[DO NOT PUBLISH]

In the

United States Court of Appeals

For the Eleventh Circuit

No. 19-14831

MAGALY PINARES,

Plaintiff,

MARCOS PINARES,

Plaintiff-Appellant,

RICHARD COTROMANO, et al.,

Consol Plaintiffs,

versus

RAYTHEON TECHNOLOGIES CORPORATION,
d.b.a. Pratt & Whitney,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Florida
D.C. Docket No. 9:10-cv-80883-KAM

Before ROSENBAUM and LUCK, Circuit Judges.*

LUCK, Circuit Judge:

Magaly and Marcos Pinares appeal the district court's order granting summary judgment in favor of Raytheon Technologies Corporation.[1] In this toxic tort case, the Pinareses alleged a Raytheon facility had leaked chemicals that poisoned their water and ultimately gave Mrs. Pinares kidney cancer. To prove their claims, they offered expert witness testimony connecting Mrs. Pinares's cancer to chemicals from the facility. But the district court excluded those experts' opinions and entered summary judgment for Raytheon. After careful consideration and with the benefit of oral argument, we affirm.

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* This opinion is being entered by a quorum pursuant to 28 U.S.C. § 46(d).

[1] United Technologies Corporation, which owned the facility during the events at issue, merged with Raytheon during this appeal. For simplicity's sake, we refer only to Raytheon.

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Raytheon operates a facility in Palm Beach County, Florida, where jet engines have been tested and manufactured since the facility opened in 1958. The Pinareses lived in The Acreage, a neighborhood about eight miles from the facility. In 2006, Mrs. Pinares was diagnosed with renal cell carcinoma—a form of kidney cancer. Two other residents of The Acreage were diagnosed with kidney cancer around the same time.

In November 2008, "the Environmental Protection Agency found 24 contaminants in the soil and water on [Raytheon's] property." *Adinolfe v. United Techs. Corp.*, 768 F.3d 1161, 1169 (11th Cir. 2014). Raytheon's own testing "confirmed" that contaminants were "present in high concentration[s] in the groundwater under and around its property." *Id.* In 2009, the Florida Department of Health concluded that The Acreage residents experienced increased rates of brain cancer from 1995 to 2007 and particularly from 2005 through 2007.

The Pinareses tested a well on their property and found three chemical compounds in their water: bromodichloromethane, chloroform, and methylene chloride. The federal government classifies each of these compounds as "[r]easonably [a]nticipated to be a [h]uman [c]arcinogen."

The Pinareses sued Raytheon in 2010.[2] Their fifth amended complaint alleged common-law strict liability, statutory strict liability, negligence, and loss of consortium. They alleged that chemicals from Raytheon's facility contaminated the aquifer and traveled through the aquifer to their property. The Pinareses alleged that Raytheon "failed to take adequate or reasonable measures to prevent the escape of [contaminants] from its property or warn" them that Raytheon's "byproducts would contaminate the groundwater underlying The Acreage." The Pinareses contended that the contaminants caused Mrs. Pinares's kidney cancer.

During discovery, the Pinareses offered testimony from several expert witnesses—including toxicologist Dr. Lawrence Wylie and physicians Dr. Dudley Danoff and Dr. Arnold Schecter—to show that the contaminants caused Mrs. Pinares's kidney cancer. Raytheon moved to exclude the experts' testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and Federal Rule of Evidence 702. Raytheon then moved for summary judgment.

The district court granted Raytheon's motions. It found that Dr. Wylie hadn't conducted a reliable dose-response assessment to show that the amount of contaminants Mrs. Pinares was exposed to could have caused her cancer. Specifically, the district court reasoned that Dr. Wylie: (1) failed to show whether "the alleged

[2] The Pinareses sued in Florida state court, and Raytheon removed the case to the Southern District of Florida based on diversity of citizenship.

carcinogens were present" in the Pinareses' water before Mrs. Pinares's diagnosis and "how long they were present"; (2) overlooked "the effects of the body in metabolizing or eliminating chemicals before any toxic effect t[ook] hold"; (3) relied on an invalid "one-hit model" of causation; (4) provided no evidence to support his calculation of Mrs. Pinares's exposure to the contaminants; and (5) failed to "isolate" Mrs. Pinares's "exposure to each of the various chemicals separately, which [wa]s necessary to analyze the potential cancer causing likelihood of each compound." The district court excluded Dr. Danoff's and Dr. Schecter's testimony, too—they hadn't performed independent dose-response assessments, so their conclusions relied on Dr. Wylie's deficient report.

