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THE REVERSE "READ AND HEED" CAUSATION PRESUMPTION: A PRESUMPTION THAT SHOULD BE GIVEN LITTLE HEED

Failure-to-warn claims in pharmaceutical and medical device litigation are under attack. Medical device manufacturers applauded the Supreme Court's landmark ruling in *Riegel v. Medtronic, Inc.*,[1] which held that state-law failure-to-warn claims involving medical devices approved through the FDA's premarket approval process are preempted. Next term, the Supreme Court will decide *Wyeth v. Levine* and pass on the viability of a similar failure-to-warn preemption defense for pharmaceutical manufacturers in cases involving FDA-approved prescription drugs. Combined, these two cases potentially affect, and may ultimately eliminate, a significant number of product liability failure-to-warn claims.

But a double victory will not end failure-to-warn claims altogether. *Riegel*, for instance, has no impact on the Supreme Court's decision in *Medtronic, Inc. v. Lohr*,[2] which found that certain failure-to-warn claims against medical devices approved through the FDA's "less rigorous" 510k approval process are not preempted. And some pundits expect that a favorable decision in *Levine* nonetheless will leave open the possibility for failure-to-warn claims in specifically defined cases involving pharmaceuticals.

For leftover failure-to-warn claims, the battleground is causation, *i.e.*, whether the alleged failure to warn proximately caused the plaintiff's injuries. Proving this element poses significant problems for plaintiffs. To survive summary judgment, they must offer evidence that, had the manufacturer given the "proper" warning, the plaintiff's injury would have been avoided. Because a failure-to-warn claim necessarily

involves a warning that was *not* given, plaintiffs must operate in a hypothetical Never-Never Land, in which their causation "evidence" often constitutes after-the-fact speculation that is properly disregarded.

Plaintiffs' difficulties are compounded by application of the learned intermediary doctrine, which has been adopted in most jurisdictions. That doctrine holds that manufacturers of prescription medical devices and pharmaceuticals have a duty to warn the physician, and not the patient, of any risks associated with use of the product. The doctrine is based, in part, on the longstanding principle that for decisions about prescription products, the physician is in the best position to counsel the patient. In failure-to-warn cases, application of this rule also means that plaintiff patients are not in control of their causation "evidence." Rather, the plaintiff must seek out testimony from the physician and hope that the testimony is not inconsistent with the plaintiff's causation theory.

To help plaintiffs' uphill causation battle, some courts hold that plaintiffs should be given a presumption of causation that essentially shifts the burden to defendants to disprove causation. But courts can reach such a result only by applying unreasonable and doctrinally inconsistent logic. Drug and device makers and their lawyers facing state-law failure-to-warn claims must be well armed to point out these flaws, make the proper arguments, and ultimately convince courts not to apply a causation presumption in a prescription product failure-to-warn case.

THE REVERSE "READ AND HEED" CAUSATION PRESUMPTION

This plaintiff-friendly causation presumption is rooted in a rule that is designed to benefit defendants. Section 402A of the Restatement (Second) of Torts imposes strict liability on manufacturers who sell "defective and unreasonably dangerous" products, including products that lack adequate warnings of dangers associated with their use. Comment j to that section states that when an adequate warning is given, the manufacturer "may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous." Some courts construe Comment j as creating a presumption, called the "read and heed" presumption. Thus, under Section 402A, defendants avoid liability entirely by showing that a warning is adequate. Defendants do not need to prove that the consumer actually read the adequate warning, as the rule presumes that an adequate warning will be read.

In failure-to-warn cases, plaintiffs routinely allege that defendants failed to provide an adequate warning to their physicians. To avoid actually proving causation, which, as shown, can be difficult, plaintiffs often argue for a *reverse* "read and heed" presumption. Plaintiffs say that since defendants get the benefit of a presumption that warnings they give will be read and followed, plaintiffs too should get a presumption—that an omitted warning would have been read and heeded *and* would have changed the decision to prescribe the drug or device. In other words, plaintiffs say they do not have to prove causation; it should be presumed.

COURTS SPLIT ON APPLICATION OF THE REVERSE "READ AND HEED" CAUSATION PRESUMPTION

Some courts have indulged a plaintiff's reverse "read and heed" causation presumption in prescription drug and medical device cases. In *Woulfe v. Eli Lilly & Co.*,[3] for example, a patient taking an antidepressant committed suicide. The patient's son sued the drug manufacturer, Eli Lilly, claiming that the antidepressant caused the suicide and that Eli Lilly failed to warn of that risk. Eli Lilly moved for summary judgment based on the son's inability to prove that the alleged failure-to-warn proximately caused the suicide. The son countered by asserting the reverse "read and heed" causation presumption. The court sided with the son.

