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Leahy Bill Would Boost Generic Drug Safety

Proposal Would Give Generic Drug Manufacturers Authority to Update Their Labeling in Light of New Safety Information

WASHINGTON, D.C. – A bill giving generic drug manufacturers the authority to revise labeling for their products when they become aware of risks that are not adequately disclosed would fill a hazardous hole in drug regulation, Public Citizen said in a letter sent today to Senate Judiciary Committee Chairman Patrick Leahy. Leahy introduced the Patient Safety and Generic Labeling Improvement Act today.

The generic drug market has grown exponentially in the past 25 years; generic drugs now constitute a majority of the prescription drugs sold in the United States. The regulatory system, however, has not adjusted to the marketplace. Leahy's bill would fix that.

The proposal is consistent with the citizen petition that Public Citizen submitted to the Food and Drug Administration (FDA) in August 2011. The petition urged the FDA to update its drug regulations to allow generic drug manufacturers to revise their product labeling to warn patients about risks associated with their drugs. The FDA has not responded substantively to the petition.

“Many potential hazards are not discovered until years after drugs have been on the market, yet generic drug manufacturers can do little to warn doctors and patients about newly discovered risks,” said Allison Zieve, director of the Public Citizen Litigation Group. “The commonsense solution is to give the manufacturers clear authority to do so.”

Added Dr. Sidney Wolfe, director of Public Citizen Health Research Group, “Given that generic drugs dominate the market, it's illogical that their manufacturers don't bear the same responsibilities as brand-name drug makers related to proper labeling of their products. The Leahy bill would correct this disparity.”

The letter is available at: <http://www.citizen.org/documents/public-citizen-letter-to-leahy.pdf>.

To read the citizen petition, visit: <http://www.citizen.org/documents/1965.pdf>.

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