The Supreme Court's Latest Ruling on Drug Liability and its Implications for Future Failure-to-Warn Litigation

Health Policy Portal

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For many years, people injured by prescription medicines have been able to sue drug manufacturers to receive compensation for their injuries when those companies fail to provide adequate warnings of known risks of those medicines. This type of suit is known as "failure-to-warn" litigation. Failure-to-warn litigation serves a vital function not just by compensating those who have been harmed but also by encouraging drug manufacturers to warn of drug risks promptly and clearly and by publicizing otherwise non-public information on the risks and benefits of prescription drugs. In May 2019, the U.S. Supreme Court decided a case, *Merck v. Albrecht*, that ensures that failure-to-warn litigation in this context will continue.[1] This article reviews the *Merck* decision and discusses some of its likely consequences.

Reactions to the *Merck* decision by legal and policy experts have varied. Some commentators have described the *Merck* decision as a win for the pharmaceutical industry;[2] others as a loss.[3] As we describe below, we believe that, on the whole, *Merck* represents a victory for physicians, patients, and the public, not for industry. *Merck* clarified the law to make it more difficult for brand-name drug manufacturer to shield themselves from liability for failure to warn of drugs' known risks. We predict that, in the wake of *Merck*, drug manufacturers are likely to update drug labeling more quickly and more often, with more cautious warning language. We explain a crucial but often overlooked benefit of failure-to-warn litigation: otherwise unavailable information on the effectiveness and safety of drugs flows from such litigation to physicians, regulators, including the U.S. Food and Drug Administration (FDA), and the public at large.

Alendronate (Fosamax) and the Risk of Atypical Femur Fracture

The *Merck v. Albrecht* case was brought by patients who took alendronate (Fosamax), a drug sold by Merck and FDA-approved in 1995 for treatment of osteoporosis in postmenopausal women. Alendronate is a bisphosphonate that treats osteoporosis by slowing bone resorption, the process by which bone tissue is broken down and recycled. The bisphosphonates were a transformational drug class in the treatment of osteoporosis, and alendronate became a blockbuster for Merck, reaching a peak of $2.5 billion annual sales.[4] But widespread experience with long-term use of alendronate uncovered a rare but potentially devastating side effect: atypical femur fracture, a fracture in which the thigh bone may fracture completely unrelated to use or injury. The plaintiffs in *Merck* are more than 500 patients who suffered such fractures between 1999 and

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2010, some of whom took alendronate for many years.[5] These patients allege that when they took alendronate, Merck's labeling for the drug failed to provide an adequate warning of the risk of such fractures even though Merck knew of the risk. The patients further allege that, had they known the true risks of alendronate, they would not have taken the drug, or would not have taken it as long as they did. These patients sued, asking the court to hold Merck liable under their states' product liability statutes or common laws for its failure to warn of the true risks of alendronate and to order Merck to compensate them for their injuries.

Alendronate's Labeling and Merck's View That It Is Not Liable for Failing to Warn of Alendronate's Risks

A key issue since the beginning of *Merck* case was the adequacy of warning language that Merck suggested to the FDA before the plaintiffs were injured. Merck gave the FDA data about risk of atypical femur fracture during the relevant time period and suggested revising alendronate's labeling to warn of the risk of "stress fractures." Merck proposed this labeling revision through the FDA's Prior Approval Supplement (PAS) pathway, which requires the FDA to approve the labeling revision before it is disseminated. The FDA rejected Merck's proposed revision, noting that the term "stress fractures" implies relatively minor risk and does not explicitly warn patients and physicians of the risk of much more serious "atypical femur fractures." While the FDA rejected Merck's specific proposed labeling change, it encouraged Merck to resubmit its application to address aspects of the warning deemed deficient.[6] Merck could have resubmitted an application with different warning language, but did not do so. Alternatively, Merck could have unilaterally added a warning about atypical femur fracture to its labeling through the FDA's Changes Being Effected (CBE) pathway. Under the CBE pathway, a drug company may initiate a labeling change to reflect newly acquired information, subject to later FDA review and validation. Merck chose not resubmit a PAS application or to revise its label under the CBE pathway.

Merck's central legal argument throughout the litigation was that it could not be held liable for failing to warn of the risk of atypical femur fractures caused by alendronate because the FDA had rejected its proposed warning about stress fractures and would have rejected any subsequent effort to add a warning about atypical femur fractures to its labeling. In Merck's view, it could not possibly have complied with federal law (rejecting a warning) and state law (requiring a warning) at the same time. Merck's argument is based on a doctrine of constitutional law known as impossibility preemption, which holds that when state and federal law conflict in a way that makes it impossible for a private party to comply with both, federal law prevails.[7] In failure-to-warn litigation brought under state law, the litigation must be dismissed if preemption applies, and the drug manufacturer will not be found liable.