After excluding the causation experts' testimony, the district court granted summary judgment for Raytheon because the Pinareses couldn't show that Raytheon caused Mrs. Pinares's cancer. Mr. Pinares[3] timely appealed the district court's three exclusion orders and summary judgment.

STANDARD OF REVIEW

We review de novo the district court's grant of summary judgment. *Williams v. Mosaic Fertilizer, LLC*, 889 F.3d 1239, 1244 (11th Cir. 2018). We review a district court's *Daubert* rulings for abuse of discretion, and we "will affirm unless the court 'has made

[3] Mrs. Pinares passed away in 2018, and Mr. Pinares was appointed personal representative of her estate.

a clear error of judgment[] or has applied an incorrect legal standard.'" *Id.* at 1245 (marks omitted). We give the district court "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). "Even where a ruling excluding expert testimony is 'outcome determinative' and the basis for a grant of summary judgment, our review is not more searching than it would otherwise be." *Adams v. Lab'y Corp. of Am.*, 760 F.3d 1322, 1327 (11th Cir. 2014) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142–43 (1973)).

DISCUSSION

Under the Federal Rules of Evidence, expert opinion testimony is admissible only if "the testimony is based upon sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(c)–(d). The district court "act[s] as a gatekeeper to [e]nsure that speculative and unreliable opinions do not reach the jury." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1237 (11th Cir. 2005) (citing *Daubert*, 509 U.S. at 589 n.7, 597). This gatekeeping role requires performing "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. "When doing so, 'the court must consider the testimony with the understanding that the burden of establishing qualification, reliability, and helpfulness rests on

the proponent of the expert opinion.'" *Williams*, 889 F.3d at 1245 (quoting *McClain*, 401 F.3d at 1238).

In toxic tort cases, we use an additional framework to sift out reliable expert testimony from unscientific speculation. Where "the medical community does not generally recognize the agent as both toxic and causing the injury plaintiff alleges," as here,[4] we conduct a two-part *Daubert* analysis that "covers not only the expert's methodology for the plaintiff-specific questions about individual causation but also the general question of whether the drug or chemical *can* cause the harm plaintiff alleges." *McClain*, 401 F.3d at 1239. "General causation is concerned with whether an agent increases the incidence of disease in a group and not whether the agent caused any given individual's disease." *Id.*

"When analyzing an expert's methodology in toxic tort cases, the court should pay careful attention to the expert's testimony about the dose-response relationship." *Id.* at 1241. "This attention is due because dose-response is 'the hallmark of basic toxicology.' Stripped to its bare essentials, a dose-response assessment estimates scientifically 'the dose or level of exposure at which the substance at issue causes harm.'" *Williams*, 889 F.3d at 1246 (cleaned up). "Dose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." *McClain*, 401 F.3d at 1242.

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[4] Neither party argues that there is a scientific consensus that the contaminants at issue cause kidney cancer.

"[G]iven the 'importance of individual responses to toxins,' a plaintiff must demonstrate both [1] the level of exposure to the allegedly harmful chemical that is hazardous to a human being and [2] the amount of the chemical to which the plaintiff was exposed." *Taylor v. Mentor Worldwide LLC*, 940 F.3d 582, 595 (11th Cir. 2019) (quoting *McClain*, 401 F.3d at 1241). An "expert who avoids or neglects the dose-response principle of toxic torts without justification casts suspicion on the reliability of his methodology." *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1339 (11th Cir. 2010) (alteration adopted) (quoting *McClain*, 401 F.3d at 1242). Although "we have never required an expert to 'give precise numbers about a dose-response relationship,' . . . we do require an expert to lay a 'reliable groundwork for determining the dose-response relationship.'" *Williams*, 889 F.3d at 1248 (quoting *McClain*, 401 F.3d at 1241 & n.6).

