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Seventh Circuit Issues Strong Endorsement of Learned Intermediary Doctrine in Medical-Device MDL

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The manufacturer of a product generally has a duty to warn the end-consumer of any serious risks associated with that product. In the context of prescription drugs and medical devices, however, the "learned intermediary" doctrine holds that the manufacturer need not warn the end-consumer (*i.e.*, patient). Instead, the manufacturer discharges its obligations by warning the prescribing physician. Last month, in *In re Zimmer, NexGen Knee Implant Product Liability Litigation*, 884 F.3d 746 (7th Cir. 2018), the U.S. Court of Appeals for the Seventh Circuit issued a powerful endorsement of the rule, applying it under Wisconsin state law for the first time.

The learned intermediary doctrine stems from the fact that prescription drugs and devices are different from other types of mass-manufactured products. Ordinarily, the end-consumer has both the practical ability and the legal capacity to make his or her own purchase decisions. Not so for prescription drugs and devices. As the Supreme Court of Texas explained several years ago:

> The entire system of [prescription drug and device] distribution in America is set up so as to place the responsibility of distribution and use upon professional people. The laws and regulations prevent [these products] from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists. These professionals are in the best position to evaluate the warnings put out by the drug industry.

Centocor, Inc. v. Hamilton, 372 S.W.3d 140 (Tex. 2012)(quoting *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App. Corpus Christi 1973)). Not only do these professionals have the expertise to evaluate drug and device warnings that the patient lacks, they also owe legal and ethical duties to the patient to remain current on the risks of the treatments they prescribe. In addition, medical professionals owe duties to use professional skill and judgment in making treatment decisions and to counsel the patient regarding material risks.

Given these unique circumstances, the doctrine requires manufacturers to direct their warnings to the titular "learned intermediary" and not directly to the individual patient. The doctrine dates back over half a century and enjoys widespread support. The highest courts of at least 35 states have endorsed it, *see Centocor*, 372 S.W.3d at 158 n.17 (collecting cases), and intermediate state courts or federal courts in another 13 states have predicted that their states' high courts would adopt the doctrine. *See Tyree v. Boston Sci. Corp.*, 56 F. Supp. 3d 826, 828 n.3 (S.D. W.Va. 2014).

In recent years, however, the plaintiffs' bar has led a push to limit the learned intermediary doctrine or eliminate it entirely. In support, they have cited the advent of direct-to-consumer advertising of prescription drugs and devices that supposedly "circumvents" the physician's traditional role. *See* James Beck, *The Renaissance of the Learned Intermediary Rule*, Drug and Device Law, Mar. 3, 2016, https://www.druganddevicelawblog.com/2016/03/the-renaissance-of-learned-intermediary.html. There is an obvious problem with this argument,

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however: as the Texas Supreme Court noted, even "patients who *seek* prescription drugs based … on [direct-to-consumer] advertising will *obtain* them only when the prescribing physician has evaluated the potential risks and benefits for the particular patient." Thus, direct-to-consumer advertising or no, "the fundamental rationale for the doctrine remains the same." *Centocor*, 372 S.W.3d at 163-64 (emphasis added).

Nonetheless, in 2007, citing this "direct-to-consumer advertising" argument, West Virginia's high court became the first to reject the doctrine. *See State ex rel. Johnson & Johnson v. Karl*, 220 S.E.2d 899 (W. Va. 2007). That victory for the plaintiffs' bar, however, was short-lived: the state's legislature abrogated the high court's decision by enacting the learned intermediary doctrine via statute. *See* W. VA. CODE § 55-7-30 (2016). Since then, the trial bar and its supporters in academia have continued to inveigh against the learned intermediary doctrine, but no other court has followed in West Virginia's footsteps. *See* Beck, *supra*.

The latest learned intermediary showdown took place in the Seventh Circuit, in the context of the *Zimmer NexGen Knee Implant* multidistrict litigation. One of the MDL plaintiffs, Theodore Joas, alleged that Zimmer had failed to warn him of the knee implant's propensity for premature loosening. The district court rejected his claim, predicting that Wisconsin's high court would adopt the learned intermediary doctrine. As such, the district court held, Zimmer had no duty to personally warn Joas. *Joas v. Zimmer, Inc. (In re Zimmer NexGen Knee Implant Prods. Liab. Litig.)*, 218 F. Supp. 3d 700 (N.D. Ill. 2016).

On appeal, Joas argued that the district court had erred in its prediction of Wisconsin law, which he called mere "speculation." Appellant's Br. at 19-20. Invoking the "direct-to-consumer advertising" argument, Joas emphasized that Zimmer had "furnished pamphlets, which promoted and marketed its product, [directly] to patients" including Joas himself, and that he had relied on those materials. Appellant's Br. at 15-16; *see also* Appellants' Reply Br. at 3 n.2, 6 (invoking a purported "direct-to-consumer advertising" exception to the doctrine). At minimum, Joas maintained, this "unresolved issue[]" of Wisconsin state law should be certified to the state's high court. Appellant's Br. at 10-12, 20, 34; Appellants' Reply Br. at 7.

The Seventh Circuit unanimously rejected these arguments and affirmed the dismissal of Joas's failure-to-warn claim. While recognizing that no Wisconsin appellate court had considered the doctrine's applicability, the *Zimmer* court "predict[ed] that the [Wisconsin] high court would follow the lead of other states and adopt [it]." *In re Zimmer*, 884 F.3d at 747. It noted that one Wisconsin state trial court and several federal district courts applying Wisconsin law had endorsed the doctrine, and that the contrary conclusion of a different Wisconsin federal district court was unreasoned. Moreover, the *Zimmer* court noted, "[t]he doctrine enjoys broad support" elsewhere and has been adopted in "the vast majority" of jurisdictions. *Id*. at 751. Lastly, the *Zimmer* court observed, the justification for the doctrine "applies even more forcefully" in cases involving surgical implants, because "it is not reasonably conceivable that an individual could obtain and implant a device that requires a trained surgeon without the intervention of a physician." *Id*. at 752.

The Seventh Circuit also rejected Joas's request to certify the issue to the Wisconsin Supreme Court. Such a step is only appropriate, the *Zimmer* court explained, if a federal court is "genuinely uncertain" about the content of state law—and here, the court explained, there was "[n]o genuine uncertainty" about how the Wisconsin Supreme Court would rule. *Id*. at 754 (quoting *Cleary v. Philip Morris Inc.*, 656 F.3d 511, 520 (7th Cir. 2011)).

Zimmer will be dispositive in many cases in the *NexGen Knee Implant* MDL and will bind federal courts in the Seventh Circuit going forward. More broadly, it is a powerful endorsement of the learned intermediary doctrine—and a rejection of the plaintiffs' bar's "direct-to-consumer advertising" critique—by one of the nation's most prominent federal courts. Indeed, it speaks volumes that the Seventh Circuit found the doctrine's applicability in Wisconsin so overwhelmingly obvious that it was not even worth letting the state's own high court weigh in. *Zimmer* suggests that the campaign against the learned intermediary doctrine may finally be running out of steam, and that the doctrine—now in its sixth decade of life—is stronger and more vital than ever.

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