



AMERICAN COMMITMENT



Competitive Enterprise Institute
Free Markets and Limited Government

June 26, 2013

The Honorable John Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

On behalf of the organizations listed below, we urge opposition to legislation that would drive up healthcare costs and line the pockets of trial lawyer by opening generic drug manufacturers to frivolous lawsuits. Although Congress should be considering policies that encourage manufacturing and jobs, they are instead bowing to special interest lobbyists and trying to circumvent the Supreme Court.

In 2011, the U.S. Supreme Court found that federal law forbids claims under state law by plaintiffs who allege that generic drug manufacturers failed to warn adequately of the risks of their products. In *PLIVA, Inc. v. Mensing*, the Court held that it was impossible for generics to change (much less strengthen) safety warnings to comply with state law and still comply with the federal law's requirement that their labeling be "the same as" FDA-approved brand drug labeling.

We must stress what this means. Brand and generic drugs must have the same label containing the same warnings. The Court did not lessen the safety and reporting obligations for generic drug manufacturers. The cases considered by the Supreme Court involve defendants that suffer from a condition that was in fact warned on the label, and the court is being asked to second guess whether the warning was sufficient or the label was designed properly.

The effect of *Mensing* is that manufacturers that label their products in compliance with FDA regulations, including all warnings as determined by the agency, cannot be sued for "failure to warn." This ruling, as you can imagine, did not sit well with the trial bar, which would like Congress or the FDA to pave a superhighway to state courthouses.

Now, as the Supreme Court once again considers a similar case with a decision due by June, the trial lawyers are trying to convince a few Members to introduce legislation that would overturn the court's earlier ruling and circumvent any new judgment. The proposed bill would give each generic manufacturer the ability to change their label in an effort to simply subject these

manufacturers to state tort claims even if they have followed all current regulations and federal laws.

This is a transparent trial lawyer ploy. The cost and burden of litigating these cases will result in increased pharmaceutical prices and force companies to spend monies that could otherwise be devoted to research and development, jobs and manufacturing.

Our healthcare system is struggling greatly under the weight of Obamacare, a law that makes the government a larger purchaser of drugs than ever before. Costs are increasing, premiums are rising at an alarming rate, and our tax obligation to support this program in addition to our out-of-pocket expenses is ever increasing. Exacerbating these problems by passing legislation which will move money from healthcare to trial lawyers is not the solution.

This bill would become one of the biggest trial lawyer bonanzas in recent history. We ask you to actively oppose such legislation when it is introduced and stop any momentum that it might hope to gain.

Sincerely,

Nathan Mehrens
President
Americans for Limited Government

Sabrina Schaeffer
Executive Director
Independent Women's Forum

Greg Conko
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