Our toxic tort cases illustrate the importance of a dose-response assessment when evaluating the reliability of expert testimony. In *McClain*, for example, the plaintiffs offered expert testimony that a supplement containing ephedrine caused heart attacks and strokes. 401 F.3d at 1239–40. We held that the district court erred in admitting the expert testimony because the expert had drawn "speculative conclusions about [the supplement's] toxicity" and had "neglect[ed] the hallmark of the science of toxic torts—the dose-response relationship." *Id.* at 1240. The expert in *McClain* "offered no testimony about the dose of [the supplement] required to injure [the p]laintiffs or anyone else" and "could not say how

much [wa]s too much." *Id.* at 1241. The expert also admitted that "hundreds of over-the-counter products" contained equal or greater levels of ephedrine than the supplement at issue, which level was "roughly half the [Food and Drug Administration's] allowable limits on ephedrine." *Id.* Without testifying about the dose-response relationship and in light of other "vague testimony about significant individual variations," the expert had "laid no reliable groundwork for determining the dose-response relationship," so we held the evidence should have been excluded. *Id.*

In *Chapman v. Procter & Gamble Distributing, LLC*, we affirmed the district court's exclusion of expert testimony that failed to show "dose-response, epidemiological evidence, and background risk of disease, methodologies [that] this circuit has recognized as indispensable to proving the effect of an ingested substance." 766 F.3d 1296, 1308 (11th Cir. 2014). There, the plaintiffs' general causation experts, and the articles upon which they relied, didn't determine "how much" of the substance needed to "be used for how long" to cause harm. *Id.* at 1307. We concluded that the district court did not abuse its discretion in excluding the testimony because the experts "failed to demonstrate the primary methods for proving" the substance caused harm, and the experts' "secondary methodologies, including plausible explanations, generalized case reports, hypotheses, and animal studies [we]re insufficient proof of general causation." *Id.* at 1308.

We arrived at a similar conclusion in *Williams*. 889 F.3d at 1244–48. There, the expert purported to conduct a dose-response

assessment, but the district court excluded the expert's testimony because "his methodology was undermined by multiple defects," especially the "failure to properly assess dose-response." *Id.* at 1245. We affirmed the district court's exclusion because the expert "never conducted an independent dose calculation specific to" the plaintiff and "failed to demonstrate a scientific basis for concluding that [the plaintiff's] exposure levels would likely produce, contribute to, or exacerbate, [her] conditions." *Id.* at 1246. We explained that the plaintiff "bore the burden of demonstrating" that the expert's determinations were "methodologically sound." *Id.* at 1248. And "when put to the task of identifying the bases of [the expert]'s dose-response conclusions with specificity," the expert and the plaintiff provided no clear answer. *Id.* at 1248 n.3. Because the plaintiff failed to establish that the expert's opinions were methodologically sound, we concluded that the district court did not abuse its discretion in excluding the testimony. *Id.* at 1245.

Exclusion of the Causation Experts' Testimony

Mr. Pinares argues that the district court's exclusion of the causation experts' testimony was "manifestly erroneous" because the experts "employed widely accepted methodologies to reach their opinions." We first discuss Dr. Wylie's opinion, then Drs. Danoff and Schecter's.

Dr. Wylie

Dr. Wylie reported that "toxic and carcinogenic chemical contaminants" were "present in The Acreage groundwater in

sufficient concentrations to cause illness in humans" and that "sufficient human exposure occurred in the case of [Mrs.] Pinares . . . to induce" her kidney cancer. The district court excluded Dr. Wylie's testimony because it found that his dose-response assessment was "lacking." We agree.

Like the expert in *Williams*, Dr. Wylie purported to conduct a dose-response assessment, but his testimony didn't identify what dose of the contaminants was "too much." *See* 889 F.3d at 1245–49; *McClain*, 401 F.3d at 1241–43. Dr. Wylie concluded that Mrs. Pinares was exposed to 8.24 micrograms of the contaminants per day, an annual dose of 3,009 micrograms. He concluded that this dosage was a "sufficient concentration[] to have provide[d] a daily dose over the years of exposure to induce a total dose that directly caused [Mrs. Pinares's] renal cell carcinoma[]." Dr. Wylie conceded, though, that this amount was "generally recognized by toxicologists" as "low." Dr. Wylie also acknowledged that this amount was well within the "safe drinking water standard" in Florida. Nevertheless, Dr. Wylie posited that "a 'threshold' or predicted 'safe' dose d[id] not likely exist for these chemicals" and that "every dose greater than zero" implicated "some human health risk." Dr. Wylie cited no authority to support his opinion that this amount of the contaminants could cause cancer.

