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SCIENCE

Makers of Generic Drugs Challenge F.D.A. Plan for Updated Warnings

By **SABRINA TAVERNISE** MARCH 27, 2015

BETHESDA, Md. — The pharmaceutical industry mounted a new challenge on Friday to a federal plan that would require generic drug companies to take the initiative to update their labels to warn consumers whenever health risks were discovered, a shift that would expose the companies to legal liability.

During a public meeting at the Food and Drug Administration, the industry proposed instead that the F.D.A. itself should decide whether new warnings on drug labels are required and, if so, order companies to make the changes. But consumer advocacy groups said the companies were trying to shift responsibility to an agency that lacks the resources to track the vast array of drugs on the market.

More than 80 percent of prescriptions in the United States are now filled by generic versions of a drug, and most states permit pharmacists to dispense a generic in place of a prescribed brand-name drug. Millions of Americans take generics.

Under current rules, generic drug makers are not allowed to update such health warnings unless the F.D.A. orders them to do so — a peculiarity of the 1984 law that governs the generics. Brand-name producers make changes as they discover risks, and the F.D.A. approves them later, prompting changes in

generic labels.

In 2013, the F.D.A. proposed a rule giving generic drug makers the same control over their labels that brand-name drug makers have.

The proposal came after the Supreme Court ruled in 2011 that generic companies did not control what their labels said and therefore could not be sued for failing to alert patients to the risks of taking the drugs.

A consumer advocacy group, Public Citizen, subsequently petitioned the F.D.A. to let generic companies have more control, a change it said would fill a safety gap that the court's decision had opened and allow consumers of generic drugs to sue a company that failed to warn about risks.

The issue has prompted intense resistance from the drug industry. In an unusual move, the F.D.A. reopened the period for public comment on its proposed rule until April 27 and held a public meeting on Friday that drew dozens of consumers and representatives of drug companies.

Generic drug companies argue that the F.D.A.'s proposed rule, by exposing the companies to expensive lawsuits, would increase costs for an industry that has helped American consumers save billions of dollars. The companies also contend that the rule could sow confusion because generic companies making the same drug might have different warning labels.

They argue that, unlike brand-name drug makers, generic companies do not have years of clinical data obtained through drug development and patent ownership, and that new warnings by any single generic producer would be based on sparse patient information. Only the F.D.A., they say, has access to the full range of data — from the brand-name producer, generic producers and other sources.

Ralph G. Neas, president of the Generic Pharmaceutical Association, the industry trade group, said the industry's proposal to make the F.D.A. responsible would significantly speed up labeling changes. The proposal would apply only when both a brand-name drug and its generic counterpart were both on the market.

"To delegate decision-making to a manufacturer who does not have all the relevant scientific information would not be responsible and could have

harmful consequences," Mr. Neas said.

Dr. Michael Carome, director of the health research group at Public Citizen, disputed the idea that drug companies do not have enough data to make decisions. The industry's proposal to put the burden on the F.D.A. was first made public last year.

Dr. Carome compared the industry's proposal to asking the Department of Transportation to take responsibility for issuing safety updates for every type of American car.

"No other industry is so shielded from liability risk," he said.

He said that legal liability would put pressure on companies to aggressively track safety and that monitoring efforts would decline without it, a contention the industry disputes.

"We're big fans of generic drugs," Dr. Carome said. "The companies have made drugs more affordable for all of us. But because they dominate the market, it's critical that they have full incentives to engage in robust monitoring of safety."

The issue might end up back in court. Mr. Neas said he had told the F.D.A., "If you do something inconsistent with Hatch-Waxman, we will go to court because you will be exceeding your legal authority." He was referring to the 1984 Hatch-Waxman Act, which governs generic drugs and states that labels on generic drugs, with a few exceptions, must be the same as those on their brand-name equivalent.

Dr. Carome of Public Citizen contended that the F.D.A. was on firm ground.

"No agency issues a rule unless they believe they have full legal authority to do it," he said.

Katie Thomas contributed reporting from New York.

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