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U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

In re: INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION,

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JEAN ADAMS, On Behalf of Herself and All Other Similarly Situated Plaintiffs,

Plaintiff-Appellant,

v.

NOVO NORDISK A/S,

Defendant-Appellee.

No. 21-55342

D.C. No. 3:13-md-02452-AJB-MDD

MEMORANDUM*

Appeal from the United States District Court
for the Southern District of California
Anthony J. Battaglia, District Judge, Presiding

Argued and Submitted March 7, 2022
San Francisco, California

Before: S.R. THOMAS and McKEOWN, Circuit Judges, and ORRICK,** District Judge.

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* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

** The Honorable William Horsley Orrick, United States District Judge for the Northern District of California, sitting by designation.

Jean Adams, on behalf of herself and similarly situated plaintiffs, appeals the summary judgment granted by the district court in favor of Novo Nordisk A/S ("Novo") on plaintiffs' claim that Novo's product liraglutide can cause pancreatic cancer, and that Novo failed to adequately warn of this risk.

Because the parties are familiar with the factual and procedural history of this case, we need not recount it here. We review orders granting summary judgment de novo, but we review for abuse of discretion the district court's decision to exclude the testimony of an expert witness. *Wendell v. GlaxoSmithKline*, 858 F.3d 1227, 1231 (9th Cir. 2017). We affirm.

I

The district court did not abuse its discretion in excluding the testimony of Dr. Robert Gale after conducting an extensive hearing pursuant to *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). Considerations relevant to evaluating the reliability of an expert's theory include, but are not limited to, whether the theory can be tested or has been subject to peer review, its known error rate, and whether it is generally accepted in the scientific community. *Id.* at 593–94. On appeal, we afford the district court "the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 142 (1999).

In making its *Daubert* determination, the district court properly relied on the uncontested fact that Dr. Gale did not independently review studies that had been published between 2015 and Dr. Gale's final 2019 report, all of which found no causal relationship between liraglutide use and the development of pancreatic cancer.

The district court did not abuse its discretion in finding that Dr. Gale's reliability was further impeded by his failure to explain his "weight-of-the-evidence" methodology. To demonstrate testability under *Daubert*, an expert must provide sufficient explanation for their methodology such that "[s]omeone else using the same data and methods [would] be able to replicate the result[s]." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1047 (9th Cir. 2014) (first alteration in original) (citation and internal quotation marks omitted). The record supports the district court's conclusion that the expert's reports did not provide a meaningful methodological explanation. In the absence of such an explanation, the district court had no means to ensure that Dr. Gale's "conclusions were not mere subjective beliefs or unsupported speculation." *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994).

Finally, the district court properly considered the fact that Dr. Gale is "alone" in the scientific community in concluding that the relevant compounds

cause pancreatic cancer, "despite years of research into the pancreatic safety of incretin mimetics conducted by various medical, scientific, and regulatory entities." *See Daubert*, 509 U.S. at 594.

Our decision in *Wendell* is not to the contrary. There, we did emphasize that experts may rely on their own "extensive clinical experience," in combination with a review of all relevant existing literature, in carrying out a differential diagnosis and formulating an opinion on specific causation. *See* 858 F.3d at 1234–35, 1237. But the expert reports here did not provide any differential diagnoses or opinions on specific causation, and nothing in *Wendell* absolves expert witnesses of the general and longstanding requirement that they explain their methods with enough detail that their results can be replicated. *See Claar*, 29 F.3d at 502.

For these and the other reasons provided by the district court, we conclude that the district court did not abuse its considerable discretion in excluding Dr. Gale's testimony under *Daubert*.

II

Plaintiffs asserting a failure-to-warn claim in the pharmaceuticals context must prove general causation—that is, that "the substance at issue had the capacity to cause the harm alleged." *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002). Proving this element generally requires expert witness

testimony. *See Lust by and through Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). Dr. Gale's expert testimony was the only evidence in the record that directly supported the plaintiffs' theory of general causation. Thus, with the exclusion of the expert testimony on causation, the district court properly entered summary judgment.

Given our resolution of this case, we need not—and do not—opine on any other theory or argument urged by the parties, or the alternate basis for summary judgment given by the district court.

AFFIRMED.