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Generic Drug Manufacturers Should Be Able to Warn of Products' Risks, Public Citizen Tells FDA

To Improve Drug Safety, FDA Should Revise Outdated Regulations That Prevent Generic Drugmakers From Updating Product Labeling and Immunize Them from Liability

WASHINGTON, D.C. – The Food and Drug Administration (FDA) should revise its regulations to allow generic drug manufacturers to update product labeling to warn patients about risks associated with their drugs, Public Citizen said in a petition sent today to the agency.

Under current FDA regulations, generic manufacturers cannot update their products' labeling, even if they become aware of a potential risk not stated in the labeling. In contrast, brand-name drug manufacturers can update warnings and precautions on product labeling before getting FDA approval. The generic drugmaker is required to match its labeling to brand-name labeling.

Over the past 25 years, the sale of generic drugs has skyrocketed. Today, generics constitute the majority of all prescriptions filled. As of 2010, 90 percent of prescriptions for drugs with generic versions were filled with a generic, rather than a brand-name, drug. In light of this shift, generic companies have access to a great deal of information about product safety and effectiveness and should have the same ability as brand-name companies to revise labeling to give physicians and patients the best available information about the safety of their products, the petition said.

The illogical disparity between labeling regulations for generic companies and brand-name companies was highlighted in a June 2011 decision of the U.S. Supreme Court. In *PLIVA v. Mensing*, the court relied on FDA regulations as the basis for its holding that patients harmed by inadequate warnings on a generic drug cannot sue the drugmaker for damages, while people who take brand-name version of the same drug can. This "absurd consequence," to quote Justice Sonia Sotomayor, turned on the fact that FDA regulations do not allow generic manufacturers to alter their labeling, even when they become aware that it is inadequate.

"Drug safety would benefit if generic manufacturers – who already have access to real-world information about adverse events – could use FDA procedures currently in place for brand-name manufacturers to revise labeling to warn of risks," said Dr. Sidney Wolfe, director of Public Citizen Health Research Group. "Filling this regulatory gap would help to protect patients."

The FDA has limited resources to monitor the tens of thousands of drugs on the market, especially considering funding and staff shortages at the agency. Accordingly, the FDA always has relied on drugmakers to identify previously unknown risks.

Public Citizen submitted an amicus brief in *PLIVA v. Mensing*, arguing that it is vital for all drug manufacturers, including generic drug manufacturers, to have incentives to respond to new safety information because potential hazards often do not become apparent until years after a drug has been on the market.

"The action we are requesting would bring FDA regulation in line with the realities of the pharmaceutical market and help to ensure that drug labeling provides adequate warnings to patients based on information that comes to light after the drug is approved for marketing," said Allison Zieve, director of the Public Citizen Litigation Group.

The petition submitted today also urges the FDA to reiterate generic drugmakers' obligation to inform the FDA whenever the manufacturer becomes aware of information suggesting an association between the product and a hazard not adequately disclosed on the labeling.

To read the petition sent to the FDA, visit: http://www.citizen.org/documents/Citizen-Petition-8-26.pdf.

To read Public Citizen's amicus brief in *PLIVA v. Mensing*, visit: http://www.citizen.org/litigation/forms/cases/getlinkforcase.cfm?cID=649.

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