The court recognized a rebuttable presumption in favor of the son that an adequate warning would have been read and heeded. The court also found, without analysis, that the presumption should apply even in context of the "learned intermediary" doctrine—under which a prescription drug or medical device maker's duty to warn runs not to the patient but to the prescribing physician. The court concluded that because of the presumption, the son "need not present any direct evidence that [the prescribing doctor] would have acted differently had a proper warning been given" to make his *prima facie* failure-to-warn case.[4]

Other courts, by contrast, have rejected the "read and heed" causation presumption in prescription drug and device cases.[5] In *Thomas v. Hoffman-LaRoche, Inc*., for example, the United

States Court of Appeals for the Fifth Circuit rejected the presumption as contrary to how a reasonable person would act under the circumstances. The court noted two types of risks—preventable and unavoidable. If a manufacturer warns of preventable risks and the consumer heeds those warnings, then the product can be used safely. With preventable risks, therefore, the consumer's choice is between heeding warnings to use the product safely and ignoring warnings against using the product unsafely.

The court reasoned that unavoidable risks are different. Unavoidable risks are, naturally, those that a consumer cannot avoid if he or she uses the product. With unavoidable risks, the choice is whether to use the product at all. Thus, with unavoidable risks, the appropriate question is whether the product's potential benefits outweigh its potential risks.

The Fifth Circuit concluded that prescription drugs pose unavoidable risks, and unless the plaintiff can establish that using the drug is riskier than not using it, then presuming that an additional warning would have caused the doctor not to prescribe the drug is inappropriate. In fact, assuming that the potential benefits outweigh the potential risks and that people act reasonably to minimize risk, the Fifth Circuit concluded that a reasonable person would not change his or her decision to use the drug even if warned of the unavoidable risk. In the learned intermediary context, the court did recognize a presumption that the prescribing doctor would have "read and heeded" an adequate warning. "But 'heed' in this context means only that the learned intermediary would have incorporated the 'additional' risk into his decisional calculus." The court still required the plaintiff to present evidence showing that the "additional non-disclosed risk was sufficiently high that it would have *changed the treating physician's decision to prescribe the product to the plaintiff*" (emphasis supplied).

THE REVERSE "READ AND HEED" CAUSATION PRESUMPTION SHOULD BE REJECTED

The Fifth Circuit got it right in *Thomas*, and the *Woulfe* court got it wrong. When plaintiffs in drug and device failure-to-warn cases rely on *Woulfe* and similarly decided cases to claim a causation presumption, drug and device makers and their lawyers must resist, and they have several grounds on which to do so.

Comment j Provides No Basis for a Causation Presumption. The *Woulfe* court based its causation presumption on Comment j to Section 402A. Because that comment provides a "read and heed" presumption that favors defendants when a proper warning is given, the court reasoned, it is fair to apply a similar presumption that favors the plaintiff when a proper warning is allegedly not given. But the two presumptions are hardly similar, and the result hardly makes sense.

The "presumption" in Comment j is only marginally beneficial in most cases to manufacturers who give adequate warnings. Those manufacturers are shielded from failure-to-warn liability because they actually provided adequate warnings; any "presumption" about what consumers did with those warnings is largely beside the point. Comment j does not change the elements of proof or increase the plaintiff's evidentiary burdens.

The reverse "read and heed" causation presumption, in sharp contrast, is a windfall to plaintiffs. It eliminates a required—and difficult—element of a plaintiff's *prima facie* case and requires the defendant to rebut the presumption by disproving causation. This is hardly the other side of the same presumption coin.

The Plaintiffs' Presumption Does Not Reflect Reality. The reverse "read and heed" causation presumption ignores the dynamics of the medical decision-making process. The presumption holds that if the manufacturer had given an adequate warning, the doctor would not have prescribed the drug or device for the patient, and the patient's injury therefore would have been avoided. But virtually every prescription drug and device comes with page after page of warnings. Yet doctors still prescribe them. That is because doctors find that the potential benefits of the drug or device outweigh the potential risks of leaving the patient's condition untreated. To simply presume that any one particular additional warning would have tipped the balance against prescribing the drug or device—in every case—is unrealistic.

Consider, for example, that the supposed risk of suicidal thoughts and/or behavior that some plaintiffs have (mostly unsuccessfully) alleged is associated with certain antidepressants. Even these plaintiffs allege that this risk exists for only a "small vulnerable subpopulation" of patients. Untreated depression itself is the leading cause of suicide.

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One commentator has compared the relatively higher risk of suicide associated with untreated depression with the relatively lower risk of suicide allegedly associated with antidepressants and explained that any reasonable person would eagerly trade the higher risk for the lower one: "Every person who takes [an antidepressant] trades in some large risk of suicide and other depressive behavior" from his untreated depression "in exchange for a small risk of suicide and a far better life style and prognosis to boot" from taking an antidepressant. "That deal is attractive from the ex ante perspective to any sane person even in the absence of any tort remedy. . . . The rational person would assume the risk; only persons with serious cognitive limitations would balk at so attractive a deal."[6] Presumptions should not rest on unlikely and unreasonable behavior.

