United States Court of Appeals
For the Eighth Circuit

No. 19-1361

Stephanie Ideus

Plaintiff - Appellant

v.

Teva Pharmaceuticals USA, Inc.

Defendant - Appellee

Teva Branded Pharmaceuticals Products R&D, Inc.

Defendant

Teva Women's Health, Inc.

Defendant - Appellee

Appeal from United States District Court
for the District of Nebraska - Lincoln

Submitted: September 23, 2020
Filed: February 8, 2021

Before KELLY, WOLLMAN, and STRAS, Circuit Judges.

STRAS, Circuit Judge.

After suffering complications from the implantation of an intrauterine device, Stephanie Ideus sued the product's manufacturer. The central question was whether it had to warn Ideus directly about the potential risks of using the device. We agree with the district court[1] that, under Nebraska tort law, it did not.

I.

Teva Pharmaceuticals USA, Inc. and Teva Women's Health, Inc. manufacture and sell a device called ParaGard T 380A Intrauterine Copper Contraceptive. This T-shaped device, which is placed in the uterus, can prevent pregnancies for up to ten years. Accompanying the product are two inserts—one for the prescribing physician and another for the patient—with warnings and instructions. Before implanting the device, physicians are supposed to give patients time to read the latter insert, discuss it with them, and answer any questions.

After going through this process with her physician, Ideus decided to have the device implanted. When she later tried to have it removed, however, her physicians discovered that it had broken apart and a piece had become embedded in her uterus. Removing it required surgery.

Ideus sued Teva in federal district court for, as relevant here, breach of its duty to warn her of the potential risks. In granting summary judgment to Teva, the court applied the learned-intermediary doctrine, which as a general rule allows manufacturers of certain types of medical products to discharge their duty by warning "medical profession[als]" of the risks rather than the patients themselves. *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 841–42 (Neb. 2000). Ideus's position, both before the district court and on appeal, is that the Nebraska Supreme Court would not apply it to contraceptive devices like ParaGard.

[1]The Honorable John M. Gerrard, Chief Judge, United States District Court for the District of Nebraska.

II.

Despite disagreeing throughout about the application of the learned-intermediary doctrine, the parties now agree on three basic points. First, Nebraska law applies. *See Menard, Inc. v. Dial-Columbus, LLC*, 781 F.3d 993, 997 (8th Cir. 2015). Second, Teva provided adequate warnings to Ideus's physician. Third, with no dispute about the adequacy of those warnings, the sole issue on appeal is whether Teva had an obligation to warn Ideus too, which raises a legal question that we review de novo. *Carson v. Simon*, 978 F.3d 1051, 1059 (8th Cir. 2020).

Like most states, Nebraska requires manufacturers to warn consumers directly about any "risk[s] or hazard[s] inherent in the way a product is designed." *Freeman*, 618 N.W.2d at 841 (quotation marks omitted). But there is an exception, known as the learned-intermediary doctrine, for prescription drugs. *Id.* at 841–42. So far, the Nebraska Supreme Court has not said whether it would apply the learned-intermediary doctrine to other products like IUDs. So our task is to predict what it would do, which requires us to look at what it has said. *See Menard, Inc.*, 781 F.3d at 997.

The key discussion is in *Freeman*. In that case, a patient developed serious health problems from the use of Accutane, a prescription acne medication. *See Freeman*, 618 N.W.2d at 832. One of her claims was that the manufacturer had misled her about the potential risks. *Id.* The Nebraska Supreme Court, in the course of considering the claim, "adopt[ed] § 6(d) of the Third Restatement" of Torts, the provision covering the learned-intermediary doctrine. *Id.* at 841–42; *see also* Restatement (Third) of Torts: Products Liability § 6(d) (Am. L. Inst. 1997). It says that

> [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.

