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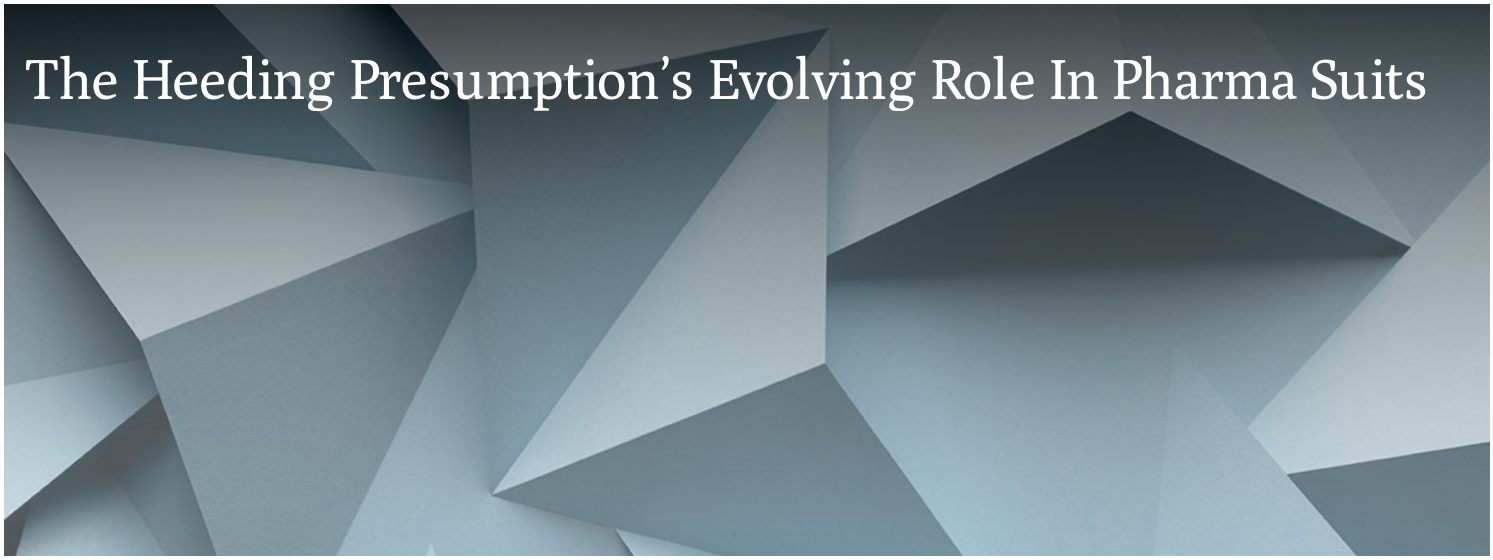
BLOG

The Heeding Presumption's Evolving Role In Pharma Suits



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It goes without saying that in a failure-to-warn case, the plaintiff must establish that the defendant's failure to warn of a specific adverse event caused the plaintiff's injury.

In states that apply the learned intermediary doctrine, a drug manufacturer's duty to warn runs to the prescribing physician, not the individual plaintiff. Thus, there can be no failure to warn where the plaintiff's prescribing physician would not have altered his or her course of treatment, even if the drug manufacturer had included the warning requested by plaintiff.[1]

A complicating factor is the so-called heeding presumption, which has been adopted by a number of states.[2] The presumption, which comes from the Restatement (Second) of Torts, provides: "Where warning is given, the seller may reasonably assume that it will be read and heeded."[3]

That presumption gives plaintiffs a leg up in proving causation, by effectively shifting to the defendant the burden to show that the prescriber would not have followed the warning.

Below, we review the approaches followed by states that have adopted the heeding presumption, states that haven't and other states that use something in-between. As the examples reveal, although the heeding presumption may have an impact at the margin, its application can be inconsistent — so the most important determinant of success at summary judgment is the quality of the prescriber testimony.

