FDA Delay Shows Generics Label Critics Gaining Ground

By Sindhu Sundar

Law360, New York (February 19, 2015, 2:03 PM ET) -- The U.S. Food and Drug Administration's upcoming hearing on a proposal to give generics makers more control over warning labels marks another delay for the rule, and attorneys say the agency's cautious approach is a recognition of loud opposition from an industry that wants the agency to take responsibility for labeling.

The FDA announced Tuesday that the public comment period on the proposal will now run until April 27 and that it plans to conduct an all-day hearing on March 27 to discuss the contentious proposal. The generics drug industry, which has vehemently opposed the measure as one that would increase healthcare costs by billions of dollars in the U.S., has proposed an alternative measure that would have the FDA make decisions on changes to warning labels.

"[The Generic Pharmaceutical Association] welcomes all indications that the FDA is taking a deliberate approach to finalizing the proposed rule on generic labeling," the group's CEO Ralph Neas said in a statement Wednesday. "GPhA and its member companies look forward to working with FDA so that any final rule avoids confusion, ensures that the agency preapproves safety labeling changes by all manufacturers, once the drug becomes multisource, and does not hinder patient access to safe, affordable generic drugs."

The FDA's proposal, in its original form, would give generics makers the power to independently change the warning labels on their products, based on new safety information they obtain. Generics makers are currently required to defer to their branded-drug makers on labeling, a requirement that generally shields them from failure-to-warn claims in product liability litigation.

GPhA's alternative proposal, which it calls "expedited agency review," is based on the claim that the FDA has the most information required to make decisions on safety-related labeling. Defense attorneys have generally backed that view, arguing that allowing generics makers to make independent label changes would be costly and would confuse patients with conflicting safety information for the same drug.

"We cannot have a situation where you could have upwards of 10 different labels, if you have nine generics on the market," said Erin Bosman of Morrison & Foerster LLP. "The labels would need to stay the same in order to maintain the [federal] sameness requirement."

That requirement stems from the 1984 Hatch-Waxman Act, which calls for generic drug products to be virtually identical to their brand-name counterparts.
GPhA, which has threatened to sue the agency if it proceeds with its rule, argues that a study it commissioned found that the FDA's proposal, if implemented, could add some $4 billion to U.S. health care costs. The FDA last year postponed issuing its final rule until September 2015.

Attorneys say the FDA must also consider whether to proceed with a proposal that would effectively unravel the influence of the U.S. Supreme Court's 2011 decision in Pliva v. Mensing. The high court held that federal law preempts state law tort claims against generic-drug manufacturers, which are required to use the same warning labels as brand-name companies.

"I think one thing the FDA is going to have to determine is if it is their role to change this preemption scheme, or instead to recognize that this is something that needs to be dealt with by Congress," Bosman said.

Plaintiffs attorneys, meanwhile, have argued that the Mensing ruling has unfairly blocked off recourse to patients injured by generic drugs and have said the FDA's proposal would bring more accountability to generics makers. In many states, product makers can be sued for injuries stemming only from products they manufactured, which hampers patients injured by generics from targeting the branded-drug maker responsible for the drug's labeling, they say.

"These generics makers, since Mensing, are really enjoying this anti-competitive position," said Tim O'Brien of injury firm Levin Papantonio Thomas Mitchell Rafferty & Proctor PA. "They have done nothing to invent the drug, and they don't want to take any liability for warnings; they just want to punch out pills and rake in money."

Generic drugs account for the vast majority — 80 percent — of drugs dispensed in the U.S., according to GPhA, which has acknowledged its growing ties in recent years with federal and state legislators, as well as FDA regulators. The association has increased its full-time staff by 40 percent over the past two years, and its revenues have increased by more than 30 percent since 2011, to $12.4 million last year, according to the group.

"Our influence in the nation's Capitol and in state legislatures has never been greater," Neas said in remarks during a keynote address in February. "We have never before worked as closely with regulators at the FDA, especially with the office of generic drugs, as we do today."

--Editing by Kat Laskowski and Christine Chun.

All Content © 2003-2015, Portfolio Media, Inc.