

Nonetheless, the extent to which gifts of food and other items will actually decrease will not be known for some time. Terms such as “occasional” and “modest” are open to interpretation. And the gifts of food and educational items that are still allowed could influence physicians’ behavior and benefit industry. It is also uncertain whether the provision of fewer gifts will lead to a decrease in overall spending on professional

promotion or will merely shift spending to other sales and marketing activities.

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The Supreme Court, Preemption, and Malpractice Liability

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The U.S. Supreme Court is currently considering the case of *Wyeth v. Levine*, whose central question is whether approval of a pharmaceutical product’s label by the Food and Drug Administration (FDA) should protect the manufacturer from litigation by patients alleging that they were inadequately warned about potential adverse effects. The FDA has suggested that if such protection (or “preemption”) were granted, it might extend to health care practitioners, thereby insulating them, as well, from tort claims “related to dissemination of risk information to patients beyond what is included in the labeling.”¹ The more likely scenario, however, is that preemption of failure-to-warn litigation against manufacturers would not reduce physicians’ malpractice risks and might actually trigger closer scrutiny of the role of physicians in warning patients about the risks associated with prescription drugs.

Product liability and medical malpractice are separate branches of personal injury law. Product-

liability claims are brought against manufacturers and generally allege defects in the design or manufacturing of products or improper warning about dangers associated with their use. Proving the existence of such a defect or failure to warn is sufficient; proof does not depend on showing that the manufacturer was negligent, which is why the standard that is applied in product-liability claims is referred to as “strict liability.”

Medical malpractice claims, on the other hand, are brought against practicing physicians. Plaintiffs must prove that the care they received fell below a standard of practice considered acceptable by the defendant’s professional peers and then go on to demonstrate that this breach caused injury. When the claims specifically involve a failure to disclose risks, courts in 25 states take a different approach: the measure, referred to as the “lay standard,” is what a reasonable patient in the plaintiff’s position would expect to be told in order

to make an informed decision about treatment.²

Product liability and medical malpractice intersect in litigation over prescription medicines, owing to the special role of the physician. The duty that any manufacturer has to warn consumers about foreseeable risks associated with its products has evolved differently in this area. Starting in the 1960s, pharmaceutical manufacturers argued that instead of warning consumers directly, it would be more effective for them to issue warnings to the gatekeepers of prescription medicines — physicians. Courts accepted that physicians’ advanced training and direct contact with patients put them in the best position to understand complex information about possible side effects and discuss the risks and benefits applicable in particular clinical circumstances. On the basis of this rationale, nearly every U.S. jurisdiction adopted the “learned-intermediary” rule, which allows pharmaceutical and device manufacturers to



David Frederick (Right), Attorney for Diana Levine (Second from Right), Speaking to Reporters after Oral Arguments in *Wyeth v. Levine* at the Supreme Court Last November.

fulfill their duty to warn by providing an accurate and adequate warning to the prescribing physician. The physician then bears responsibility for conveying those warnings to patients.

In some situations, the manufacturer may lose its ability to transfer its warning obligations to the physician through the learned-intermediary rule. For example, when the information given to physicians is deficient — omitting, underemphasizing, misstating, or obfuscating dangers — the patient maintains a right of redress against the manufacturer if those dangers materialize and cause injury. Alternatively, if a manufacturer markets its product very aggressively and without sufficient attention to certain risks, courts may rule that it has essentially undone the physician's warning. Direct-to-consumer advertising (DTCA) has struck at the foundations of the learned-intermediary rule by undercutting its main assumptions — that patients are largely ignorant of the risks associated with prescription drugs and that manufacturers lack a

means of interacting with patients other than through physicians. The New Jersey Supreme Court ruled in 1999 that DTCA created a limited exception to the learned-intermediary defense,³ and in 2007 the West Virginia Supreme Court rejected that defense in its entirety on this basis,⁴ raising questions about the rule's future. Nonetheless, in most jurisdictions, the learned-intermediary rule stands.

