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Heeding the Heeding Presumption in Pharmaceutical and Medical Device Failure to Warn Litigation

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In litigation, legal presumptions allow a party to establish a fact without proof until the other party offers sufficient evidence to rebut it. An example specific to products liability law is the "heeding presumption," which allows for a presumption that, had the plaintiff been provided with an adequate warning by the manufacturer, the plaintiff would have read and heeded that warning. This presumption, though, is not only contrary to human behavior but also results in an inequitable shifting of the burden of proving causation from the plaintiff to the manufacturer. Many jurisdictions no longer recognize the heeding presumption; however, in those that do, it is further complicated by its potential intersection with the learned intermediary doctrine, pursuant to which manufacturing defendants' duty to warn extends only to physicians in their role as a learned intermediary between the manufac-

turer and the patient. Fortunately, in those jurisdictions that still apply it, the defendant can rebut the heeding presumption with the use of certain evidence. This article will provide a brief background on the history of the heeding presumption, identify case law addressing the complexities of its application in the context of the learned intermediary doctrine, and, finally, offer strategies for effectively rebutting the presumption.

The History Behind the Heeding Presumption

Comment j to the Restatement (Second) of Torts long recognized that when a product warning is provided, a manufacturer may "reasonably assume that it will be read and heeded" and that the product is not "unreasonably dangerous" if that product is safe for use when that warning is followed. Restatement (Second) of Torts §402A cmt. j (1965). The unfortunate corollary to this presumption, called the "heeding presumption," was introduced by the Texas Supreme Court in *Technical Chem. Co. v. Jacobs,* 480 S.W.2d 602 (Tex. 1972). The *Jacobs* Court construed the language of comment j to the Restatement (Second) of Torts as suggesting that the law "should supply the presumption that an adequate warning would have been read." *Id.* at 606 (citing Restatement (Second) of Torts §402A, cmt. j). The Court reasoned that "[w]here there is no warning, as in this case, however, the presumption that the user would have read an adequate warning works in favor of the plaintiff user." *Id.* It further held that "[t]he presumption, may, however, be rebutted if the manufacturer comes forward with contrary evidence that the presumed fact did not exist." *Id.* (internal citation omitted). In doing so, the *Jacobs* Court created an illogical corollary to this reasonable presumption in products liability law that would effectively allow future litigants to prove causation by simply relying on the heeding presumption.

In reality, however, neither the heeding presumption—nor the original presumption set forth in Comment j, for that matter—represent an accurate reflection of human behavior. Even if it can be presumed that a reasonable person would have read an adequate warning if one was provided, there is nonetheless no guarantee, or even indication, that the reasonable person would heed that warning. For example, traffic signs and the mandatory Surgeon General's warnings on both cigarette packaging and alcohol are examples of warnings that millions of "reasonable" people fail to heed daily despite their knowledge of the risks associated with the behavior against which they warn.

In fact, when Section 402A was superseded by Restatement (Third) of Torts, the drafters of the Third Restatement expressly recognized this principle, characterizing the language in §402A, Comment j as "unfortunate" and acknowledging criticism that the presumption "embodies the behavioral assumption" that "reasonable" users of a product will heed the warnings. *See* Restatement (Third) of Torts, Prod. Liab. §2, cmt. l (1998) (citing Howard Latin, *"Good" Warnings, Bad Products, and Cognitive Limitations*, 41 UCLA L. Rev. 1193 (1994)). In doing so, the Third Restatement has rejected the application of both the presumption in favor of the defendant and the heeding presumption. Hildy Bowbeer, Wendy F. Lumish, and Jeffrey A. Cohen, *Warning! Failure to Read This Article May Be Hazardous to Your Failure to Warn Defense*, 27 Wm. Mitchell L. Rev. 439, 462 (2000). Regardless, many jurisdictions continue to apply the "heeding presumption," notwithstanding the clear guidance from the Restatement (Third) of Torts.

In jurisdictions that recognize the heeding presumption, the plaintiff must initially prove only that "the manufacturer owed a duty to warn and failed to adequately do so: it is then presumed the user would have followed an adequate warning." *Id.* at 462. If the defendant successfully rebuts the presumption, the plaintiff must meet his original burden of proof—that the manufacturer's failure to warn was the proximate cause of his injury by a preponderance of the evidence. *Id.* If the manufacturer fails to introduce evidence to rebut the presumption, however, the plaintiff is relieved of this burden and can rely on the presumption to establish the essential element of causation. Historically, the heeding presumption is rebutted by introducing three different categories of evidence: the plaintiff's knowledge of the risk of which the allegedly absent warning was supposed to warn; the circumstances surrounding the plaintiff's use of the product that would "call into question whether the plaintiff would have noticed a warning if provided and would have been motivated to heed the warning if he had noticed it"; and, finally, plaintiff attitudes and any conduct that "demonstrates an indifference to safety warnings generally." *Id.* at 463.

