Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

Is Impossibility Preemption Impossible? Federal Drug Law and Preemption of State Tort Claims

January 19, 2018

Federal preemption, which is grounded in the Constitution's Supremacy Clause, has long been one of the most important and heavily debated defenses for the manufacturers of drugs and medical devices against state tort lawsuits. In this vein, the question of when "impossibility preemption"— a form of implied preemption that exists where it is impossible for a private party to comply with both state and federal law— should shield drug manufacturers from liability in state-law failure-to-warn claims has long been the subject of dispute, resulting in conflicting opinions from the Supreme and lower courts. The crux of the tension surrounding preemption in this context is a policy debate— while consumer advocates argue that state tort liability is key to ensuring patient safety, drug manufacturers urge that such laws may limit patient access to drugs by leaving innovators vulnerable to costly litigation and undermining FDA's authority. Against this backdrop, the Supreme Court is considering whether to grant a petition for certiorari in what would be its fourth FDA preemption case in the last decade. In *Merck v. Albrecht*, the petition asks the court to clarify when a brand-name drug manufacturer has met the burden for showing that the impossibility preemption defense should apply. This Sidebar begins by providing a brief background on federal drug labeling law and the Supreme Court's preemption case law, including the seminal decision of *Wyeth v. Levine*. The Sidebar concludes with an overview of the *Merck* petition, analyzing the key issues of interest for Congress that the petition raises.

Background. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), before a new drug (i.e., brand-name drug) may be legally marketed in the United States, manufacturers are required to obtain FDA approval through submission of a new drug application (NDA). As part of the NDA, the manufacturer must propose labeling that is neither false nor misleading. While FDA approval of a new drug encompasses approval of the product's labeling, manufacturers are required to ensure that warnings on the label remain adequate as long as the product is on the market. To this end, manufacturers may revise warnings on drug labels in two ways. First, under FDA's "Changes Being Effected" (CBE) regulation, a manufacturer may unilaterally, through the submission of a supplement to the NDA, change a drug label to reflect "newly required information," subject to later FDA review and approval. Such changes may "add or strengthen a contraindication, warning, precaution, or adverse reaction." To add a warning to the label via a CBE submission, "there need only be 'reasonable' evidence of a casual

Congressional Research Service
https://crsreports.congress.gov
LSB10064

association with the drug, a standard that could be met by a wide range of evidence." Alternatively, another FDA regulation provides that a manufacturer may seek to make "major changes" to the warning on a product's label by filing a "Prior Approval Supplement" (PAS). Unlike a CBE change, a change made via a PAS requires prior FDA approval before it can be implemented. FDA will reject changes proposed through either method if there is insufficient evidence of a causal link between use of the drug and the adverse event.

The ability of a brand-name drug manufacturer to make unilateral changes via the CBE regulation was central to the Supreme Court's landmark 2009 decision in *Wyeth v. Levine*. The dispute in *Wyeth* centered on whether a brand-name drug manufacturer could be sued for liability under state tort law as a result of failing to warn adequately consumers regarding concerns associated with a method of administering a drug when FDA had approved the drug label without such a warning. The *Wyeth* Court held that federal law displaces failure-to-warn claims only when a brand-name manufacturer can show "clear evidence" that FDA would not have approved a manufacturer's labeling changes. Because the CBE regulation provides an opportunity for brand-name drug manufacturers to unilaterally strengthen a warning on a product label and Wyeth had made no such attempt, the Court reasoned, it was not impossible for the drug manufacturer to change its product label and still comply with federal law. In the years following *Wyeth*, the Court, while not backtracking on its holding concerning the impossibility preemption defense for *brand-name* drug manufacturers, has twice held that impossibility preemption is a more viable defense in the context of generic drugs, where there is no comparable CBE regulation.

In Re Fosamax. A more recent preemption case concerning federal drug law—*In Re Fosamax*— arose from a dispute centered on Fosamax, a brand-named drug manufactured by Merck and approved by FDA for the treatment and prevention of bone-loss associated with osteoporosis. Upon reports that a class of drugs called bisphosphonates, which includes Fosamax, may possibly be associated with femoral (i.e. thigh) fractures, Merck submitted a request to FDA to amend its label, adding language warning of those risks. FDA rejected Merck's proposed label changes on the basis that certain terms included were imprecise and possibly misleading. A year later, after reviewing new data, FDA announced that it would require all manufacturers of bisphosphonates to make labeling changes warning of the risk of atypical femoral fractures. After Merck changed the Fosamax warning label in accordance with the new FDA requirement, hundreds of patients that suffered atypical femoral fractures after taking Fosamax alleged that Merck violated state tort laws by failing to adequately warn of that risk. Applying the Supreme Court's decision in *Wyeth*, the district court, noting *Wyeth's* "clear evidence" rule, concluded that FDA's denial of Merck's request to add language to Fosamax's label addressing atypical femoral fractures served as such evidence, resulting in the preemption of the state law tort claims.