The Heeding Presumption *Missouri*

In Abt v. Ethicon, the defendants moved for summary judgment following remand to the U.S. District Court for the Eastern District of Missouri from the Ethicon pelvic mesh multidistrict litigation.[4] The MDL consisted of various claims for injuries relating to "the Gynecare TVT Obturator … manufactured by the defendants, Ethicon, Inc. and Johnson & Johnson, Inc.," which is "a medical device that includes a mechanism used to place a mesh tape, or sling, under the urethra to provide support to the urethra to treat stress urinary incontinence."[5]

The defendants argued that summary judgment was appropriate as to Abt's failure-to-warn claim, since "Abt cannot show the implant caused her injuries because she cannot show additional warnings would have altered the behavior of her physician."[6] The court agreed, and granted summary judgment in August.[7]

The court noted that under Missouri law, "[a] rebuttable presumption applies that 'a warning, if provided, will be read and heeded.'"[8] Turning to the facts, the court noted that the prescribing physician:

> testified he stands by his decision to select the TVT-O for Abt, that he would not have changed his decision to implant the TVT-O in Abt even if the instructions for its use had included each of the additional risks Abt alleges were not included, and that he relied more on medical literature (rather than manufacturer's warnings) in deciding what implants to use.[9]

The court concluded, based on the testimony, that the "Defendants have rebutted that presumption with Dr. Mertins's testimony."[10]

No Heeding Presumption

On the other hand, many states have rejected the heeding presumption, leaving intact plaintiffs' burden to prove all elements of their product liability claims.

Nevada

Just a few months before Abt, the U.S. District Court for the District of Nevada in Heinrich v. Ethicon[11] considered testimony facially similar to that in Abt — at least on the surface. There, following remand, Ethicon moved for summary judgment, arguing that the plaintiff's physician "would not have changed his recommendation of the TVT-S to address Heinrich's" condition even with additional warnings.[12]

In this case, despite the absence of a heeding presumption and similar evidence as in Abt, the court issued a ruling in April denying summary judgment as to the failure-to-warn claim.[13]

The court first had to consider whether Nevada would adopt the learned-intermediary doctrine under the circumstances, and concluded that it would.[14] The court next determined that Nevada would not recognize a heeding presumption.[15] The court then turned to the merits of the learned intermediary arguments.

The court was not persuaded that the record was sufficiently clear for summary judgment. As in Abt, the provider had "testified that he knew about the risks associated with every injury Heinrich claims to have suffered" and that "warnings would not have changed his recommendation of the TVT-S to address [plaintiff's condition]."[16]

But based on testimony that the provider "was not aware of complications and failures reported in Australia and Germany related to the TVT-S" and that he changed some of his practices after receiving the warning, the court decided that "[a] reasonable jury could conclude from this evidence that [the provider] would have considered additional information if provided to him."[17]

According to the court, "[w]hether [the provider] would have changed either his recommendation of the TVT-S to Heinrich or the information he provided to her are matters for the jury to resolve, as is [his] credibility."[18]

The Limited Heeding Presumption

Still other states recognize only a limited heeding presumption in product liability cases. But even in states that limit the doctrine, developing certain deposition testimony is key for discharging a manufacturer's liability.

New Jersey

New Jersey, for example, has adopted the presumption, but restricts its application in prescription medical product liability litigation primarily to instances where, as the New Jersey Superior Court said in McDarby v. Merck & Co. Inc. in 2008, a "plaintiff lacks the ability to prove by direct evidence that a proper warning, if given, would have been heeded."[19] Where a treating physician is available to testify in a deposition or trial, New Jersey "render[s] use of a presumption unnecessary."[20]

Additionally, the presumption is rebuttable if evidence is submitted that the physician would have prescribed the medication anyway, even if provided the warning information.[21] If the physician was aware of the risks, or would not have read the warning at all, a drug manufacturer is not liable under the learned intermediary doctrine because of the break in the chain of causation.[22]

In Baker v. App Pharmaceuticals, for instance, the U.S. District Court for the District of New Jersey held in 2012 that summary judgment in favor of the drug manufacturer was appropriate where the prescribing physician testified that he regularly used the drug in question, was familiar with its risks and benefits, continued to believe the drug was appropriate for the plaintiff, and did not frequently read the label of drugs he prescribes.[23]

Therefore, even in states that have limited the application of the heeding presumption, it is important to elicit testimony from a plaintiff's prescribing doctor that the warning would not have made a difference in the treatment plan.