Recognizing the Problem of Applying the Heeding Presumption in the Context of the Learned Intermediary Doctrine

In addition to the issues with applying the heeding presumption in traditional products liability cases, the application of the heeding presumption alongside the learned intermediary doctrine is particularly problematic, as it seemingly refuses to consider both the weight of the

learned intermediary's risk-benefit calculation and the relative nature of the alleged injury compared to the product's benefit. Under a traditional reading of the heeding presumption, "heeding" the warning would mean that the plaintiff would necessarily avoid the risk altogether. The application of the heeding presumption under these circumstances, however, runs afoul of the well-known principle that all pharmaceutical and medical device products have inherent risks and benefits, as recognized by Comment k to the Restatement (Second) of Torts, which states that certain products are "unavoidably unsafe." *See* Restatement (Second) of Torts §402A cmt. k (1965). This, of course, is the very foundation of the learned intermediary doctrine: that the physician, as a learned intermediary standing between the manufacturer and the patient, is in the best position to evaluate those risks and benefits and to advise the patient accordingly in order to maximize the chance that the patient will avoid potential injury. *See Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).

The United States Court of Appeal for the Tenth Circuit analyzed the complexities of applying both the learned intermediary doctrine and the heeding presumption in *Eck v. Parke, Davis & Co.,* 256 F.3d 1013, 1018 (10th Cir. 2001). In *Eck,* the manufacturing defendants filed for summary judgment on the plaintiffs' failure to warn claims. Pursuant to Oklahoma law, the Tenth Circuit applied the heeding presumption in the plaintiffs' favor, noting that it could be successfully rebutted by proving that, "although the prescribing physician would have 'read and heeded' the warning or additional information, this would not have changed the prescribing physician's course of treatment." *Id.* at 1019. The court disagreed with plaintiffs' definition of "heed," which, according to plaintiffs, meant that the prescribing physician would have both read *and given* the warning to the patient. *Id.* at 1021. Rather, the court reasoned, in the context of the learned intermediary doctrine, the word "heed" means "only that the learned intermediary would have incorporated the 'additional' risk into [her] decisional calculus." *Id.* (internal citations omitted).

Notably, however, the Tenth Circuit declined to go so far as to hold that the "physician's conduct automatically acts as an intervening cause relieving the manufacturer of liability," but rather recognized that Oklahoma law shifts the burden back to the plaintiff "to allow him to controvert the physician's testimony." *Id.* at 1023. The *Eck C*ourt found, however, that plaintiffs failed to controvert the defendant's evidence and that the patient's prescribing and treating physicians would not have changed their course of treatment if provided with the additional risk information. *Id.* at 1024. The court ultimately affirmed the district court's summary judgment ruling in favor of defendants, holding that the plaintiffs could not establish causation. *Id.*

In *Nall v. C. R. Bard, Inc.,* an MDL court specifically recognized the problem of applying the heeding presumption in the context of the learned intermediary doctrine when the defendant manufacturer sought summary judgment on plaintiff's failure to warn claims. No. 2:13-CV-01526, 2018 WL 521791 (S.D.W. Va. Jan. 23, 2018). Pursuant to Missouri law, which the court applied under the applicable choice-of-law provisions, the court recognized that both the learned intermediary doctrine and the heeding presumption applied to the claims. *Id.* at *3-4. The defendant sought to rebut the presumption by presenting the treating physician's testimony that he did not rely on the product's "instructions for use" before recommending the product to the plaintiff. *Id.* at *3. The court acknowledged that, based on the physician's testimony, whether the plaintiff could prove that an adequate warning would have affected the physician's conduct was "of course, speculative." *Id.* Reasoning that Missouri law had not yet determined the application or scope of the heeding presumption in the context of a learned intermediary, the Court ultimately reserved the defendant's motion on those points for trial. *Id.* at *4. The Court held that the issue of "[w]hether the heeding presumption transfers to a physician" was a determination for the court on remand, and that whether the physician would have "altered his recommendation" of defendant's product had it "provided an adequate warning" was a question for a jury. *Id.*

