Companion legislation was introduced in the Senate by Senator Patrick Leahy (D-VT).

Under federal law, generic drug manufacturers are required to use the same label approved by the Food and Drug Administration (FDA) for their brand-name equivalents. While FDA regulations allow brand name manufacturers to independently update their labels if they identify new risks or side-effects, generic drugs can only adopt the approved changes made by the brand-name. Last year's Supreme Court decision in *Pliva v. Mensing* highlighted the inconsistency in these labeling regulations. The Court ruled that federal law precludes generics from independently changing their labels and therefore they cannot be held liable for failing to add or strengthen the warnings on their products. As a result, consumers harmed by generic drugs with insufficient labels have no legal remedy, whereas consumers harmed by brand-name drugs do. The Patient Safety and Drug Labeling Improvement Act resolves this situation by authorizing generics to revise their labels using the same processes that are currently available to brand-name manufacturers.

"Consumers have the right to know the truth about the safety of drugs they are taking – both brand and generic. We must ensure that all manufacturers have the ability to update their labels to reflect newly discovered risks and side-effects of their products. This legislation will ensure that families and their doctors have access to the most accurate information about their medication and can make the best choices. It addresses a serious problem that has impacted people in my district and across the country, and I hope the bill will be given immediate consideration," **said Congressman Van Hollen.**

"The Institute of Medicine estimates that each year at least 1.5 million preventable drug errors occur in American health care facilities, adding an average of $5,000 to the cost of a hospital admission where an error occurs. American patients deserve to have faith in the safety of their prescription drugs, and these types of errors are costing billions of dollars to our health care system. Yet, many drug labels still have inaccurate, outdated safety information. This is a dangerous situation for American families, and the Patient Safety and Drug Labeling Improvement Act will fix this problem. Doctors and consumers deserve accurate and up-to-date safety information, and taxpayers should not continue to be on the hook when patients are injured due to bad information. There is no excuse for inaccurate drug labeling, and I urge my colleagues to pass this bill and fix this problem," **said Congressman Braley.**

The Patient Safety and Drug Labeling Improvement Act is supported by AARP, Alliance for Justice, Consumer Action, Consumer Federation of America, Consumers Union, Consumer Watchdog, National Association of Consumer Advocates, and US PIRG. Click here and here to read their letters of support.