Restatement (Third) of Torts: Products Liability § 6(d) (emphasis added). What this provision does is insulate a manufacturer of "prescription drug[s] or medical device[s]" from duty-to-warn liability if it "adequate[ly]" communicates the risks to "health-care providers," *id.* § 6(d) & cmt. e, unless "special facts require a direct warning to the consumer," *Freeman*, 618 N.W.2d at 842. The rationale is that medical professionals are typically "in the best position to" analyze the potential risks and decide "whether the patient should use the product." *Id.* at 841–42 (quotation marks omitted).

Although *Freeman* involved a "prescription drug," the Restatement treats "medical device[s]" no differently, which suggests that the Nebraska Supreme Court would, if faced with the question, apply the learned-intermediary doctrine to devices like ParaGard. *See id.* at 842 (quoting Restatement (Third) of Torts: Products Liability § 6(d)). Indeed, just like Accutane, it is prescribed by physicians, so it fits within the rationale for the rule: they will be "in the best position to" advise their patients about the risks of using it. *Id.* at 841–42 (quotation marks omitted).

Nevertheless, Ideus argues that the Nebraska Supreme Court would recognize an exception to the learned-intermediary doctrine for prescription contraceptives. She points to three cases, one from Massachusetts and two from federal district courts in Michigan, that require direct warnings to consumers for those types of products. *See* Restatement (Third) of Torts: Products Liability § 6 cmt. e ("leav[ing]" open the possibility for other "exceptions" in "developing case law").

There is no question that Massachusetts has adopted a prescription-contraceptives exception, *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70 (Mass. 1985), but the law in Michigan "is less than clear," *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1032 n.5 (D.N.J. 1988). Some courts have suggested that Michigan would follow Massachusetts's lead, *see Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 879 (E.D. Mich. 1985); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 381 (E.D. Mich. 1985), although others have reached the opposite conclusion, *see Beyette v. Ortho Pharm. Corp.*, 823 F.2d 990, 992–93 (6th Cir. 1987) (applying the learned-intermediary doctrine to an IUD under Michigan law); *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1291 (E.D. Mich. 1991) (predicting that "the learned[-]intermediary doctrine does apply to oral contraceptives under Michigan law"). The bottom line is that Massachusetts stands alone in unequivocally adopting it.

On the other side of the ledger are a number of states that have rejected it. Among them are Arkansas, Colorado, Delaware, Florida, Illinois, Indiana, Kansas, Louisiana, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, and Washington.[2] Numerous federal courts have done so too, including for IUDs. *See, e.g.*, *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *Gonzalez v. Bayer Healthcare Pharms., Inc.*, 930 F. Supp. 2d 808, 820–21 (S.D. Tex. 2013);

[2]*West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991); *Hamilton v. Hardy*, 549 P.2d 1099, 1110 (Colo. App. 1976), *overruled on other grounds by State Bd. of Med. Exam'rs v. McCroskey*, 880 P.2d 1188 (Colo. 1994); *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.*, 661 N.E.2d 352, 356–57 (Ill. 1996); *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 548–49 (Ind. Ct. App. 1979); *Humes v. Clinton*, 792 P.2d 1032, 1041 (Kan. 1990); *Cobb v. Syntex Lab'ys, Inc.*, 444 So. 2d 203, 205 (La. Ct. App. 1983); *Hoffman-Rattet v. Ortho Pharm. Corp.*, 516 N.Y.S.2d 856, 859 (Sup. Ct. 1987); *Seley v. G. D. Searle & Co.*, 423 N.E.2d 831, 839–40 (Ohio 1981); *McKee v. Moore*, 648 P.2d 21, 25 (Okla. 1982); *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 528–30 (Or. 1974); *Brecher v. Cutler*, 578 A.2d 481, 485 (Pa. Super. Ct. 1990); *Wyeth-Ayerst Lab'ys Co. v. Medrano*, 28 S.W.3d 87, 92 (Tex. App. 2000); *Terhune v. A. H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) (en banc).

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