Key Precedent: *Wyeth v. Levine*

Shortly after *Merck v. Albrecht* was filed in 2009, the US Supreme Court decided another key case, *Wyeth v. Levine*, which established binding precedent on the preemption doctrine in the context of drug labeling.[8] The *Wyeth* lawsuit was brought against Wyeth by a patient, Diana Levine, who was improperly injected with Wyeth's promethazine product (Phenergan) and subsequently experienced a severe adverse reaction, leading to gangrene and amputation of her forearm.[9] Levine alleged that Wyeth had failed to provide an adequate warning of the risk of gangrene and that that failure to warn constituted a violation of Vermont state law. Wyeth argued that Levine's state-law-based case should be dismissed under preemption doctrine since the drug's warnings were FDA-approved. The Supreme Court sided with Levine, explaining that "absent clear evidence that the FDA would not have approved a change" to the drug label, a court must "not conclude that it was impossible … to comply with both federal and state requirements" and holding that Wyeth had failed to prove that the FDA would have rejected an adequate warning in the labeling.[10] However, *Wyeth* left open some ambiguity as to what constitutes "clear evidence that the FDA would not have approved a change" to the labeling.

The Supreme Court's Decision in *Merck v. Albrecht*

The Supreme Court resolved any remaining ambiguity about preemption in the context of drug labeling in *Merck v. Albrecht*. The Court's opinion held that "showing that federal law prohibited the drug manufacturer from adding a warning that would satisfy state law requires the drug manufacturer to show that it fully informed the FDA of the justifications for the warning required by state law *and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning*."[11] In other words, only evidence that FDA *actually* considered and then rejected the warning required under state law suffices to establish that the drug manufacturer was caught in an impossible conflict between state and federal law. A drug manufacturer must meet this demanding standard to show that a state law failure-to-warn claim is preempted by federal law. It is not enough for the drug manufacturer to show that the FDA probably or even almost certainly would have rejected an adequate warning. The court thus announced a legal standard that appears to favor plaintiffs and disfavor drug manufacturers.

The Supreme Court did not decide the ultimate question of whether Merck is liable for the plaintiffs' injuries. Instead, the Court vacated the judgment of the lower court and remanded the case, asking the lower court to apply the Court's newly-announced legal standard and requiring that a judge, not a jury, decide the question of whether the impossibility preemption applies.[12] However, the Court's decision suggests that Merck

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has not made out a convincing case under the newly articulated standard, because Merck has not shown that it would have been impossible to add to its labeling an adequate warning about the risk of "atypical femur fractures" rather than "stress fractures." Indeed, the Supreme Court observed that Merck could have used the CBE pathway to proactively add a warning about atypical femur fractures to its labeling, without waiting for the FDA, and the Court stated that because "the CBE regulation permits changes, [] a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both."[13]

Implications of Merck for Failure-to-Warn Litigation

Failure-to-warn litigation serves many socially useful functions beyond compensating people harmed by drugs. Failure-to-warn litigation uncovers and publicizes otherwise unknown drug hazards; incentivizes drug companies to disclose risks promptly; and ensures that drug manufacturers, which have the greatest access to information about their products, bear primary responsibility for warning the public of risks. The *Merck* decision is therefore important not just to lawyers but to physicians, the FDA and other regulators, and the public at large. There are two particularly relevant implications:

1. Failure-to-warn litigation will continue

First, failure-to-warn litigation will continue after *Merck*. Many legal scholars and public interest groups had feared that the Supreme Court would accept Merck's invitation to rewrite the law to permit drug companies to immunize themselves more easily from failure-to-warn liability by raising the preemption defense. That fear did not come to pass. Because the standard announced in *Merck* requires a drug company to show that FDA actually considered and then rejected an adequate warning — a rare scenario — we expect that relatively few failure-to-warn lawsuits relating to FDA-approved drugs will be dismissed under the preemption doctrine set down in the *Merck* case. *Merck* thus ensures that most injured patients will continue to be able to rely on bringing these cases.[15]

