Congress of the United States

Washington, DC 20515

June 24, 2013

Doctor Margaret Hamburg Commissioner, Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, Maryland 20993-0002

Dear Commissioner Hamburg:

We write to urge the Food and Drug Administration (FDA) to expedite its consideration of revisions to the FDA's drug labeling regulations to enable manufacturers of generic drugs to update patient safety labeling in appropriate circumstances. These changes are critically important to ensure that the public is adequately informed of the risks and benefits of prescription drugs, and that consumers who are injured by generic drugs have the same legal rights as those who are injured by the brand-name versions of the same drugs.

In the 2011 case *PLIVA v. Mensing*, the United States Supreme Court held that patients cannot hold generic drug manufacturers accountable for failure to warn of injuries associated with their products. As a result, consumers who are injured by the generic version of a prescription drug may be foreclosed from seeking any remedy, even though consumers who take the brand-name version of the drug can seek recourse for their injury. The Supreme Court based its decision on the FDA's statements that a generic drug manufacturer cannot revise its labeling to provide updated safety information, except to mirror a revision made by the manufacturer of the brand-name equivalent.

The FDA's statements and the Court's decision raise serious concerns about patient safety and accountability for manufacturers. Almost 80 percent of all prescriptions are filled by the generic version of a drug. Although existing FDA regulations require generic manufacturers to collect adverse event information, generic manufacturers are not permitted to strengthen their labeling information to respond to such data. We urge the FDA to revise this position and amend its labeling regulations so that generic manufacturers may participate fully in the labeling process, using a process akin to the Changes Being Effected process that is available to brands.

In April 2012, several signatories of this letter introduced legislation in the Senate and House of Representatives that would permit manufacturers of generic drugs to update their labeling to provide additional safety information, in the same way as the FDA permits brand-name manufacturers to do. We were encouraged by the FDA's announcement in January 2013, in its Supreme Court amicus curiae brief in *Mutual Pharmaceutical Company v. Bartlett*, that it is considering a regulatory change along the lines of that legislation. Unfortunately, we have yet to see any action from the FDA on this matter. In the meantime, the safety gap created by the current regulations and the Supreme Court's decision continues to put patients at risk.

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The facts of the *Bartlett* case illustrate the gravity of the problem. Karen Bartlett was severely injured after taking a generic drug, sulindac, that was prescribed for shoulder pain. Clinoril, the brandname version of sulindac, was approved in 1978, and generic versions came to market beginning in 1988. Sulindac poses a risk for patients of a devastating condition known as Stevens-Johnson Syndrome/toxic epidermal necrolysis (SJS/TEN), a potentially deadly disease involving damage to the skin and mucous membranes similar to the damage caused by severe burns. When Ms. Bartlett was prescribed sulindac in 2004, the warnings section of its labeling did not mention SJS/TEN. Ms. Bartlett subsequently contracted the disease, with devastating consequences, ultimately losing 60 to 65 percent of her skin. She is now permanently disabled, with extensive damage to her lungs and esophagus, and is legally blind despite 13 eye operations. It appears that little was known about the association between SJS/TEN and sulindac at the time of its initial approval: as is often the case, information about the extent of the risk came to light only through post-marketing adverse event reports. Since 2005—too late for Ms. Bartlett—the FDA has required manufacturers to include a strengthened SJS/TEN warning on sulindac.

The *Bartlett* case is one example of many that show how the longevity of a drug on the market is no guarantee that all of its risks are known to the public or to the doctors on whom patients rely—even when manufacturers are or should be aware of those risks. There is an imperative need for *all* drug manufacturers to remain vigilant about adverse effects and to have the ability to update their labeling to disclose risks when they become known, so that drugs can be used as safely and effectively as possible.

Today, the United States Supreme Court issued its decision in the *Bartlett* case. The Court held that Ms. Bartlett, despite her severe injury, could not sue the drug's manufacturer for defective design—again, because she received the generic version of the drug. Although the principal issue in this case involved "defective design" instead of "failure to warn," the decision compounds the harsh consequences of the *Mensing* case, further foreclosing legal remedies for patients who take the generic version of a prescription drug. This outcome penalizes the millions of Americans across the country who rely on the generic versions of prescription drugs, and jeopardizes our nation's commitment to promoting safe, affordable generic medications.

We urge the FDA to expedite its review of the current rules governing generic drug labeling changes and promulgate regulations to ensure that generic drug manufacturers can improve the warning information for their products in a manner similar to that available to brand-name manufacturers. Responsible brand-name and generic manufacturers alike should have the ability, and the obligation, to give doctors and patients the information they need to avoid injuries.

Sincerely,

PATRICK LEAHY
Chairman, Senate Judiciary Committee

CHRIS VAN HOLLEN
United States Representative

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TOM HARKIN

Chairman, Senate Health, Education, Labor and Pensions Committee

United States Representative

United States Senator

United States Representative

MATT CARTWRIGHT

United States Representative