These decisions articulate just a few of the many issues raised by applying the heeding presumption into the framework of the learned intermediary doctrine. *Eck* highlights the problem with interpreting the meaning of the word "heed" in the context of the learned intermediary doctrine, which may not be consistent across jurisdictions that apply the presumption. Further, *Nall* demonstrates the overall difficulty in determining the scope of the presumption while also applying the learned intermediary doctrine—after all, by definition, the learned intermediary must analyze a warning label that is both sophisticated and highly technical, assess the relative risks and benefits of a product based on his or her knowledge and experience, and then advise patients of a recommendation within his or her medical judgment.

Yet another issue is that many of the traditional evidentiary bases used to rebut the presumption—such as demonstrating whether the plaintiff was motivated to heed the warning, for example, or establishing a general indifference to safety warnings—simply don't translate

neatly when the learned intermediary doctrine also applies. The presumption can be rebutted, though, in the context of the learned intermediary doctrine by producing evidence that may break the causal link between the manufacturing defendant and the plaintiff.

Rebutting the Heeding Presumption

Generally, in pharmaceutical and medical device litigation, the heeding presumption may be rebutted with evidence that additional warning information would not have changed the learned intermediary's treatment decision. This can be accomplished with evidence that the inclusion of additional warning information would have been futile, because the physician would not have read it, or that the inclusion of such information would not have changed the treatment decision of the learned intermediary, because the physician had already considered the risk and factored it into the risk-benefit analysis. Thus, when deposing a prescribing or treating physician, it is particularly important to ask specific questions that may further these arguments, including whether the physician was aware of the alleged risk independent from the product label; whether the physician based treatment decisions on medical training rather than relying on product labels; whether the physician failed to read any labels for a particular product after a certain date; or whether the physician would have made the same treatment decision even if the additional warning information had been included in the product labeling. And although such testimony is key in nearly every case in which the learned intermediary doctrine applies, it is especially critical to elicit testimony that is precise and unequivocal when rebutting the heeding presumption.

For example, in *Baker v. App Pharms, LLP,* the District of New Jersey applied the heeding presumption when considering defendant's summary judgment motion under New Jersey law, finding that the presumption permits a finding "that the plaintiff's physician would not have prescribed the drug to the plaintiff if there had been an adequate warning." No. 09-05725, 2012 WL 3598841, at *8 (D.N.J. Aug. 21, 2012). It noted that the presumption could be rebutted by the manufacturer, however, with a showing that the prescriber "was aware of the risks of the drug that [he] prescribed, and having conducted a risk-benefit analysis, nonetheless determined its use to be warranted." *Id.* (internal citations omitted). The court further recognized that "a manufacturer who fails to warn the medical community of a particular risk" may be relieved of liability under the learned intermediary doctrine if "the prescribing physician either did not read the warning at all, . . . or if the physician was aware of the risk from other sources and considered the risk in prescribing the product," as this would constitute a "superseding or intervening cause that breaks the chain of liability" between the manufacturer and plaintiff. *Id.* (internal citations omitted).

In *Baker*, the physician's testimony revealed that he regularly used the product at issue, did not read the labels of pharmaceutical products that he "prescribed often" (which included the product at issue), stood by his decision to use the product under the circumstances, and was familiar with both the risks and benefits of the product—including the risk at issue. *Id.* at *9. Further, the court recognized that the plaintiff failed to introduce any evidence that the physician would have consulted additional warnings. *Id.* Therefore, it held that a different warning would not have made a difference in the plaintiff's treatment or outcome because her physician "would not have reviewed it." *Id.* The court ultimately concluded that "no reasonable jury could conclude that a different label" would have changed the physician's decision and thus granted the defendant's motion for summary judgment. *Id.* at *10.

There are many arguments in favor of abandoning the heeding presumption altogether and, indeed, many jurisdictions have adopted this approach. In jurisdictions that continue to apply the heeding presumption in pharmaceutical and medical device failure to warn cases, it is necessary to take steps early in the litigation in order to sufficiently protect the interests of your client. An important first step is to determine whether the presumption applies in the jurisdiction in which your case is pending and, if it does, review the applicable case law on the evidence necessary to rebut the presumption. Whatever you do, be sure to heed the heeding presumption and its potential effect on the outcome of your opponent's failure to warn claims.

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