The district court correctly held that Dr. Wylie failed to support his opinion with scientific evidence. *Cf. McClain*, 401 F.3d at 1242 (excluding expert when he "simply substituted his own *ipse dixit* for scientific proof"). As in *McClain*, Dr. Wylie didn't establish

a dose-response relationship but asserted that *any* amount of the contaminants was too much. *See id.* at 1243. But *McClain* rejected the "any amount" approach because it "clearly contradicts the principles of reliable methodology." *Id.* We explained that "low dose exposures—even for many years—will [often] have no consequence at all," because "the body is often able to completely detoxify low doses before they do any damage." *Id.* at 1242 (citation omitted). And we observed that, "for most types of dose-response relationships following chronic (repeated) exposure, thresholds exist, such that there is some dose below which even repeated, long-term exposure would not cause an effect in any individual." *Id.* (citation omitted).

Because Dr. Wylie didn't explain how much exposure to the Raytheon facility chemicals is "too much," his opinion wasn't sufficiently reliable under *Daubert* to be admissible expert testimony. *See id.* at 1242–43; *Chapman*, 766 F.3d at 1307; *Williams*, 889 F.3d at 1246–48. Rather than provide a scientifically rigorous basis for his opinion, Dr. Wylie stated only that the level of contaminants in the Pinareses' water supply was "sufficient to support a [one]- or two- . . . hit model[] of cancer initiation and promotion" given Mrs. Pinares's "low-dose exposure to multiple toxic and carcinogenic chemicals." The one-hit theory of causation "posits that [a] decedent's cancer was caused by a single exposure—regardless of the quantity of the dosage—of toxic chemicals." *Wills v. Amerada Hess Corp.*, 379 F.3d 32, 49 (2d Cir. 2004) (rejecting expert witness's one-hit theory of causation as unreliable). But Dr. Wylie provided

no explanation for why a model that ignores dosage, which we've deemed "the single most important factor to consider" in toxic tort cases, is appropriate here. *See McClain*, 401 F.3d at 1242.

Mr. Pinares argues that this case is distinguishable from *McClain*, *Chapman*, and *Williams*, "where the experts failed to calculate the dose-response relationship," because Dr. Wylie "performed" the dose-response assessment when he concluded that eight thousand micrograms was a sufficient dose to cause Mrs. Pinares's kidney cancer. But Dr. Wylie skipped the first step of a reliable dose-response assessment: he never "demonstrate[d] . . . the level of exposure to the allegedly harmful chemical that is hazardous to a human being." *See Taylor*, 940 F.3d at 595. He thus provided no reliable baseline against which the district court could evaluate his conclusions as to Mrs. Pinares's estimated exposure.

Because Dr. Wylie "laid no reliable groundwork for determining the dose-response relationship," we cannot say that the district court "made a clear error of judgment" or "applied an incorrect legal standard." *See McClain*, 401 F.3d at 1238, 1241 (quotation omitted). The district court thus did not abuse its discretion in excluding Dr. Wylie's testimony.

Dr. Danoff and Dr. Schecter

Dr. Danoff concluded that Mrs. Pinares's kidney cancer was "caused by exposure to carcinogenic chemicals known to be present in the well water that [she] . . . consumed and [was] exposed to through other means in [her] community." Similarly, Dr.

Schecter concluded that Mrs. Pinares's kidney cancer "was more likely than not caused by or contributed to by exposure to multiple carcinogenic chemicals present in the well water that she consumed and was exposed to through ingestion, inhalation, and dermal exposure." The district court excluded both experts' testimony because the experts "did not perform a dose-response calculation," couldn't have relied on Dr. Wylie's dose-response assessment, and needed a dose-response relationship for their opinions to be reliable. We agree.

