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Case No. 13-3908

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

FILED
May 30, 2014
DEBORAH S. HUNT, Clerk

FERNANDO RODRIGUES,)	
)	
Plaintiff-Appellant,)	
)	ON APPEAL FROM THE UNITED
v.)	STATES DISTRICT COURT FOR
)	THE NORTHERN DISTRICT OF
BAXTER HEALTHCARE CORPORATION,)	OHIO
et al.,)	
)	
Defendants-Appellees.)	
)	

BEFORE: SUTTON and COOK, Circuit Judges; MARBLEY, District Judge.*

SUTTON, Circuit Judge. Fernando Rodrigues received an allegedly contaminated dose of heparin during his heart bypass surgery. He suffered complications during the surgery. Suspecting a connection, he sued the companies who made and distributed the heparin. The district court granted summary judgment for the companies because Rodrigues could not establish causation—that the heparin caused his complications. We affirm.

Baxter Healthcare Corporation manufactures heparin, a drug commonly used to reduce the risk of blood clots. Baxter issued a recall of heparin in 2008 after a spike in reports of

^{*} The Honorable Algenon L. Marbley, United States District Judge for the Southern District of Ohio, sitting by designation.

adverse reactions to it. The Centers for Disease Control and the Food and Drug Administration investigated and found that Baxter's heparin contained another heparin-like drug, one that could have caused the adverse reactions. *See In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 720–23 (N.D. Ohio 2011).

Fernando Rodrigues received a dose of allegedly contaminated heparin during bypass surgery for "[c]ritical three-vessel coronary artery disease." R.28-1 at 1. His blood pressure dropped, and he experienced swelling when his surgeons took him off bypass. These and other complications required him to stay in the intensive care unit, sedated and with his chest still open, for three days until the swelling went down and the surgeons could close the incision.

Rodrigues sued Baxter and a distributor of the drug, McKesson Corporation, in Connecticut state court under the state's products liability statute. The defendants removed the case to federal court, where the judicial panel on multidistrict litigation consolidated it with other similar cases in the Northern District of Ohio.

In the multidistrict proceeding, the district court ruled that the admissible expert testimony supported only claims "in which one or more symptoms were apparent within the sixty minute period" after receiving the contaminated heparin. *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d at 754. That is to say, the available evidence did not support a causal link between contaminated heparin and complications that arose more than sixty minutes after the patient received the drug. *See id.* at 753–54.

Relying on this ruling, Baxter filed a motion for summary judgment against Rodrigues in this individual action. The district court granted the motion. It held that Rodrigues did not have

evidence that his symptoms began less than sixty minutes after he received heparin and thus did not have evidence of a causal link between the heparin and his injuries. Rodrigues appealed.

As Rodrigues sees it, the district court erred in excluding proposed expert testimony from one of Rodrigues' expert witnesses that would have supported a cognizable theory of causation. As we see it, the district court properly performed its "gatekeeping role" under Federal Rule of Evidence Rule 702, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), in excluding the testimony.

Under Rule 702, a person qualified as an expert may offer an opinion if that expert's scientific knowledge will help the fact finder decide a disputed fact and if that opinion passes the threshold of reliability. The district court as an initial matter found that Dr. Debra Hoppensteadt, Rodrigues' proposed expert witness, qualified as an expert and that her testimony, if reliable, would help a fact finder understand the relevant science. In re Heparin Prods. Liab. Litig., 803 F. Supp. 2d at 729–31, 740. But it found that Dr. Hoppensteadt's testimony on whether "contaminated heparin could cause effects beyond the sixty-minute time period—well beyond the time-frame established by the [Centers for Disease Control] case definition for onset of symptoms"—was unreliable. *Id.* at 738–39. Dr. Hoppensteadt relied on one study on the effect of the contaminated heparin on a biological pathway that regulates blood pressure. That study noted activity in the pathway "at the end of the sixty-minute observation time" but did not observe any "effects experienced by the animals in these studies beyond a few minutes after administration." Id. Dr. Hoppensteadt could "not explain the process by which the onset of symptoms would be delayed," leading the district court to find that her proposed testimony—that the contaminated heparin could cause an onset of symptoms more than sixty minutes after administration—was "speculative" and unreliable. Id. at 739.

The district court permissibly excluded Dr. Hoppensteadt's testimony. Rule 702 requires "more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. "Proposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known." *Id.* Dr. Hoppensteadt's unexplained conclusion failed to connect the dots—to provide a satisfactory reason why contaminated heparin might first cause symptoms more than sixty minutes after doctors administered it.

Rodrigues misunderstands Rule 702 when he faults the district court for straying beyond "the specific issue of whether a witness is qualified to be deemed an expert." App. Br. at 13. Yes, the rule requires an expert to be qualified. But no, its requirements do not end there. A district court may exclude expert testimony "connected to existing data only by the *ipse dixit* of the expert" when it sees "too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). The district court did just that here, and as a result we have no basis for upsetting its *Daubert* ruling or the summary judgment decision that flowed from it.

For these reasons, we affirm the judgment of the district court.