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Eighth Circuit Court of Appeals Applies Learned-Intermediary Doctrine to IUD Case

By Beth Bauer and Emilee Bramstedt on February 18, 2021
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In *Ideus v. Teva Pharm. USA, Inc.*, 2021 WL 415774 (8th Cir. Feb. 8, 2021), the Eighth Circuit held that under Nebraska tort law a manufacturer need not warn a consumer directly about the potential risks of using its contraceptive device. This decision may have implications beyond applicability to actions in Nebraska because the Eighth Circuit recognized that the majority position in jurisdictions around the country has been to apply the learned-intermediary doctrine to failure-to-warn claims regarding medical devices, including contraceptive devices. Thus, the case may signal broader thinking by the Eighth Circuit in future medical device failure-to-warn cases.

Case Background

Teva Pharmaceuticals USA, Inc., and Teva Women's Health, Inc., manufactured and sold Paragard Intrauterine Copper Contraceptive, a T-shaped device placed in the uterus as a form of birth control lasting up to ten years. *Ideus*, 2021 WL 415774, *1. The device came with two inserts, one for the physician and one for the patient. The warnings and instructions directed the physician to have the patient read the insert before discussing the procedure and device with the patient and answering any questions the patient had. *Id.* Following this process with her physician, Plaintiff had the device implanted. When she decided to have it removed, her physician discovered that the device had broken after implantation, and pieces were embedded in her uterus, requiring surgery for complete removal. *Id.*

Plaintiff sued the Teva Defendants in federal district court for breach of duty to warn of the potential risks of the device. *Id.* Defendants filed a motion for summary judgment, contending that the learned-intermediary doctrine applied. *See id.* The learned-intermediary doctrine is "a general rule allow[ing] manufacturers of certain types of medical products to discharge their duty by warning 'medical profession[als]' of the risks rather than the patients themselves." *Id.* Plaintiff argued that the doctrine did not apply to contraceptive devices like the one at issue, relying on one case from Massachusetts and two cases from federal district courts in Michigan that applied a prescription-contraceptives exception. *Id.* at *1-*2. The United States District Court for the District of Nebraska granted summary judgment to Defendants, holding that the learned-intermediary doctrine applied. *Id.* at *1.

Analysis of Appellate Court Decision

Plaintiff appealed the district court's decision to the U. S. Court of Appeals for the Eighth Circuit. *Id.* While the parties agreed that Nebraska law applied and that Defendants provided adequate warnings to Plaintiff's physician, the main issue on appeal was whether Defendants had the obligation to warn Plaintiff as well. *Id.*

The Eighth Circuit concluded the learned-intermediary doctrine applied to the contraceptive device in this case, a departure from its holding in *Hill*.[1] *Id.* at *3. The court relied heavily on the Nebraska Supreme Court's application of the learned-intermediary doctrine to pharmaceutical drugs in making its decision. *Id.* at *1. The court noted that in *Freeman*, ***[2]*** the Nebraska Supreme Court adopted Section 6 of the Third Restatement of Torts[3] and applied it to a patient who developed serious health problems from the use of a prescription drug. *Id.* at *1-*2. Although *Freeman* discussed only the application of the learned-intermediary doctrine to prescription drugs, the Eighth Circuit recognized that the language of the Restatement treats medical devices and prescription drugs the same, holding that the Nebraska Supreme Court would likely apply the doctrine in a case regarding an Intrauterine device (IUD) or other medical device the same as it did in *Freeman*. *Id.* at *2.

The Eighth Circuit acknowledged that while the two Michigan federal courts recognized an exception to the doctrine, the law in Michigan has been inconsistent on this topic (*Id.* at *2), leaving Massachusetts as the only state that has fully adopted the prescription-contraceptives exception. (In the Massachusetts case, *MacDonald*,[4] the court reasoned that "[o]ral contraceptives. . . bear peculiar characteristics which warrant the imposition of a common law duty on the manufacturer to warn users directly of associated risks.") Therefore, the overwhelming majority of courts have applied the learned-intermediary doctrine to contraceptives the same as they would apply the doctrine to other prescription drugs and medical devices. *Id.*[5]

Further, the court addressed its prior decision in *Hill* in which it declined to apply the learned-intermediary doctrine where an IUD was alleged to have caused a plaintiff harm. *Id.*at *3. The Eighth Circuit held in *Ideus* that *Hill* "does not tie [the court's] hands" because (1) *Hill* was decided under Arkansas law; (2) Nebraska embraced the learned-intermediary doctrine in *Freeman*, but in *Hill* the court was "writing on a blank slate"; and (3) "more courts have weighed in over the past three decades, so the legal landscape looks different now than it did then." *Id.* at *3.

The Takeaway

Although this case was decided under Nebraska law, one promising takeaway that can be applied more broadly is that the Eighth Circuit has recognized that the majority consensus is to apply the learned-intermediary doctrine to medical devices, like IUDs, because it would be "no different from other prescription drugs and medical devices, at least in terms of the level of 'guidance,' 'knowledge,' and 'skill' required of physicians." *Id.* at *2.

[1] *Hill v. Searle Laboratories, a Div. of Searle Pharmaceuticals, Inc.*, 884 F.2d 1064 (8th Cir. 1989).

[2] *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (2000) (adopting §6(d) of the Third Restatement of Torts on application of the learned intermediary doctrine).

[3] Restatement (Third) of Torts: Prod. Liab. § 6(d) (1998) ("A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2)

the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.).

[4] *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 137 (1985).

[5] *Citing Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989); *Upjohn Co. v. MacMurdo*, 562 So. 2d 680, 683 (Fla. 1990); *Martin by Martin v. Ortho Pharm. Corp.*, 169 Ill.2d 234, 214 Ill.Dec. 498, 661 N.E.2d 352, 356–57 (1996); *Ortho Pharm. Corp. v. Chapman*, 180 Ind.App. 33, 388 N.E.2d 541, 548–49 (1979); *Humes v. Clinton*, 246 Kan. 590, 792 P.2d 1032, 1041 (1990); *Cobb v. Syntex Lab'ys, Inc.*, 444 So. 2d 203, 205 (La. Ct. App. 1983); *Hoffman-Rattet v. Ortho Pharm. Corp.*, 135 Misc.2d 750, 516 N.Y.S.2d 856, 859 (Sup. Ct. 1987); *Seley v. G. D. Searle & Co.*, 67 Ohio St.2d 192, 423 N.E.2d 831, 839–40 (1981); *McKee v. Moore*, 648 P.2d 21, 25 (Okla. 1982); *McEwen v. Ortho Pharm. Corp.*, 270 Or. 375, 528 P.2d 522, 528–30 (1974); *Brecher v. Cutler*, 396 Pa.Super. 211, 578 A.2d 481, 485 (1990); *Wyeth-Ayerst Lab'ys Co. v. Medrano*, 28 S. W.3d 87, 92 (Tex. App. 2000); *Terhune v. A. H. Robins Co.*, 90 Wash.2d 9, 577 P.2d 975, 978 (1978) (en banc)).

Tags: Intrauterine Devices, IUD, Learned-Intermediary Doctrine