

FILED

MAR 28 2022

MOLLY C. DWYER, CLERK
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NOT FOR PUBLICATION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,

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.

* 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.

United States Court of Appeals for the Ninth Circuit

Office of the Clerk
95 Seventh Street
San Francisco, CA 94103

Information Regarding Judgment and Post-Judgment Proceedings

Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate ECF system or, if you are a pro se litigant or an attorney with an exemption from using appellate ECF, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1)

Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) A. Purpose (Panel Rehearing):

- A party should seek panel rehearing only if one or more of the following grounds exist:
 - ▶ A material point of fact or law was overlooked in the decision;
 - ▶ A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
 - ▶ An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Purpose (Rehearing En Banc)

- A party should seek en banc rehearing only if one or more of the following grounds exist:

- ▶ Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
- ▶ The proceeding involves a question of exceptional importance; or
- ▶ The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing may be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- See Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- A response, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or response must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms*.
- You may file a petition electronically via the appellate ECF system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at www.ca9.uscourts.gov under *Forms*.

Attorneys Fees

- Ninth Circuit Rule 39-1 describes the content and due dates for attorneys fees applications.
- All relevant forms are available on our website at www.ca9.uscourts.gov under *Forms* or by telephoning (415) 355-7806.

Petition for a Writ of Certiorari

- Please refer to the Rules of the United States Supreme Court at www.supremecourt.gov

Counsel Listing in Published Opinions

- Please check counsel listing on the attached decision.
- If there are any errors in a published opinion, please send an email or letter **in writing within 10 days** to:
 - ▶ Thomson Reuters; 610 Opperman Drive; PO Box 64526; Eagan, MN 55123 (Attn: Maria Evangelista (maria.b.evangelista@tr.com));
 - ▶ and electronically file a copy of the letter via the appellate ECF system by using “File Correspondence to Court,” or if you are an attorney exempted from using the appellate ECF system, mail the Court one copy of the letter.

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT
Form 10. Bill of Costs**

Instructions for this form: <http://www.ca9.uscourts.gov/forms/form10instructions.pdf>

9th Cir. Case Number(s)

Case Name

The Clerk is requested to award costs to *(party name(s))*:

I swear under penalty of perjury that the copies for which costs are requested were actually and necessarily produced, and that the requested costs were actually expended.

Signature

Date

(use "s/[typed name]" to sign electronically-filed documents)

COST TAXABLE	REQUESTED (each column must be completed)			
	No. of Copies	Pages per Copy	Cost per Page	TOTAL COST
Excerpts of Record*	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>	\$ <input type="text"/>
Principal Brief(s) (Opening Brief; Answering Brief; 1st, 2nd, and/or 3rd Brief on Cross-Appeal; Intervenor Brief)	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>	\$ <input type="text"/>
Reply Brief / Cross-Appeal Reply Brief	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>	\$ <input type="text"/>
Supplemental Brief(s)	<input type="text"/>	<input type="text"/>	\$ <input type="text"/>	\$ <input type="text"/>
Petition for Review Docket Fee / Petition for Writ of Mandamus Docket Fee / Appeal from Bankruptcy Appellate Panel Docket Fee				\$ <input type="text"/>
TOTAL:				\$ <input type="text"/>

***Example:** Calculate 4 copies of 3 volumes of excerpts of record that total 500 pages [Vol. 1 (10 pgs.) + Vol. 2 (250 pgs.) + Vol. 3 (240 pgs.)] as:

No. of Copies: 4; Pages per Copy: 500; Cost per Page: \$.10 (or actual cost IF less than \$.10);

TOTAL: 4 x 500 x \$.10 = \$200.

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov