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IN THIS ISSUE

This article is a short guide to creative legal arguments and unconventional evidence to establish lack of warnings causation in cases where the plaintiff benefits from the so-called "heeding presumption."

Reviving Failure to Warn Defenses in Cases Involving Deceased Prescribing Physicians

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The doctor is dead.

For plaintiffs bringing product liability actions against pharmaceutical drug and medical device manufacturers, this usually sounds the death knell for their failure to warn claims. That is because a plaintiff has the burden of proving that the physician would have changed his or her prescribing decision if provided a different, adequate warning. If the doctor is dead (or far less dramatic, simply unavailable to testify), the plaintiff cannot establish her cause of action, and her claim is dismissed.

But some states turn that rule on its head. In states that have adopted the "heeding presumption," the law *assumes* that the physician would have read—and heeded—the proposed adequate warning. While every state that has adopted the presumption has recognized that it is rebuttable—that is, that the opposing party may present evidence to the contrary—it is nearly impossible to rebut the presumption at the summary judgment stage as a matter of law where the defense is unable to secure testimony from an unavailable prescribing physician.

Once at trial, the negative manifestations of the heeding presumption are palpable: directed verdict is possible, and a devastating jury instruction is almost inevitable. But with some forethought during the course of discovery, alternative legal arguments can be made and evidence sought to allow traditional causation principles to arise from the ashes.

Argument No. 1: The Heeding Presumption is DOA to the Pharmaceutical Context

Whether the heeding presumption accurately illustrates a prescriber's likely reaction to a particular warning is highly suspect. That is because when a doctor "heeds" a warning, there are innumerable circumstances in which that does not automatically mean that he or she will not prescribe the drug or device. As the Fifth Circuit Court of Appeals has explained, "to heed" a warning accompanying a pharmaceutical product "means only that the learned intermediary would have incorporated the 'additional' risk into his decisional calculus. The burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 814 (5th Cir. 1992).

This issue was squarely addressed in the ObTape pelvic mesh litigation. Judge Clay Land of the Middle District of Georgia recognized that the presumption "would simply permit the Court to presume that [deceased] Dr. Rothschild would have considered ObTape's tissue ingrowth risks and the infection and erosion rates—among other considerations—in determining which product to select for Burke. The presumption does not, however, permit the Court to speculate about how Dr. Rothschild would have weighed the additional warnings." *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, No. 4:13-cv-229 (Burke), 2016 WL 4611572, at *3 (M.D. Ga. Sept. 2, 2016).

Argument No. 2: The Heeding Presumption is Procedural, Rather than Substantive

Choice of law considerations may also favor the inapplicability of the heeding presumption. It is black letter law that the law of the forum applies to procedural matters, including—arguably—evidentiary sufficiency and burdens of proof, even if the substantive law is guided by another state that recognizes the heeding presumption.

As many states recognize, presumptions are evidentiary in nature; that is, they operate in the absence of evidence, and are thus procedural in nature. *See Ayers v. Woodard*, 140 N.E.2d 401, 402-03 (Ohio 1957) ("A presumption is a procedural device which is resorted to only in the absence of evidence by the party in whose favor a presumption would otherwise operate."); *Crawford v. Manhattan Life Ins. Co. of N.Y.*, 221 A.2d 877, 884 n. 2 (Pa. Super. Ct. 1966) ("[Q]uestions of presumption and burden of proof in this regard are, of course, procedural and to be determined by the law of the forum.").

To determine whether a specific state's heeding presumption is procedural in nature, the Restatement (Second) of Conflict of Laws § 134 asks whether the "primary purpose" of the relevant presumption "is to affect decision of the issue rather than to regulate the conduct of trial." While some presumptions may cross the threshold into substantive law, the heeding presumption is arguably not one of them (but will depend on the law of the state). That is because, most often, these presumptions are rebuttable and, importantly, do not shift the burden of the proof thus are not "conclusive." *See* Restatement (Second) of Conflict of Laws § 134 Burden of Going Forward With the Evidence; Presumptions, cmt. a ("[T]his Section is not concerned with so-called conclusive presumptions which require the trier of fact to find the existence of one fact from proof of the existence of another fact. Such presumptions are in reality rules of substantive law stated in the form of a presumption."); *Weber v. Continental Cas. Co.*, 379 F.2d 729, 732 (10th Cir. 1967) ("Oklahoma clearly regards rebuttable presumptions as mere procedural means for ordering the presentation of proof. Hence, the presumption is only a matter of procedure, and not a part of the substantive law of California that the Oklahoma courts would apply.").

Argument No. 3: The Presumption Was "Burst" By Evidence, Therefore Ceases to Operate

Where legal arguments fail, of course there are the facts. Many courts recognize that presumptions can be "burst," which simply means that the existence of *minimal* evidence "bursts" the balloon that is presumption, and the presumption drops out of the case. *See Universal Ins. Co. of N. Am. v. Warfel*, 82 S0.3d 47, 51-52 (Fla. 2002); *but see* Advisory Committee Notes, Fed. R. Evid. 301 ("The so-called 'bursting bubble' theory, under which a presumption vanishes upon the introduction of evidence which would support a finding of the nonexistence of the presumed fact, even though not believed, is rejected as according presumptions too 'slight and evanescent' an effect."). While this is not the same as rebutting the presumption as a matter of

law, so long as there is *some* evidence—whether direct evidence or by inference—to support the notion that the prescribing physician would not have changed his or her prescribing decision, untoward outcomes, such as directed verdict or a jury instruction on the heeding presumption, can be avoided. *See Ayers*, 140 N.E.2d at 403 syll. at 3.

Types of Evidence to Help Burst Heeding Presumption when the Prescriber is Unavailable

Bursting the heeding presumption where the prescriber is unavailable is challenging, but not impossible. While the possible evidence to "burst" the heeding presumption will vary by the facts in each case, the following are potential avenues to investigate in establishing lack of warnings causation:

- Evidence that the prescriber did not pass along other serious warnings to patients (like death, or other serious harm) provided in the prescribing information. For example, the prescriber may not have included these warnings in written consents or discussed them with the plaintiff. To the extent not included in the records or admitted by plaintiff, a nurse practitioner from the same office may be able to speak to the prescriber's habit, routine, and practice when it comes to consenting patients.

- Evidence that the prescriber was experienced with the product at issue, and therefore aware of the risks of the product. The physician's practice may maintain order records with respect to the product; similarly, the manufacturer may track the prescriber's attendance at training seminars. Also, a nurse or other physician from the same practice may be able to testify as to extent of the prescriber's experience with the products.

- Evidence that the prescriber kept apprised of the medical literature. If the relevant product risks were published in medical literature, there may be another physician or nurse from the same practice as the prescriber who can establish this evidence, which suggests that the physician was aware of the risks but nevertheless prescribed the drug or device anyway. This also applies to the prescriber's receipt of FDA Advisories or Public Health Notifications.

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