

Material Intelligence by Pharmawire

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Story * Narrow decision expected in Wyeth v. Levine

* Bills to be reintroduced dealing with devices

Congress is likely to address the issue of preemption during the first half of the year, sources said, but may only tackle the issue as it relates to medical devices, leaving pharmaceutical companies to wait for a decision from the Supreme Court in Wyeth v. Levine.

Legislation intended to preserve the right to file product liability lawsuits against drug makers and medical device manufacturers has widely been expected ever since Democrats increased their majorities in both houses of Congress last November, this news service has previously reported.

But with a decision expected in Wyeth v. Levine as early as next month, some legal experts in Washington said it is more likely legislators will deal with medical device manufacturers first. Preemption - or the idea that federal law supercedes state law - is explicitly spelled out in the approval process for medical devices. The Food Drug and Cosmetic Act, however, raises stickier questions about implied preemption, and lawmakers are likely to wait and see how the Supreme Court tackles the issue, these experts said.

In February of last year, the Supreme Court ruled on Riegel v. Medtronic, which barred patients injured by a medical device from suing the manufacturer if the FDA had approved the product - citing the preemption doctrine.

Already, lawmakers have voiced their intentions to reverse the Court's decision in Riegel. Reps. Henry Waxman (D-CA) has said he plans on introducing a bill that would do just that, and Sens. Edward Kennedy (D-MA) and Patrick Leahy (D-VT) are likely to reintroduce a bill that died in the Senate last year, sources in Washington said.

But a much narrower decision is expected in Wyeth v. Levine, according to Arnold Friede, of counsel in the health law department of McDermott Will & Emery.

That case centers on Diana Levine, who lost her hand and forearm to gangrene after receiving Wyeth's anti-nausea drug Phenergan via a "push IV." Wyeth has argued the company is not liable because the FDA knew about the risk of using the method and did not require any update to the drug's label.

Friede said the court may very well find preemption "viable on a very narrow basis, likely having to do with situations where its entirely clear the label [update] was expressly rejected by the FDA. I think that even someone like Waxman would probably agree that there may be circumstances in which FDA has all of the right information, and preemption is viable."

But even if the Wyeth decision is an outright victory for the drug maker, and Democratic lawmakers decide to push for a legislative solution, they are likely to do so separately from their efforts to reverse Riegel, said Sol Weiss, who attended oral arguments for Wyeth and is a director at Anapol Schwartz.

Weiss pointed out legislation reversing the Riegel decision had already been considered last term, giving it an enormous head start and ensuring that piece of legislation would be tackled as a way to pave the path for addressing whatever decision comes out of Wyeth.

Regardless, the first piece of anti-preemption legislation to be considered will be the Food and Drug Administration Globalization Act of 2009, introduced earlier this month by Rep. John Dingell (D-MI), pointed out Mark Mansour, a partner in the food and drug practice group at Bryan Cave.

That bill, which was motivated by the peanut butter salmonella scare, includes anti-preemption language. "This Act and the amendments made by this Act may not be construed as modifying or otherwise affecting any action or the liability of any person (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) under the law of any State," the bill states.

That sweeping clause could be enough to stave off preemption for all products under the FDA's purview, Mansour said. The bill will be taken up by the House Energy and Commerce Committee in the coming weeks, he said.

For now, all eyes will be on the Court's decision in Wyeth, according to Heather Hodges, counsel at Crowell & Moring, and just how narrow the finding turns out. "From our perspective, that's the question mark," Hodges said. "If there is implied preemption what's the scope of that?"

by Marc Longpré

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