NOT FOR PUBLICATION

In the
United States Court of Appeals
For the Eleventh Circuit

No. 25-13895
Non-Argument Calendar

MARYANN RUDZINSKAS,

Plaintiff-Appellant,

versus

RETRACTABLE TECHNOLOGIES, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Georgia
D.C. Docket No. 4:24-cv-00009-RSB-CLR

Before ROSENBAUM, GRANT, and BRASHER, Circuit Judges.

PER CURIAM:

Maryann Rudzinskas appeals the district court's order granting summary judgment to Retractable Technologies, Inc. She con-

tends the district court abused its discretion by excluding the testimony of her expert witness. She also contends the district court erred in granting summary judgment to Retractable on her negligent manufacturing and negligent failure-to-warn claims. Because the district court did not abuse its discretion by finding that Mrs. Rudzinskas's expert was not qualified, we affirm the district court's evidentiary ruling. And because Mrs. Rudzinskas cannot meet her burden on her negligence claims, we affirm the district court's grant of summary judgment to Retractable.

I.

Maryann Rudzinskas, a resident of Georgia, alleged she was injured by a defective VanishPoint syringe manufactured by Retractable Technologies, Inc., a Texas corporation. In January 2023, Mrs. Rudzinskas's husband, Joseph Rudzinskas, administered an injection into her buttock, allegedly using a VanishPoint syringe. According to Retractable, VanishPoint syringes are designed to automatically retract the needle into the syringe once the plunger handle is fully depressed. But according to Mrs. Rudzinskas, the needle "shot into [her] like a slingshot" and became lodged inside her body. Doc. 21-2 at 62. She immediately sought treatment at a hospital, where an ultrasound revealed a "linear echogenic focus" in her right buttock. *Id.* at 113. The "clinical indication" for the ultrasound was that a "[n]eedle broke off in right buttock." *Id.*

Mrs. Rudzinskas subsequently consulted general surgeon Dr. John Odom, who examined the syringe used to administer the injection and observed that the device was a VanishPoint syringe

without a retracted needle. Dr. Odom performed exploratory surgery and tracked the needle under fluoroscopy but was unable to retrieve it.

In March 2023, Mr. Rudzinskas administered another injection, this time into Mrs. Rudzinskas's arm. Mrs. Rudzinskas alleges that she again used a VanishPoint syringe and the needle again lodged beneath her skin. Dr. Odom performed an x-ray but could not detect the needle.

Mrs. Rudzinskas asserted two Georgia law claims against Retractable: negligent manufacturing and negligent failure-to-warn. During discovery, Mrs. Rudzinskas produced to Retractable what she represented to be the two syringes that dislodged their needles into her body, along with several other syringes. However, all syringes Mrs. Rudzinskas sent to Retractable still contained needles. Mrs. Rudzinskas later said she had inadvertently provided the wrong syringes, and she no longer knew where the syringes used in the January and March 2023 injections were.

Retractable's expert witness testified that every VanishPoint syringe is extensively tested, that it would "defy physics" for a VanishPoint needle to shoot forward into a patient's body, and that he was unaware of any instances of VanishPoint syringes forcing needles into patients. Doc. 21-2 at 177–80. He also stated that without examining the syringes that allegedly injured Mrs. Rudzinskas, he could not determine whether those syringes had a manufacturing defect.

Mrs. Rudzinskas identified Dr. Odom as an expert witness. In his expert witness report, Dr. Odom opined that "a medical needle should be designed and manufactured so as not to break off from [the] syringe," but "[t]he needle of the [VanishPoint] syringe broke off from the syringe and lodged into [Mrs. Rudzinskas's] body on two separate occasions" because of "manufacturing issues and a defective product/design." Doc. 21-1 at 125. Dr. Odom used VanishPoint syringes in his medical practice. But Mrs. Rudzinskas stipulated that Dr. Odom is not a manufacturing or design expert.