2. Drug manufacturers may update drug labeling more quickly and more often, with more cautious warning language

A second consequence of *Merck* is a potential increase in use of the CBE pathway by drug manufacturers to revise their labels more quickly and more often, with more cautious warning language to ward off failure-to-warn liability. As noted above, the CBE pathway permits drug manufacturers to change a drug's labeling without prior FDA approval if the change is designed to "add or strengthen a … warning" where there is "newly acquired information" about the "evidence of a causal association" between the drug and a risk of harm.[16] After a CBE labeling change, the FDA has 30 days to review and amend the labeling if it deems necessary — for example, in the event of an "overwarning," in which exaggerated warnings could discourage appropriate use of generally beneficial drugs.[17]

To the extent that drug manufacturers make more frequent and more timely revisions to drug labels to reflect new safety information, patients and physicians will benefit from having the opportunity to be better informed. Patients and physicians will also benefit if manufacturers provide more detailed warnings in their drug labels, to reduce the risk of failure-to-warn liability. Of course, manufacturers will still have a substantial financial incentive to delay or de-emphasize safety warnings for their products, knowing that prominent new warnings in the labeling — and their associated publicity — may reduce use.[18] Damages emerging from failure-to-warn cases hardly ever outweigh the substantial revenues that manufacturers can earn from downplaying known risks of their prescription drugs.[19]

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The future of failure-to-warn litigation

As long as failure-to-warn litigation endures, physicians, the FDA, and the public at large will continue to benefit from exposure of the otherwise unavailable information on the effectiveness and safety of drugs that flows from this litigation. For decades, the litigation discovery process, in which plaintiffs commonly receive access to millions of pages of internal drug company documents, has revealed important new information on the benefits and risks of many drug products.[20] In some instances, such information has prompted action by the FDA or the manufacturer. For example, previ-

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ously hidden information on the cardiovascular risks of Merck's rofecoxib (Vioxx) product uncovered in failure-to-warn litigation (and subsequent public outcry) prompted Merck to withdraw the product from the market.[21] Information uncovered in failure-to-warn litigation can also reveal omissions, inaccuracies, and outright distortions in the medical literature, the correction of which can lead to changes in standards of care and prescribing habits. For example, a failure-to-warn suit against Glaxo-SmithKline concerning excess risk of suicide in adolescent patients taking paroxetine (Paxil) revealed that the manufacturer had inaccurately and misleadingly represented efficacy and safety in a published study relied on in marketing.[22]

Information uncovered in failure-to-warn litigation is today perhaps more important than ever. While Merck contended in *Merck v. Albrecht* that it presented all relevant scientific data on the risks of alendronate to the FDA, in practice the FDA almost invariably lacks complete information on the benefits and risks of prescription drugs, particularly at the time of approval. The benefit/risk balance for any drug varies by indication and by patient, and is informed by the continued accumulation of experience with using the drug as long as it is available on the market, not just based on the information on drug safety submitted to the FDA during the pre-approval clinical trial process — which increasingly are approvals based on early-phase trials and effects on surrogate endpoints rather than clinical measures of patient outcome.[23] Post-approval safety actions taken by the FDA are common, as one-third of all novel therapeutics approved between 2001 and 2010 were followed by drug safety communications, new boxed warnings, or (in rare cases) withdrawals due to safety concerns.[24] At least one safety-related labeling update was made to the labels of over 70% of new molecular entity drug products approved between 2002 and 2014.[25] The FDA itself recently recognized that "the true picture of a product's safety actually evolves over the months and even years that make up a product's lifetime."[26] Failure-to-warn litigation has served and will continue to serve as a critical safeguard, incentivizing drug companies to report risk information to the FDA promptly, thoroughly, and accurately and exposing instances where drug companies have failed to meet their obligations.

Still, failure-to-warn litigation remains limited in important respects going forward. First, unlike brand-name drug manufacturers, generic drug manufacturers are generally not subject to liability for failure to warn of known risks of prescription drugs, due to interpretations of the law made by the Supreme Court in a series of other cases.[27] This gap is particularly striking given that approximately 90% of prescriptions in the US are now filled using generic drugs,[28] which means the many patients who take these drugs have little or no legal recourse if they are injured. State and federal courts have similarly insulated manufacturers of high-risk medical devices from such litigation in many cases.[29] Second, it is unclear that labeling is the most effective way to warn patients and physicians of the risks of prescription drugs, as few patients and physicians consistently or closely read drug labels.[30] Thus, while more frequent revisions to drug labeling to reflect newly discovered risks offers the opportunity for physicians and patients to be better informed, additional steps may be needed to ensure this risk information is taken into consideration during heath care decision making.

