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Supreme Court to examine a common legal strategy drug makers use to sidestep patient lawsuits

By Ike Swetlitz @ikeswetlitz

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WASHINGTON — The Supreme Court will next week consider a case that has the potential to upend how drug companies can defend themselves from patient lawsuits.

The case, Merck Sharp & Dohme Corp. v. Doris Albrecht, began as a collection of lawsuits by more than a thousand patients who used the osteoporosis drug Fosamax[1]. The patients say the drug maker failed to adequately warn them that taking the drug might make them more likely to fracture their femurs.

The drug maker, however, argues that it offered to warn patients by updating the drug label — but the Food and Drug Administration told the company it wasn't allowed.

The Supreme Court is set to weigh in on how companies can use that defense, which is a common legal strategy in the pharmaceutical industry. The maneuver allows drug makers to quickly resolve cases and avoid otherwise costly legal battles.

"Regardless of the outcome of the case, this is going to be a very big deal, because [this defense is] a really important issue with respect to drug manufacturer liability," said Patti Zettler, an associate

professor at Georgia State University College of Law who used to work in the FDA's office of chief counsel.

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In the late aughts, some patients taking osteoporosis drugs like Fosamax who suffered from fractures in their femurs started to sue the drug manufacturers, claiming the company should have warned them they might develop fractures if they took the drugs. The patients argued that the drug makers were breaking state "failure to warn" laws, which require companies to warn consumers about any dangers associated with their products.

But drugs are a special case — because the FDA so tightly regulates what drug companies are and are not allowed to say about their products, the Supreme Court has previously ruled that a drug company can't be punished to failing to warn consumers about a risk if the FDA would have forbidden the company from doing so.

And that, Merck argues, is exactly what happened. Over the course of a few years, Merck and the FDA went back and forth about adding a warning about fractures, and, up until the end of 2010, the FDA blocked Merck's proposed warnings, the company argues. Therefore, Merck was not responsible for patients who suffered bone fractures at that time.

The patients say Merck never really asked the FDA for permission to include the warning that the patients wanted. They argue the company proposed a watered-down warning about a more benign type of fracture than they were experiencing. The FDA did indeed reject the weaker warning, but they might not have rejected a stronger warning. Therefore, the patients argue, the principle that the company can't be held liable for failing to include a warning the FDA would have rejected does not apply.

Merck's line of argument in this case is a common and popular one for drug makers. If a pharmaceutical company is able to successfully argue that federal law prevented it from changing its labels, then it really doesn't matter if the drug actually harmed the patient. Even if it did, the company can't be held responsible because federal law prohibited them from warning the patients.

"It's used every time they have a chance to use it," said Michael Krauss, a professor of law at the Antonin Scalia Law School at George Mason University.

Related: [2]
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While the case at hand involves arcane details of dialogue between the FDA and drug companies, it rests on a fundamental legal question that has challenged the country since its founding — what happens when state law and federal law appear to be in conflict?

In this case, the federal laws at issue are those that govern how companies can update the official, FDA-approved informational labels about their brand-name prescription drugs when the company learns that the drugs might be more dangerous than it initially thought. The law sets up a framework for how these

updates can happen, and gives the FDA power both to change the label independent of the company and to stop a company from changing its label.

At the same time, various state laws require companies to warn a consumer if its products are or could be dangerous.

Which law takes precedence — in legalese, whether the federal law preempts the state law — is central to the Supreme Court's case.

Attorneys who are not personally involved in this case told STAT that there are two big questions that the Supreme Court might help answer about when drug companies can use this preemption defense. First, who gets to answer that question, the judge or the jury? And second, what standard of evidence should they use to make the decision?

Who gets to decide?

Lower courts disagreed over whether a judge or jury should determine whether there is enough evidence to support Merck's argument that federal law prevented it from updating its FDA label.

A district court in New Jersey ruled in 2013 that a judge could decide whether or not there was sufficient evidence to allow Merck to argue that federal law prevented it from making the change. It was a win for drug companies, since it gives them a chance to avoid a costly and potentially chaotic jury trial.

The patients appealed and the appellate court reversed the decision.

