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FDA Could Make Generics Liable Amid Push To Undo Mensing

By **Erin Fuchs**

Law360, New York (March 28, 2012, 8:04 PM ET) -- Recent public outcry over the U.S. Supreme Court's decision in Pliva v. Mensing to shield generic-drug makers from product liability suits could push the U.S. Food and Drug Administration to enact regulations that would make them liable for failure-to-warn claims, experts say.

On Monday, Sen. Patrick Leahy, D-Vt., promised legislation that would counteract Mensing, joining public interest groups in criticizing the June ruling that federal law preempts state failure-to-warn claims against generics companies as one that creates a "two-track system" that punishes consumers who take generic drugs.

While Leahy's bill — which was has yet to be officially proposed — isn't likely to pass in an election year with a Republican House, it builds on a broader push that could spur the FDA to pass its own regulations making generics liable for failure-to-warn claims in the wake of Mensing, according to experts.

"Congress right now is having trouble keeping the lights on sometimes, or raising the debt limit so the [U.S. Department of the] Treasury can stay open," said William Cash, an attorney at plaintiffs firm Levin Papantonio Thomas Mitchell Rafferty & Proctor PA, who specializes in generic-drug cases. "But I think the FDA would be open to taking a closer look."

Consumer advocacy group Public Citizen already petitioned the FDA in August to allow generic-drug makers to change their labels more quickly to disclose previously unknown safety risks, in a change that would effectively expose generics companies to consumer failure-to-warn litigation.

On March 2, plaintiffs lawyers group The American Association for Justice filed comments to support the Public Citizen petition to the FDA, pointing out that 70 percent of prescriptions filled in the U.S. are for generic drugs and that "increased responsibilities" come with that growth.

Then, on March 21, The New York Times ran a front-page article titled "Generic Drugs Proving Resistant to Damage Suits," revealing dozens of suits against generics companies had been dismissed after the Supreme Court ruled consumers could not sue generics makers for failure-to-warn because those companies did not actually have control over their labels.

"I think there is a lot of activity heating up around this issue that has happened in the past month," Cash told Law360. "For whatever reason, I think the issue is getting traction."

While some experts may believe Congress must amend the Federal Food, Drug and Cosmetic Act to counteract Mensing, Cash contends the FDA can tackle the issue because that law dictates that drugs must be appropriately labeled and not misbranded, and the agency can "fill in the details" on how to reach that goal.

Unlike Congress, the FDA could be well-positioned to address the perceived unfairness of Mensing because the agency aims to ensure that labels for the same drugs are the same, according to Jim Huston, who heads the trial practice group at Morrison & Foerster LLP.

"If everybody changes their labels without FDA approval, then you have eight or 10 or 15 labels on exactly the same drug," Huston said. "Uniformity of labeling is one of the primary objectives of the FDA."

To respond to concerns over Mensing, the agency may enact regulations requiring generics companies to notify both branded drug companies and the agency with suggestions for label changes to disclose new risks, Huston predicted.

Public Citizen, meanwhile, is asking the FDA to allow generic-drug companies to add new warnings to their labels without approval from the agency — a regulation that could confuse consumers, lawyers said.

New warnings added haphazardly might even create new risks for patients, according to Ralph Hall, a law professor at the University of Minnesota and lawyer at Faegre Baker Daniels. Warnings on antidepressants about suicide risks, for example, might have done more harm than good by stopping depressives from taking the medicine they needed, he said.

"We need to be careful to avoid the law of unintended consequences," Hall told Law360 on Wednesday. "Just willy-nilly adding a warning may have negative consequences on patient use of a product."

Still, as the law stands post-Mensing, generics makers have no liability for their warning labels, even if they know their warnings are inadequate, Leahy said in a statement Monday, pointing out that a number of advocacy groups had urged both Congress and the FDA to grapple with the outcome in Mensing.

That push could ultimately play a role in persuading the FDA to address the Mensing issue in its rules, Huston said.

"I think regulatory agencies, just like any human being, respond to public scrutiny and outcry," Huston said. "I think they respond to that — and should."

--Editing by Elizabeth Bowen.