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
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> (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).

Amore v. G.D. Searle & Co., 748 F. Supp. 845, 849–50 (S.D. Fla. 1990). One consistent theme in their analysis is that contraceptives are no different from other prescription drugs and medical devices, at least in terms of the level of "guidance," "knowledge," and "skill" required of physicians. *Terhune*, 577 P.2d at 978.

Every indication is that the Nebraska Supreme Court would follow what has become an "overwhelming majority" rule. *Spychala*, 705 F. Supp. at 1032; *see also In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 704 n.18 (E.D. Tex. 1997) (collecting cases), *aff'd*, 165 F.3d 374 (5th Cir. 1999). After all, by adopting the Restatement and noting that the learned-intermediary doctrine has been widely adopted, it has already signaled its hesitance to become an outlier. *Freeman*, 618 N.W.2d at 842.

It is true, as Ideus points out, that this case is not *our* first foray into the area. Over 30 years ago, in *Hill v. Searle Laboratories, a Division of Searle Pharmaceuticals, Inc.*, we concluded that the learned-intermediary doctrine does not apply to IUDs. 884 F.2d 1064, 1070–71 (8th Cir. 1989). Still, for at least three reasons, *Hill* does not tie our hands here. First, *Hill* arose under *Arkansas* law, not *Nebraska* law. *See id.* Second, we were writing on a blank slate in *Hill*, *see id.*, whereas here the Nebraska Supreme Court has already embraced the learned-intermediary doctrine and defined its contours by adopting the Restatement, *Freeman*, 618 N.W.2d at 842. Third, more courts have weighed in over the past three decades, so the legal landscape looks different now than it did then.[3] *See In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. at 704 n.18.

[3]As for the dissent's suggestion that we should certify the question to the Nebraska Supreme Court, neither party has requested it, we did not certify in *Hill*, 884 F.2d at 1070–71, and we had even less to go on there. In this case, *Freeman* already provides an extensive analysis of the learned-intermediary doctrine, 618 N.W.2d at 841–42, and no one disputes that it has been more than 35 years since the last state appellate court adopted a prescription-contraceptives exception.

For these reasons, we agree with the district court that Teva was entitled to summary judgment.[4] All it was required to do under Nebraska law was warn medical professionals like Ideus's physician about ParaGard's potential risks.

III.

We accordingly affirm the judgment of the district court.

KELLY, Circuit Judge, dissenting.

Because I believe we lack sufficient guidance from the Nebraska courts as to whether Nebraska would apply the learned-intermediary doctrine to intrauterine devices and other contraceptives, I would certify the question to the Nebraska Supreme Court before deciding the merits of this appeal.

The Nebraska Supreme Court's decision in Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827 (Neb. 2000), tells us little more than that Nebraska applies the learned-intermediary doctrine to prescription acne medication. The court today emphasizes that Freeman "adopt[ed] § 6(d) of the Third Restatement," 618 N.W.2d at 842. But it is unclear why adopting this provision means that Nebraska would refuse to recognize exceptions to the learned-intermediary doctrine. Indeed, the very text of § 6(d) recognizes an exception for direct-to-consumer warnings. Specifically, it provides 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" either:

[4]Ideus separately argues that the Nebraska Supreme Court would adopt a direct-to-consumer-advertising exception. *See Perez v. Wyeth Lab'ys Inc.*, 734 A.2d 1245, 1257 (N.J. 1999) (holding "that the learned[-]intermediary doctrine does not apply to the direct marketing of drugs to consumers"). Even assuming that Nebraska would follow New Jersey's lead, this case does not involve direct-to-consumer advertising. The patient insert does not qualify, *see id.*, nor does a magazine advertisement postdating the implantation of her device by over six years.

> (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
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> (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) (Am. L. Inst. 1997) (emphasis added).

In fact, in acknowledging that the "[learned-intermediary] doctrine as stated in the Third Restatement has . . . been adopted in other jurisdictions," the Nebraska Supreme Court in Freeman cited as an example a New Jersey decision declining to apply the doctrine where the manufacturer advertised directly to consumers (one of the very exceptions sought by Ideus in this case). 618 N.W.2d at 842 (citing Perez v. Wyeth Lab'ys, Inc., 734 A.2d 1245 (N.J. 1999)). The court also explained that the learned-intermediary doctrine "is followed in virtually all jurisdictions that have considered whether to adopt it," including some which recognize "exceptions for instances where special facts require a direct warning to the consumer." Id. But the Nebraska Supreme Court did not elaborate as to whether it would follow suit and recognize such exceptions. And it didn't need to. The facts in Freeman did not trigger that analysis, and the court's brief discussion of the doctrine simply does not tell us one way or another what Nebraska would do in future cases. In the absence of guidance from Nebraska courts, I find insufficient support for the court's conclusion that Nebraska would follow the "majority" rule.

Where, as here, "we find no state law precedent on point and where the public policy aims are conflicting the case may properly be certified to the state court." Hatfield, by Hatfield v. Bishop Clarkson Mem'l Hosp., 701 F.2d 1266, 1267 (8th Cir. 1983) (en banc). The question of whether to carve out a contraceptives exception to the learned-intermediary doctrine—and thus, to impose on

contraceptives manufacturers a duty to warn consumers directly—depends in large part on whether a state views the prescribing of contraceptives as different than that of other drugs or medical devices. See, e.g., MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 68-69 (Mass. 1985). A decision in either direction, and in "so uncertain an area of tort law," involves a value judgment that we need not—and should not—venture into "without first seeking guidance" from the Nebraska Supreme Court. McKesson v. Doe, 141 S. Ct. 48, 51 (2020) (per curiam) (holding that federal court should have certified question of Louisiana tort law where inquiry involved considering "moral, social, and economic factors," including "the fairness of imposing liability" (cleaned up)); see also Danler v. Rosen Auto Leasing, Inc., 609 N.W.2d 27, 32 (Neb. 2000) (explaining that Nebraska employs "a risk-utility balancing test" to determine whether to impose a legal duty, considering factors such as "the magnitude of the risk" and "the policy interest in the proposed solution"); cf. West v. Searle Co., 806 S.W.2d 608, 614 (Ark. 1991) (citing public policy reasons to apply the learned-intermediary doctrine to oral contraceptives despite the Eighth Circuit's recent decision in Hill v. Searle Lab'ys, a Div. of Searle Pharm., Inc., 884 F.2d 1064, 1070-71 (8th Cir. 1989), that—under Arkansas law—the learned-intermediary doctrine did not apply to IUDs and other forms of birth control).

In this case, "certification would not deprive th[e] court of jurisdiction, nor would it force the parties into state court, but rather would afford the parties a state forum for a state law question which process may obviate further extensive consideration by this court." Hatfield, 701 F.2d at 1268; see also id. at 1269 ("The fact that the district court did not certify this question does not bar this court from utilizing the certification procedure."); Neb. Rev. Stat. § 24-219 (permitting Nebraska Supreme Court to answer certified questions when the federal proceeding involves a question of state law that "may be determinative of the [pending] cause" and the certifying court believes "there is no controlling precedent"). Though a federal court sitting in diversity generally has a duty to resolve state-law issues properly before it, in my view, this case presents one of the unusual circumstances where certification is necessary.

For these reasons, I respectfully dissent.