Related: [3]
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But the nature of these cases can make a jury's job difficult, Krauss, the Antonin Scalia Law School professor, explained. They might get instructions like, "Your job isn't to decide whether or not Merck should have added the warning; instead, it's to determine whether or not the FDA would have rejected the warning, had Merck tried to add it." (And in this case, Merck argues that it did indeed try to add the warning.)

"Quite often, two-thirds of the jurors might not even understand [the] instruction," Krauss said.

That's dangerous for drug companies because juries can make decisions based on whatever they want. They don't actually have to follow the law. The jury could just decide that the drug company should have added the warning — even though the judge told it not to — and then just pick out a set of facts that prevent the drug company from using the preemption defense.

"[This] undermines the very idea of a legal preemption defense," Krauss said.

How much evidence is required?

Whether the judge or jury makes the decision, there's still the question of what standard they need to use. That's also at issue in this case.

"The inquiry becomes, how much evidence do you need about whether FDA would accept or reject a proposed warning that the plaintiffs are asserting the manufacturer should have included?" said Stephen Klein, an attorney at Hollingsworth LLP, who represents Novartis, which manufactures a Fosamax-like drug, but is not directly involved in the Supreme Court case.

The current standard was established in a 2009 case called Wyeth v. Levine. In that case, the Supreme Court ruled that in order for a drug company to argue that federal law prevented them from changing the label, there must exist clear evidence that the label change would have been rejected by the FDA.

In that case, the court ruled there was no clear evidence that the FDA would have rejected the change because Wyeth did not actually ask the FDA to make the label change at issue in the case.

But in Merck v. Albrecht, the drug company argues that it did, in fact, ask the FDA to make the very change that the patients are arguing should have been made — and the FDA rejected it.

"Now Merck is like, 'Um, we did ask and the FDA said no. What else do you want from us?'" said Elizabeth McCuskey, a professor of law at the University of Toledo. "If this isn't clear evidence of a rejection, then what is?"

But, the patients are arguing, that's not true — Merck actually did not ask FDA to make the specific change they wanted. Instead, the drug company proposed a warning about "stress fractures," a much less severe condition than the fractures from which the patients were suffering. The FDA did indeed forbid Merck from including that warning about stress fractures.

But, the patients argue, that's because the warning was too weak and should have been stronger. They argue that there's not clear evidence the FDA would have rejected the specific warning about the more severe fractures that the patients suffered.

Whichever way the Supreme Court rules, McCuskey said, it will likely encourage companies to get more clarity from the FDA about why the agency rejects label changes. Even if the Supreme Court rules that there was sufficient evidence in this case, companies will want to make sure they meet that standard in the future because they know that if they do, they'll be able to use this defense.

The FDA weighs in — kind of

It would seem that this is a simple question for the FDA: What did you mean when you rejected Merck's proposed warning?

A hint of that answer appears in an amicus brief filed with the Supreme Court from the Department of Justice and the Department of Health and Human Services, which contains FDA. In it, the government sided with Merck, arguing that the FDA was clear in its communications with the company. Merck's defense was therefore appropriate, the government wrote in the brief.

"FDA determined that existing information about atypical femoral fractures was insufficient to warrant a change to Fosamax's Warnings and Precautions section [on its label]," it said.

But, McCuskey said, what's less clear is if the government's argument actually represents the opinion of the FDA. Arguments on behalf of the U.S. government before the Supreme Court come from the solicitor general, who is chosen by the president.

"[The] solicitor general and senior positions are political appointees, so the government's position on preemption changes with the executive view of litigation and preemption," McCuskey said.

The FDA declined to comment on the case.

Lawyers representing the patients and Merck will argue their sides before the Supreme Court on Jan. 7, and the justices will issue a ruling some time before the end of their term, usually in June. In the meantime, lawyers are waiting with bated breath.

"Just about every attorney on both the plaintiff side and the defense side involved in pharmaceutical litigation is watching this case," Klein said.

About the Author

Ike Swetlitz[7]

Washington Correspondent

Ike is a Washington correspondent, reporting at the intersection of life science and national politics.

ike.swetlitz@statnews.com[8]
@ikeswetlitz[9]

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