April 17, 2012

The Honorable Chris Van Hollen
1707 Longworth H.O.B.
Washington, DC 20515

The Honorable Bruce Braley
1727 Longworth H.O.B.
Washington, DC 20515

Consumer Groups Strongly Support the
Patient Safety and Drug Labeling Improvement Act

Dear Congressmen Van Hollen and Braley:

We write to express our strong support for the Patient Safety and Drug Labeling Improvement Act, which would promote consumer safety by ensuring that generic drug companies can improve the warning information for their products in the same way that brand manufacturers can under existing law.

By authorizing generic manufacturers to improve their labels using the same "Changes Being Effected" process that is currently available to brand-name manufacturers, this legislation will help protect millions of Americans. The Department of Health and Human Services reports that generic drugs now make up 75 percent of the market for pharmaceuticals, and studies show that when a generic version of a drug is available 90 percent of prescriptions are filled with the generic.

This much-needed legislation responds to the Supreme Court's 2011 decision in *PLIVA v. Mensing*, in which the Court held 5-4 that a Minnesota woman, Gladys Mensing, could not recover damages for debilitating injuries she received from a drug with an inadequate warning label simply because her prescription was filled with the generic version of the drug, rather than with the brand-name drug. The Court previously held in *Wyeth v. Levine* (2009) that federal law does not preempt failure-to-warn claims against brand-name drug manufacturers. The *Mensing* decision thus created an arbitrary distinction whereby a court's ruling on whether or not a consumer can obtain relief turns solely on the happenstance of whether his or her prescription was filled with a brand-name or generic drug.

This troubling and unfair inconsistency in the law is exacerbated by the fact that many consumers have little control over which version of a drug they are given. Many brand-name manufacturers exit the market after generics are introduced. Moreover, many state laws and health insurance plans require consumers to be given generics if they are available.

Given the inherent unfairness of the current law and the ongoing harm to millions of Americans, the Senate should pass this legislation without delay.

Sincerely,

Alliance for Justice
Consumer Action
Consumer Federation of America
Consumers Union
Consumer Watchdog
National Association of Consumer Advocates
US PIRG