Focusing on FDA's stated basis for denying Merck's proposed warning label changes— that certain terminology used was imprecise and potentially misleading— the U.S. Court of Appeals for the Third Circuit (Third Circuit) reversed the district court, holding that FDA's rejection of Merck's proposed changes to the warning label alone did not satisfy the *Wyeth* test. Instead, the Third Circuit held that an assessment of FDA's reasoning as to *why* the agency rejected Merck's proposed warning label change was required. Explaining that the "clear evidence" test articulated in *Wyeth* should be treated as a "demanding" standard for preempting state law claims, the Third Circuit panel concluded that Merck failed to show that it was "highly probable" that a reasonable jury would find that FDA would have rejected a warning that used more precise terminology to address the risks of atypical femoral fractures. In so doing, the panel determined that the basic *Wyeth* inquiry— "what do you think FDA would have done?"— is most appropriately resolved as a matter of fact by a jury, rather than as a matter of law by the courts, noting that, although an assessment of agency decision making is complex, it does not require special legal competence or training.

Ultimately, *In Re Fosamax* appears to have—at least in the Third Circuit—heightened the difficulty in showing impossibility preemption in two ways. First, according to the Third Circuit, FDA's *actual*

rejection of a warning proposed by a brand-name drug manufacturer is insufficient to show "clear and convincing evidence" under the *Wyeth* test. Instead, *In Re Fosamax* requires the manufacturer to also account for what the agency would have done if the warning were differently worded, a seemingly difficult burden. Second, the Third Circuit concluded that whether "clear and convincing" evidence exists to warrant preemption is a fact-finding issue for a jury to resolve rather than a matter of law for the courts to decide, meaning drug manufacturers must allow for the expenses of a jury trial in order to prevail with a preemption defense.

Significance of the Questions Raised by the *Merck v. Albrecht* Petition. Following the appellate court's decision, Merck filed a petition for certiorari, now captioned *Merck v. Albrecht*, on August 22, 2017. In the petition, Merck asks the Supreme Court to consider whether "a state-law failure-to-warn claim [is] preempted when the FDA rejected the drug manufacturer's proposal to warn about the risk after being provided with the relevant scientific data; or [whether] such a case [must] go to a jury for conjecture as to *why* the FDA rejected the proposed warning."

While the Court's reasoning in *Wyeth* provides insight as to when a manufacturer does not show "clear evidence" that FDA would have rejected a proposed label change, it is less informative with respect to when that burden is met, a question that has been left to the lower courts. Some legal experts have cautioned that the lower courts have interpreted the *Wyeth* test such that impossibility preemption is all but impossible, ignoring the Supreme Court's warning in a later case, *PLIVA v. Mensing*, that preemption cannot be rendered "all but meaningless." In its petition, Merck argues that the Third Circuit's *In Re Fosamax* decision places brand-name drug manufacturers in a precarious position—"if they cooperate with the FDA, share their safety data, and follow the agency's direction to 'hold off' on adding label warnings, they still cannot escape costly, burdensome tort litigation complaining about those labels." As a consequence, the petition goes on to argue, brand-name drug manufacturers will feel it necessary to account for the growing potential for costly litigation by increasing drug prices and attempting to ward off such litigation by inundating FDA with "alternative proposals [and] requests for clarification." In contrast, patients alleging injury caused by Fosamax (Respondents) responded to the petition, contending that the Third Circuit "faithfully applied *Wyeth v. Levine*." Respondents maintain that Merck's petition asks the Court for a "bright line rule that *any* FDA rejection of proposed warning language relating to a medical risk 'should suffice—as matter of law— to preempt state tort liability' for all failure-to-warn claims relating to such a risk," even where FDA's rejection provides that the warning was rejected because the manufacturer's description of the risk was inaccurate or misleading. Such an argument, respondents explain, "ignores [*Wyeth's*] fundamental teaching that, under federal law, 'the manufacturer bears responsibility for the content of its label at all times.'"

Although the Supreme Court has not yet decided whether it will grant the Petition, it has signaled interest by inviting the Solicitor General to file a brief expressing the views of the United States. Should the Court move forward with hearing the case, it could serve as a vehicle for addressing a perennial issue of congressional interest— how to balance patient safety with patient access to innovative drugs. More broadly, regardless of the Court's interest in this particular case, Congress has the power to amend federal drug law and clarify its preemptive scope with respect to state tort claims, something the legislature has done in the medical device context.

Author Information

Kathryn B. Armstrong
Legislative Attorney

Disclaimer