Public Citizen Group Files FDA Petition To Fix Problems Exposed By Mensing Case Ruling

Generic Drug Companies Should Have To Update Side Effect Warnings Or Face Drug Injury Lawsuits

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 2, 2011; see http://bit.ly/pnD5hT)

On August 29, 2011 the consumer advocacy group Public Citizen took action in an attempt to (1) require generic drug companies to warn about serious side effects caused by their prescription medications, and (2) to gain back for patients harmed by a generic medicine the right to file a drug injury lawsuit.

As background, the *Pliva, Inc., et al. v. Mensing* case was decided by the Supreme Court of the United States on June 23, 2011. As reported by this *Reuters* article, "Supreme Court rejects generic drug labeling suits", the bottom line is that the Supreme Court ruled in favor of the generic drug company and against the injured patient.

Justice Sonia Sotomayor, in her dissent opinion (at page 26 of this PDF of the Court's Opinion), did well in pointing out the apparent absurdity of this new Supreme Court ruling about generic drug company lawsuits:

> As a result of today's decision, whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug. The [majority opinion of this] Court gets one thing right: this outcome "makes little sense."

The essence of this August 2011 Citizen Petition submitted to the FDA by the Public Citizen group is set forth in the title and sub-title of their press release:

> 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Should Be Able to Warn of Products' Risks, Public Citizen Tells FDA -- To Improve Drug Safety, FDA Should Revise Outdated Regulations That Prevent Generic Drugmakers From Updating Product Labeling and Immunize Them from Liability

In more detail, their basic arguments are found in the three parts, below, which make up the "STATEMENT OF GROUNDS" section of this 11-page Citizens Petition:

> A. MANUFACTURERS OF GENERIC DRUGS PRODUCE A MAJORITY OF THE
> PRESCRIPTION DRUGS SOLD IN THE UNITED STATES.
>
> B. POST-APPROVAL MONITORING IS ESSENTIAL TO THE SAFETY OF DRUGS AND
> IS A SHARED RESPONSIBILITY OF THE FDA AND MANUFACTURERS.
>
> C. GENERIC MANUFACTURERS' LACK OF RESPONSIBILITY FOR ENSURING THE
> POST-APPROVAL ADEQUACY OF PRODUCT LABELING THREATENS

PATIENT
SAFETY.

From this third part, we excerpt the following passage, which seems to make a compelling case as to why the FDA should take those steps necessary to rectify the negative effect of this recent *Mensing* case ruling by the Supreme Court:

> Generic manufacturers' immunity from state common-law suits is contingent on the Court's finding that the manufacturers' cannot change their products' labeling under current FDA regulations, even if they learn about new risks. According to the Court, the inability to change labeling renders it impossible for generic manufacturers to comply with both federal and state obligations, giving rise to implied preemption of state law. Amending FDA regulations to permit generic manufacturers to make use of PAS and CBE procedures in response to new risk information would undo this impossibility. In that event, common law could once again complement the FDA's mandate to monitor drug safety across the full range of drugs, rather than just the decreasing portion occupied by brand-name drugs. The action requested in this petition would not only eliminate the absurd inconsistency in common-law protections based on the happenstance of whether the patient ingested the generic or brand-name form of the drug, it would also restore marketplace equality, as both types of manufacturers would face the same potential liability for failures to adequately warn of hazards associated with their products.

We will end with this query: Generic drugs may save consumers money at the pharmacy, but at what cost?

Feel free to let us know what you think about the Supreme Court's *Mensing* ruling and/or this August 2011 Citizen Petition sent to the FDA from the consumer group Public Citizen by submitting a Comment, below.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
http://www.DrugInjuryWatch.com