At the close of discovery, both parties filed motions in limine to exclude the opposing party's expert testimony. The district court denied both of Mrs. Rudzinskas's motions but granted Retractable's motion in part. The court excluded Dr. Odom's opinions regarding the design and manufacturing of the VanishPoint syringes, concluding that Mrs. Rudzinskas had not "borne her burden of showing that Dr. Odom is qualified to testify competently about the design, manufacturing, or alleged defect of the at-issue product." Doc. 21-4 at 28 (citation modified). The court also excluded Dr. Odom's opinion that a needle remained lodged in Mrs. Rudzinskas's arm, but it permitted his opinion that there was a needle in her buttock. The district court then granted Retractable's motion for summary judgment. Mrs. Rudzinskas timely appealed.

II.

Mrs. Rudzinskas makes two arguments. First, she challenges the district court's exclusion of Dr. Odom's testimony regarding

the design and manufacturing of the syringes. Second, she challenges the court's grant of summary judgment to Retractable. Retractable argues Dr. Odom's testimony was properly excluded and that summary judgment was properly granted. We agree with Retractable. We will address each issue in turn.

A.

We will start with whether Dr. Odom was qualified to testify about the manufacturing and design of the syringe. The admissibility of expert testimony is controlled by Federal Rule of Evidence 702, as explained in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). In their role as gatekeepers of expert testimony, district courts are instructed to consider the qualifications of the expert, the reliability of the expert's methodology, and the "helpfulness" of the expert's testimony to the factfinder. *Id.* at 589–91, 597. Among other things, an expert must be "qualified to testify competently regarding the matters he intends to address." *City of Tuscaloosa v. Harcos Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998). The party offering the witness bears the burden to establish the expert's qualifications by a preponderance of the evidence. *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1256 (11th Cir. 2002).

Here, the parties dispute whether Dr. Odom was qualified to testify regarding the alleged manufacturing defect in the VanishPoint syringes. Doc. 17 at 22. We review a district court's decision to admit or exclude evidence for abuse of discretion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142–43 (1997). Because the district court is the "gatekeeper" of evidence, we will not reverse a district court's

decision to exclude expert testimony unless the decision was "manifestly erroneous." *Id.* at 142.

We conclude the district court did not abuse its discretion when it found Dr. Odom unqualified to opine that "the subject needles separated from the syringes, due to manufacturing issues and a defective product/design." Doc 21-1 at 125. Under Rule 702, "experts may be qualified in various ways," including by knowledge, education, and experience. *United States v. Frazier*, 387 F.3d 1244, 1260–61 (11th Cir. 2004). But "[e]xpertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Child. & Fams.*, 772 F.3d 1352, 1368–69 (11th Cir. 2014) (affirming the district court's exclusion of a psychiatrist's testimony about rates of drug use among a particular population). Accordingly, a district court may disqualify a proposed design-defect expert, even if the expert has some isolated experience using a product. *See United States v. Brown*, 415 F.3d 1257, 1263, 1269 (11th Cir. 2005) (affirming that a freelance chemistry consultant with a Ph.D. in plant pathology was not qualified to opine on whether one drug was a "controlled substance analogue" of another because he worked with the drugs "on isolated projects" and did not have a "license to work with controlled substances").

The district court did not abuse its discretion by excluding Dr. Odom's testimony. We are not persuaded by Mrs. Rudzinskas's argument that Dr. Odom's surgical experience or his familiarity with VanishPoint syringes means he "barely passes the qualification threshold" to testify regarding the intended operation of the

VanishPoint syringes, Doc. 17 at 22–23, or to opine, as he did in his expert report, that "the subject needles separated from the syringes, due to manufacturing issues and a defective product/design," Doc 21-2 at 125. The parties agree that Dr. Odom is not a manufacturing or design expert. Dr. Odom's limited experience using VanishPoint syringes is not enough to render him an expert in the design or manufacturing of the syringes. His past use of the syringes does not give him a basis to hypothesize about how the manufacturer intended the syringes to operate or whether a manufacturing defect could cause the needles to separate from the syringes. A "common sense" understanding that a syringe is not supposed to dislodge its needle into a patient does not qualify a physician to conclude that Mrs. Rudzinskas's syringes did so because of a manufacturing defect, as opposed to user error or the like. Doc. 21-1 at 106.

B.