Implications of Merck *for patients*

Merck has important implications for patients who use prescription drugs as well, even beyond the expected availability of otherwise unavailable information on the effectiveness and safety of drugs that is derived from failure-to-warn litigation. The relatively small number of patients who bring failure-to-warn suits after being injured by brand-name prescription drugs may be in a stronger position against manufacturers, because *Merck* raises the burden on drug manufacturers to prove that preemption applies and thus makes it more difficult for drug manufacturers to dismiss these suits. Patients may win an increased proportion of failure-to-warn litigation, and patients who settle with drug manufacturers rather than litigate to judgment may be able to negotiate more generous settlements. At the same time, *Merck*'s holding that the question of preemption is to be decided by a judge, not a jury, may lead to more judges deciding the question of preemption early in litigation, well before trial, which may lead to quicker disposition of failure-to-warn suits and possibly to more settlements earlier in litigation. Settlements earlier in litigation could benefit patients who bring failure-to-warn suits by reducing the cost, time, and stress associated with litigation.

Of course, most patients who take prescription drugs are never seriously injured, and most patients who are injured never bring failure-to-warn suits. Nonetheless, all patients will be affected by *Merck* insofar as their decisions as to when and how to consume prescription drugs are informed by the warnings that drug manufacturers choose to include in their labeling. If, as we predict, drug manufacturers begin to revise their labels more quickly and more often, with more cautious warning language to ward off failure-to-warn liability, there remains some risk of overwarning, potentially confusing patients' (and physicians') decision-making. The risk of overwarning underscores the need for the FDA to carefully review and, as needed, amend drug labeling when manufacturers make unilateral revisions through the CBE pathway.

In conclusion, the May 2019 U.S. Supreme Court decision in *Merck v. Albrecht* ensures that failure-to-warn litigation will continue to serve a vital function, not just by compensating those who have been harmed by prescription drugs but also by encouraging drug manufacturers to warn of drug risks promptly and clearly and by publicizing otherwise non-public information on the risks and benefits of prescription drugs.