Pennsylvania

Similarly, courts in Pennsylvania apply the heeding presumption only when a plaintiff was forced to be exposed to products causing harm.[24] This effectively eliminates the heeding presumption in prescription drug cases.

Furthermore, Pennsylvania courts do not presume proximate cause is established in such cases, as a plaintiff must show evidence from which it can be inferred that a different warning would have changed the course of treatment.[25]

In Bock v. Novartis Pharmaceuticals Corp., for example, the fact that the plaintiff's physicians testified that they were already aware of the drug's risk at issue, would have discussed that risk with the plaintiff and would still prescribe the drug to a patient like the plaintiff because of their evaluation of the drug's risk-benefit analysis was determinative.[26]

In its 2016 decision, the U.S. District Court for the Western District of Pennsylvania also found significant that there was no evidence that the plaintiff would have refused to take the medication if given a different warning about the drug's risk.[27] Summary judgment was thus deemed appropriate.[28]

Conclusion

As the heeding presumption continues to develop across the country, companies should be aware of the implications of litigating in jurisdictions that either recognize or reject the doctrine. Ultimately, a strategically developed factual record with key deposition admissions are critical to insulating a drug manufacturer from liability in failure-to-warn cases.

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[1] E.g., Bodie v. Purdue Pharma Co., 236 F. App'x 511, 521 (11th Cir. 2007).

[2] The Drug and Device Blog provides an excellent (though now somewhat dated) survey of states: https://www.druganddevicelawblog.com/2014/11/who-heeds-heeding-presumption.html.

[3] § 402(a), comment j.

[4] Abt v. Ethicon Inc., 2020 WL 4887022, at *1 (E.D. Mo. Aug. 20, 2020).

[5] See Huskey v. Ethicon Inc., 29 F. Supp. 3d 736, 738 (S.D.W. Va. 2014).

[6] Id. at *2.

[7] Id.

[8] Abt, 2020 WL 4887022, at *2 (quoting Johnson v. Medtronic Inc., 365 S.W.3d 226, 232 (Mo. Ct. App. 2012)).

[9] Id.

[10] Id.

[11] Heinrich v. Ethicon Inc., 2020 WL 1916877, at *5 (D. Nev. April 17, 2020).

[12] Id. at *2.

[13] Id. at *5.

[14] Id. at *3.

[15] Id. at *4.

[16] Id. at *2.

[17] Id. at *5.

[18] Id.

[19] See McDarby v. Merck & Co. Inc., 401 N.J. Super. 10, 82, 949 A.2d 223, 268 (App. Div. 2008).

[20] Id.

[21] In re Diet Drug Litig., 384 N.J. Super. 525, 544–45, 895 A.2d 480, 492 (Law. Div. 2005).

[22] See Baker v. App Pharm. LLP, 2012 WL 3598841, at *8–9 (D.N.J. Aug. 21, 2012).

[23] Id. at *9.

[24] See Viguers v. Philip Morris USA Inc., 837 A.2d 534, 538 (2003),aff'd, 881 A.2d 1262 (2005).

[25] See Bock v. Novartis Pharm. Corp., 137 F. Supp. 3d 802, 808 (W.D. Pa. 2015), aff'd,661 F. App'x 227 (3d Cir. 2016).

[26] Id. at 810–11.

[27] Id.

[28] Id.

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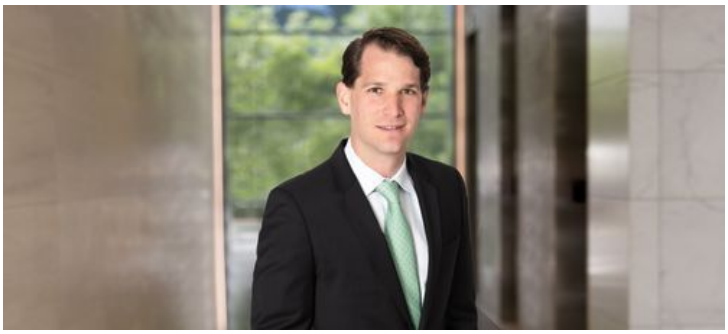

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