How might manufacturers' and physicians' duties to warn about risks of prescription drugs be affected by a broad preemption of product-liability claims against pharmaceutical manufacturers for failure to warn? It is helpful to consider three different scenarios in which such a claim may arise. In the first scenario, the FDA's approval of the warning label is based on information from a manufacturer that omits important risks. In the second scenario, the FDA's approval is based on its direct consideration of full information and the warning label is clear and complete. And in the third scenario,

the FDA has full information, but it is later alleged that the approved warnings are unclear or incomplete.

Physicians' exposure to liability in the first and second scenarios should be unaffected by the outcome of *Levine*. In the first scenario, the manufacturer would continue to be accountable through laws of product liability and possibly also fraud. The only possible recourse against the prescribing physician would be a claim that the missing warning involved a risk that physicians, as part of their general clinical knowledge, should reasonably have been aware of and informed the patient about, regardless of what warnings the manufacturer issued. In the second scenario, the learned-intermediary rule exposes the physician, rather than the manufacturer, to liability for failure to explain risks appropriately. That exposure increases if the physician departs from customary prescribing practices in other ways, such as filling prescriptions without examining the patient or prescribing for unreasonable off-label uses.

The third scenario most closely resembles the facts in *Levine*. Today, attention would focus on whether the quality and completeness of the warning were sufficient to allow the learned-intermediary defense to shield the manufacturer. Introduction of a preemption shield would probably create more comprehensive protection for manufacturers, overshadowing the learned-intermediary defense in breadth and depth. From a strict legal standpoint, little would change for physicians. Their behavior would continue to be evaluated against a negligence standard. The benchmark would be what a reasonable fellow practitioner would

have done when confronted with problematic warning information from the manufacturer. For claims alleging a breach of informed consent brought in states that apply a lay standard, the benchmark would remain the reasonable expectations of a patient regarding disclosure of relevant risks.

From a practical standpoint, on the other hand, preemption might leave the plaintiff with only one clear liability target: the physician. Consequently, the physician's conduct in the face of incomplete warnings might fall more squarely in the spotlight. Should the physician have sought more information before prescribing? Should the physician have known about studies suggesting dangers with the drug that the FDA did not act on? There is no legal reason why such questions could not be posed today. But if pharmaceutical companies are immunized in failure-to-warn cases, the motivation for plaintiffs to ask these questions of physicians may become stronger.

Even with such heightened scrutiny, however, other practical considerations make it unlikely that preemption would lead to substantial new avenues of liability for physicians. First, malprac-

tice claims against physicians alleging failure to warn about the side effects of medications have been very uncommon. Of nearly 145,000 paid malpractice claims against physicians reported to the National Practitioner Data Bank between 1998 and 2007, 5% involved medication-related allegations.⁵ Of these, 4% (approximately 1 in 450 paid claims overall) were categorized as involving failures to communicate, warn, or obtain informed consent. Disputes over negligence in ordering and administration currently dominate the litigation in this area and are likely to continue to do so.

Second, the economic aspects of bringing failure-to-warn litigation against physicians are less attractive to plaintiff's attorneys than those of bringing such claims against manufacturers. Product-liability claims often permit large numbers of plaintiffs to be joined into a single action against manufacturers. Failure-to-warn claims against physicians are unlikely to satisfy the rules for class consolidation. Case-by-case actions, in contrast, are expensive to mount and cannot be justified financially unless the injury is very severe or the defendant's fault is glaring. In addition, juries tend to have

more sympathy for physicians as defendants than for pharmaceutical companies, further eroding the plaintiff's cost-benefit calculus. Thus, although preemption of claims against pharmaceutical companies might increase the attention that plaintiffs' lawyers, and possibly also regulators, pay to the role of physicians in issuing warnings, practical considerations make a surge in failure-to-warn claims against physicians unlikely.

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