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References

1. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019).
2. *See, e.g.*, M.C. Johnston, M.M. Boumil, and G. Curfman, "A New Supreme Court Ruling on Drug Liability," *JAMA* 322, no.7 (2019): 607-608; J. Steinberg, "Merck Wins New Look at Fosamax Preemption Case at SCOTUS," *Bloomberg Law*, May 20, 2019, *available at* <https://news.bloomberglaw.com/product-liability-and-toxics-law/merck-wins-fosamax-preemption-case-at-scotus> (last visited November 19, 2019); T. Mauro, "Unusual Supreme Court Lineup Gives Merck a Win on Fosamax Litigation," Law.com, May 20, 2019, *available at* <https://www.law.com/nationallawjournal/2019/05/20/unusual-supreme-court-lineup-gives-merck-a-win-on-fosamax-litigation/> (last visited November 19, 2019); J. Greenwald, "High Court Hands Win to Drugmakers in Preemption Case," *Business Insurance*, May 28, 2019, *available at* <https://www.businessinsurance.com/article/20190528/NEWS06/912328657/High-court-hands-win-to-drugmakers-in-preemption-case> (last visited November 19, 2019).
3. *See, e.g.*, M. Kennerly, "*Merck v. Albrecht*: The Supreme Court Eviscerates Preemption In Branded Drug Lawsuits," LexBlog, May 31, 2019, *available at* <https://www.lexblog.com/2019/05/31/merck-v-albrecht-impossibility-preemption/> (last visited November 19, 2019); B. Wolfman, "Supreme Court strongly reaffirms 2009 no-preemption decision in *Wyeth v. Levine*," Public Citizen Consumer Law & Policy Blog, May 20, 2019, *available at* <https://pubcit.typepad.com/clpblog/2019/05/supreme-court-strongly-reaffirms-earlier-no-preemption-decision-in-wyeth-v-levine.html> (last visited November 19, 2019).
4. T. Neilan, "Merck Pulls Vioxx Painkiller From Market, and Stock Plunges," *The New York Times*, September 30, 2004, *available at* <https://www.nytimes.com/2004/09/30/business/merck-pulls-vioxx-painkiller-from-market-and-stock-plunges.html> (last visited November 19, 2019).
5. *Merck*, 139 S. Ct. at 1675.
6. *Id.* at 1674.
7. *Id.* at 1678.
8. *Wyeth v. Levine*, 555 U.S. 555, 575 (2009).
9. G.J. Annas, "Good Law from Tragic Facts — Congress, the FDA, and preemption," *New England Journal of Medicine* 361, no. 12 (2009):1206-1211.
10. *Wyeth*, 555 U.S. at 571.
11. *Merck*, 139 S. Ct. at 1678 (emphasis added).
12. *Id.* at 1680.
13. *Id.* at 1679.
14. *Wyeth*, 555 U.S. at 570-71.
15. In our view, this central holding of the *Merck* decision represents a major victory for patients and a major defeat for drug manufacturers. As noted above, a separate portion of *Merck* decided a procedural issue: should the question of whether preemption applies in a given case be decided by a judge or a jury? *Merck* held that the question should be decided by a judge, not a jury. *Merck*, 139 S. Ct. at 1680. This outcome permits judges to dismiss some failure-to-warn lawsuits prior to trial, and it may favor industry to the extent that juries are more likely than judges to side with a sympathetic plaintiff. However, we believe the import of *Merck*'s central holding on the legal standard for preemption outweighs the import of the procedural judge-versus-jury question, and we therefore disagree that *Merck* represents a victory for industry, on the whole.
16. 21 C.F.R. § 314.70(c).
17. *Merck*, 139 S. Ct. at 1673. 21 C.F.R. § 314.70(c) sets the 30 day deadline for FDA review of CBE labeling changes.
18. S.B. Dusetzina, A.S. Higashi, E.R. Dorsey, R. Conti, H.A. Huskamp, S. Zhu, C.F. Garfield, and G.C. Alexander, "Impact of FDA Drug Risk Communications on Health Care Utilization and Health Behaviors: A Systematic Review," *Medical Care* 50, no. 6 (2012): 466-478.
19. A.S. Kesselheim, D.L. Darby, D.M. Studdert, R.J. Glynn, R.L. Levin, and J. Avorn, "False Claims Act Prosecution Did Not Deter Off-label Drug Use in the Case of Neurontin," *Health Affairs* 30, no. 12 (2011): 2318-2327.
20. A.C. Egilman, A.S. Kesselheim, H.M. Krumholz, J.S. Ross, J. Kim, and A. Kapczynski, "Confidentiality Orders and Public Interest in Drug and Medical Device Litigation," *JAMA Internal Medicine*, published online October 28, 2019. doi:https://doi.org/10.1001/jamainternmed.2019.5161.
21. H.M. Krumholz, J.S. Ross, A.H. Presler, and D.S. Egilman, "What Have We Learnt from Vioxx?" *BMJ* 334 (2007): 120–123.
22. J.N. Jureidini, L.B. McHenry, and P.R. Mansfield, "Clinical Trials and Drug Promotion: Selective Reporting of Study 329," *International Journal of Risk & Safety in Medicine* 20 (2008): 73-81.
23. N.S. Downing, J.A. Aminawung, N.D. Shah, H.M. Krumholz, and J.S. Ross, "Clinical Trial Evidence Supporting FDA Approval of Novel Therapeutic Agents, 2005-2012," *JAMA* 311, no. 4 (2014): 368-377; A.S. Kesselheim, B. Wang, J. M. Franklin, and J.J. Darrow, "Trends in Utilization of FDA Expedited Drug Development and Approval Programs, 1987-2014: Cohort Study," *BMJ* 351 (2015): h4633.
24. N.S. Downing, N.D. Shah, J.A. Aminawung, A.M. Pease, J.-D. Zeitoun, H.M. Krumholz, and J.S. Ross, "Postmarket Safety Events Among Novel Therapeutics Approved by the US Food and Drug Administration Between 2001 and 2010," *JAMA* 317, no. 18 (2017): 1854–1863.
25. E. Pinnow, S. Amr, S.M. Bentzen, S. Brajovic, L. Hungerford, D.M. St. George, and G. Dal Pan, "Postmarket Safety Outcomes for New Molecular Entity (NME) Drugs Approved by the Food and Drug Administration Between 2002 and 2014," *Clinical Pharmacology & Therapeutics*, 104, no. 2 (2017): 390-400.
26. FDA, Step 5: FDA Post-Marketing Drug Safety Monitoring, Jan. 4, 2018, *available at* <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405579.htm> (last visited November 19, 2019).
27. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011).
28. Association for Accessible Medicines, *2018 Generic Drug Access & Savings Report*, *available at* <https://accessiblemeds.org/resources/blog/2018-generic-drug-access-and-savings-report> (last visited November 19, 2019).
29. For a recent court decision, *see In re Zimmer (Nexgen Knee Implant Products Liability Litigation)*, 884 F.3d 746 (7th Cir. 2018).
30. J. Avorn and W. Shrank, "Highlights and a Hidden Hazard — the FDA's New Labeling Regulations," *New England Journal of Medicine* 354, no. 23 (2006): 2409-2411.

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