The Causation Presumption Undermines the Learned Intermediary Doctrine. The reverse "read and heed" causation presumption in drug and device cases is inconsistent with the learned intermediary doctrine. The learned intermediary doctrine recognizes that physicians play a crucial role in assessing the risks and benefits of a patient's treatment. The doctor is charged with applying his or her specialized learning to the patient's particular condition, analyzing the risks and benefits of different treatments, and recommending a patient-specific course of action. A doctor may have two patients with the same condition and prescribe a different treatment to each, based on myriad factors, including the patients' history, age, and sex. The one-size-fits-all "read and heed" causation presumption undermines the foundation of the learned intermediary doctrine by presuming, across the board, that no physician would prescribe the subject drug or device to any patient if the allegedly omitted warning had been provided.

Some courts have recognized this and expressly declined to apply the causation presumption in learned intermediary situations. Recently, in *Ackermann v. Wyeth Pharmaceuticals*,[7] the United States Court of Appeals for the Fifth Circuit refused to recognize the reverse "read and heed" presumption in a prescription drug case. There, the plaintiff alleged that Wyeth failed to adequately warn of the risk of suicide associated with its antidepressant drug. Lacking any evidence of causation, the plaintiff attempted to invoke the reverse "read and heed" presumption to satisfy this element of her claim. The Fifth Circuit, applying Texas law, recognized that "[i]n general" a rebuttable presumption arises that shifts the burden of proving causation to the defendant. But the court refused to apply that presumption to a "pharmaceutical case[ ] involving [a] learned intermediar[y]." While in some cases a warning about an ordinary consumer product might reasonably be presumed to cause the consumer to change his or her behavior to avoid the risk entirely, that presumption should not apply to a doctor, who must balance risks of various treatments with the benefits of those treatments and the risks of leaving a condition untreated or using a lesser treatment. Thus, the court in *Ackermann* followed the cases holding that "to 'read and heed,' in the context of a learned intermediary, means only that the physician would have incorporated the additional risk into his decisional calculus."

The Causation Presumption Is Contrary to Principles of Presumption Law. The "read and heed" causation presumption also flies in the face of law governing presumptions generally. A presumption works such that, if a party establishes a certain fact, the trier of fact must also accept additional facts as being true (the presumed facts) unless the other side disproves the truth of the presumed facts. The justification for presumptions is the "substantial likelihood" that if the predicate fact is true, the presumed facts must also be true. Presumptions are also used to offset a party's lack of availability to evidence. Neither reason for recognizing a presumption works here.[8]

It may be reasonable to presume that if a manufacturer had provided a warning, the prescribing doctor would have read the warning. But it does not necessarily—or even probably—follow that upon reading the warning, the doctor would have stopped prescribing that product for all patients. As discussed above, the learned intermediary doctrine presumes that doctors will weigh a drug's benefits and risks for a particular patient before making prescription decisions. Manufacturers warn of many potentially adverse reactions, and doctors still prescribe these drugs and devices every day.

The reverse "read and heed" causation presumption also is not needed to balance an access-to-evidence disparity. The source of causation evidence is the prescribing doctor. The plaintiff has at least as much access to his or her own doctor as the defendant does and has even more access than the defendant in those jurisdictions that prohibit defendants from interviewing treating physicians *ex parte*. At bottom, there simply is no basis in the law of presumptions for the reverse "read and heed" presumption of causation.

CONCLUSION

Plaintiffs should not be permitted to avoid their burden to prove causation in prescription product failure-to-warn cases, and the reverse "read and heed" causation presumption does just that. Those courts that have adopted the plaintiff-friendly presumption have not meaningfully analyzed whether the presumption makes sense—logically or realistically—or whether the presumption is grounded in sound principles of law. But that is not always the court's fault. Defense counsel representing drug and device manufacturers in failure-to-warn cases must fully understand the legal and factual issues surrounding the presumption and be prepared to properly educate the court through briefing and arguments before, or at, the summary-judgment stage. Well-developed arguments encompassing the issues outlined above should result in rejection of the reverse "read and heed" causation presumption. ■

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[1] 128 S. Ct. 999, 169 L. Ed. 2d 892, 76 U.S.L.W. 4087, No. 06-179, 2008 U.S. LEXIS 2013 (Feb. 20, 2008).

[2] 518 U.S. 470 (1996).

[3] 965 F. Supp. 1478 (E.D. Okla. 1997).

[4] Eli Lilly was ultimately able to rebut the presumption with testimony from the prescribing physician that he still would have prescribed the anti-depressant if Lilly had provided an "adequate" warning of suicide risk. *Id.* at 1485.

[5] *See, e.g.*, *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 813–14 (5th Cir. 1992); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991–95 (C.D. Cal. 2001).

[6] Richard A. Epstein, "Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda," 1 J. Tort L., Iss. 1, Art. 5, at 25 (2006).

[7] *E.g.*, *Ackermann v. Wyeth Pharms.*, No. 06-41774, slip op. at 15 (5th Cir. Apr. 24, 2008). Jones Day represented Wyeth in the *Ackermann* case.

[8] 29 Am. Jur. 2d *Evidence* §§ 181, 185 (1994).