We will turn now to the district court's grant of summary judgment. We review a grant of summary judgment *de novo*, viewing all facts in the light most favorable to the nonmoving party. *Lebron*, 772 F.3d at 1359. We grant summary judgment if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). We must grant summary judgment if the nonmoving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party

will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

To prevail on a Georgia law negligence claim, a plaintiff must establish a legal duty, a breach of that duty, an injury, and a causal connection between the breach and the injury. *R & R Insulation Servs., Inc. v. Royal Indem. Co.*, 705 S.E.2d 223, 232 (Ga. Ct. App. 2010). To establish a negligent manufacturing claim, the plaintiff must prove "that there was a defect in the product when it left the manufacturer, the defect was caused by the manufacturer's negligence, and the defect caused her injury." *Sheats v. Kroger Co.*, 784 S.E.2d 442, 446 (Ga. Ct. App. 2016).

Georgia law does not require that plaintiffs produce the particular items that caused the injury. *Rose v. Figgie Int'l, Inc.*, 495 S.E.2d 77, 81 (Ga. Ct. App. 1997). Because defective products are often destroyed, the existence of a manufacturing defect at the time the product left the manufacturer may be inferred from circumstantial evidence. *Id.* Claimants can show that units of the same good produced by the manufacturer around the same time contained the alleged defect. *Id.* at 82–83 (finding a jury could infer a fire extinguisher contained a manufacturing defect after it exploded because there were over fifty other spontaneous explosions involving the same model); *Sheats*, 784 S.E.2d at 446 (affirming summary judgment because the package that injured plaintiff had been discarded and none of the other packages produced by the manufacturer had a similar problem). Claimants can also use expert manu-

facturing testimony to demonstrate the only reasonable explanation for an incident is that the product that caused the injury was defective when it left the manufacturer. *Skil Corp. v. Ludgsdin*, 309 S.E.2d 921, 924 (Ga. Ct. App. 1983).

Drawing all inferences in Mrs. Rudzinskas's favor, summary judgment was properly granted to Retractable on the negligent manufacturing claim. Mrs. Rudzinskas cannot establish a genuine dispute of fact as to whether the VanishPoint syringes that allegedly caused her injury contained a manufacturing defect at the time they left Retractable. Mrs. Rudzinskas cannot produce the VanishPoint syringes that allegedly caused her injury for inspection. Aside from the two incidents she alleges in her complaint, Mrs. Rudzinskas presents no evidence that other VanishPoint syringes caused similar injuries or contained a similar defect. And Mrs. Rudzinskas does not present testimony, expert or otherwise, to suggest the syringes deviated from manufacturing specifications or contained a manufacturing defect. We are not persuaded by Mrs. Rudzinskas's argument that she has created "a triable issue of fact" by offering testimony asserting the VanishPoint syringe "did not function as intended and instead shot a needle into [Mrs. Rudzinskas's] body." Doc. 17 at 26. Under Georgia law, "the mere failure of [the VanishPoint syringes] is not itself evidence of an original defect since the failure can be the result of myriad causes not related to [their] manufacture." *Miller v. Ford Motor Co.*, 653 S.E.2d 82, 84 (Ga. Ct. App. 2007) (citation modified). Therefore, Mrs. Rudzinskas provides no evidence that would allow a reasonable jury to infer the VanishPoint syringes were defective when they left

Retractable. Accordingly, we conclude the district court did not err in granting summary judgment to Retractable on the negligent manufacturing claim.

Because Mrs. Rudzinskas cannot establish the existence of a manufacturing defect, she also cannot establish that Retractable breached any duty to warn her of a defect. To survive summary judgment for her negligent failure-to-warn claim, Mrs. Rudzinskas must establish that Retractable breached its legal duty to warn purchasers of the VanishPoint syringes of "foreseeable dangers arising from the reasonable use for which the product is intended." *R & R Insulation*, 705 S.E.2d at 427. "In failure to warn cases, the duty to warn arises whenever the manufacturer knows or reasonably should know of the danger arising from the use of its product." *Chrysler Corp v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994). Mrs. Rudzinskas concedes that her failure-to-warn claim is derivative of her negligent manufacturing claim. Because she has not established the existence of a defect in the VanishPoint syringes, she cannot prove that Retractable knew of a "danger" associated with the syringes. The district court properly granted summary judgment to Retractable on the negligent failure-to-warn claim.

III.

The district court is **AFFIRMED**.