Dr. Danoff and Dr. Schecter couldn't rely on Dr. Wylie's dose-response assessment because Dr. Wylie's report was properly excluded by the district court. *See Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1294 (11th Cir. 2005) (holding that the specific causation experts' testimony was "irrelevant" once toxicologist's general causation "foundational testimony" had been excluded). And without a dose-response assessment to establish general causation that the contaminants could generally cause kidney cancer, Dr. Danoff and Dr. Schecter had no "reliable groundwork" to support their specific causation opinions that the contaminants specifically caused Mrs. Pinares's kidney cancer. *See Williams*, 889 F.3d at 1248 (quotation omitted).

To demonstrate specific causation, Dr. Danoff and Dr. Schecter "needed to perform or rely upon a methodologically sound dose-response assessment specifically relevant" to Mrs. Pinares. *Id.* at 1245 n.2. Mr. Pinares argues that Dr. Danoff and Dr. Schecter "employed a differential diagnosis," excluding other

possible causes to conclude that chemicals from the Raytheon facility caused her cancer. But a differential diagnosis "will not usually overcome the fundamental failure of laying a scientific groundwork for the general toxicity of the drug and that it can cause the harm the plaintiff suffered." *McClain*, 401 F.3d at 1252. "Setting general causation aside," an expert must still "reliably calculate" whether a plaintiff was "exposed to enough of the toxin to cause the alleged injury" to show specific causation. *Williams*, 889 F.3d at 1245 n.2. The Pinareses admit that Drs. Danoff and Schecter "buil[t] upon" Dr. Wylie's report as to the dose-response relationship, so their derivative reports did not "reliably calculate[e] *how much* exposure would have adversely affected" Ms. Pinares. *Id.* The district court did not abuse its discretion in excluding their testimony.

CONCLUSION

The district court didn't abuse its discretion in excluding the causation experts' testimony. Without that testimony, the Pinareses could not establish that Raytheon caused Mrs. Pinares's cancer. Raytheon was thus entitled to summary judgment.

AFFIRMED.

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

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March 28, 2023

MEMORANDUM TO COUNSEL OR PARTIES

Appeal Number: 19-14831-DD
Case Style: Marcos Pinares v. United Technologies Corp.
District Court Docket No: 9:10-cv-80883-KAM

All counsel must file documents electronically using the Electronic Case Files ("ECF") system, unless exempted for good cause. Although not required, non-incarcerated pro se parties are permitted to use the ECF system by registering for an account at www.pacer.gov. Information and training materials related to electronic filing are available on the Court's website. Enclosed is a copy of the court's decision filed today in this appeal. Judgment has this day been entered pursuant to FRAP 36. The court's mandate will issue at a later date in accordance with FRAP 41(b).

The time for filing a petition for rehearing is governed by 11th Cir. R. 40-3, and the time for filing a petition for rehearing en banc is governed by 11th Cir. R. 35-2. Except as otherwise provided by FRAP 25(a) for inmate filings, a petition for rehearing or for rehearing en banc is timely only if received in the clerk's office within the time specified in the rules. Costs are governed by FRAP 39 and 11th Cir.R. 39-1. The timing, format, and content of a motion for attorney's fees and an objection thereto is governed by 11th Cir. R. 39-2 and 39-3.

Please note that a petition for rehearing en banc must include in the Certificate of Interested Persons a complete list of all persons and entities listed on all certificates previously filed by any party in the appeal. See 11th Cir. R. 26.1-1. In addition, a copy of the opinion sought to be reheard must be included in any petition for rehearing or petition for rehearing en banc. See 11th Cir. R. 35-5(k) and 40-1 .

Counsel appointed under the Criminal Justice Act (CJA) must submit a voucher claiming compensation for time spent on the appeal no later than 60 days after either issuance of mandate or filing with the U.S. Supreme Court of a petition for writ of certiorari (whichever is later) via the eVoucher system. Please contact the CJA Team at (404) 335-6167 or cja_evoucher@ca11.uscourts.gov for questions regarding CJA vouchers or the eVoucher system.

Pursuant to Fed.R.App.P. 39, costs taxed against appellant.

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OPIN-1A Issuance of Opinion With Costs