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File Name: 24a0028p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

In re: ONGLYZA (SAXAGLIPTIN) AND KOMBIGLYZE (SAXAGLIPTIN AND METFORMIN) PRODUCTS LIABILITY LITIGATION - MDL 2809.

LEATHA TAYLOR, individually and as administratrix of the estate of David Taylor, et al.,

Plaintiffs-Appellants,

v.

BRISTOL-MYERS SQUIBB COMPANY; ASTRAZENECA PHARMACEUTICALS LP; IPR PHARMACEUTICALS INC.; MCKESSON CORPORATION; ASTRAZENECA LP,

Defendants-Appellees.

No. 22-6078

Appeal from Multi-District Litigation 2809.
No. 5:18-md-02809—Karen K. Caldwell, District Judge,
United States District Court for the Eastern District of Kentucky at Lexington.

ORIGINATING CASES

18-cv-00053–57	18-cv-00127–32	18-cv-00250	18-cv-00320–21	18-cv-00578–79
18-cv-00062–63	18-cv-00134	18-cv-00252–53	18-cv-00325–26	18-cv-00596
18-cv-00065–67	18-cv-00139	18-cv-00256	18-cv-00328	18-cv-00598
18-cv-00070	18-cv-00145	18-cv-00258	18-cv-00330–31	18-cv-00634
18-cv-00072–74	18-cv-00148	18-cv-00260	18-cv-00333	18-cv-00648
18-cv-00076–78	18-cv-00150–51	18-cv-00266	18-cv-00336–39	19-cv-00023
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19-cv-00138–45	19-cv-00221	19-cv-00401	20-cv-00141	20-cv-00383
19-cv-00147–56	19-cv-00223	19-cv-00403	20-cv-00143	20-cv-00405
19-cv-00161	19-cv-00227	19-cv-00422	20-cv-00153	20-cv-00419
19-cv-00166	19-cv-00230–32	19-cv-00439	20-cv-00206–08	20-cv-00438
19-cv-00169	19-cv-00252	19-cv-00461–63	20-cv-00236	
19-cv-00173	19-cv-00287	19-cv-00499	20-cv-00247	
19-cv-00190	19-cv-00350	20-cv-00007	20-cv-00281	
19-cv-00194	19-cv-00393	20-cv-00072–73	20-cv-00330	

Argued: December 7, 2023

Decided and Filed: February 13, 2024

Before: SILER, NALBANDIAN, and DAVIS, Circuit Judges.

COUNSEL

ARGUED: Ashton Rose Smith, MOORE LAW GROUP, PLLC, Louisville, Kentucky, for Appellants. Paul W. Schmidt, COVINGTON & BURLING LLP, New York, New York, for Appellees. **ON BRIEF:** Ashton Rose Smith, Jennifer A. Moore, MOORE LAW GROUP, PLLC, Louisville, Kentucky, for Appellants. Paul W. Schmidt, COVINGTON & BURLING LLP, New York, New York, Carol Dan Browning, STITES & HARBISON PLLC, Louisville, Kentucky, Emily S. Ullman, COVINGTON & BURLING LLP, Washington, D.C., for Appellees.

OPINION

NALBANDIAN, Circuit Judge. In this multi-district litigation, plaintiffs claim that saxagliptin, a diabetes drug, caused their heart failure. During expert discovery, plaintiffs presented a single expert to show the drug can cause heart failure. After a *Daubert* hearing and expert motions, the district court excluded the expert, finding that methodological flaws rendered his testimony unreliable under Federal Rule of Evidence 702. The district court then granted summary judgment for defendants, rejecting plaintiffs' claim that other evidence created a

genuine issue of material fact as well as their request for ninety days to find a replacement expert.

On appeal, plaintiffs challenge the district court's exclusion of their expert, its grant of summary judgment, and its refusal to give plaintiffs more time to find another expert witness. Because we conclude all three claims lack merit, we AFFIRM.

I.

Defendants (Bristol-Myers Squibb, AstraZeneca, and McKesson) manufacture and sell FDA-approved type 2 diabetes drugs containing saxagliptin, a dipeptidyl-peptidase-4 (DPP-4) inhibitor.

In 2008, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee recommended more clinical studies evaluating the link between diabetes drugs and cardiovascular risk.

SAVOR ("Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus"), a randomized-controlled trial (RCT), was commissioned in response. SAVOR "randomly assigned 16,492 patients with type 2 diabetes who had a history of, or were at risk for, cardiovascular events to receive saxagliptin or placebo and followed them for a median of 2.1 years." Benjamin M. Scirica et al., *Saxagliptin and Cardiovascular Outcomes in Patients with Type 2 Diabetes Mellitus*, 369 New Eng. J. Med. 1317, 1317 (2013). SAVOR examined cardiovascular risk on a primary endpoint ("a composite of cardiovascular death, myocardial infarction, or ischemic stroke"), as well as a secondary endpoint ("a composite of cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, coronary revascularization, or heart failure"). *Id.* SAVOR found no statistically significant difference between the groups for the primary endpoint or for five components of the secondary endpoint. *Id.* at 1322.

But the study did find a statistically significant difference between saxagliptin and a placebo on hospitalizations for heart failure (HHF). *Id.* at 1317, 1321–22. The study observed a statistically significant 27% increase in hospitalization for heart failure rates in patients

administered saxagliptin compared to patients receiving a placebo (3.5% vs. 2.8%). *Id.* at 1317. But the study cautioned that the observed association "was unexpected and should be considered within the context of multiple testing that may have resulted in a false positive." *Id.* at 1324. The study also noted that the HHF "finding merits further investigation and needs to be confirmed in other ongoing studies, and a class effect should not be presumed." *Id.*

Saxagliptin's drug label was updated in response. The warning, directed at prescribing physicians, states:

> In a cardiovascular outcomes trial enrolling participants with established ASCVD [atherosclerotic cardiovascular disease] or multiple risk factors for ASCVD (SAVOR trial), more patients randomized to [saxagliptin] (289/8280, 3.5%) were hospitalized for heart failure compared to patients randomized to placebo (228/8212, 2.8%). In a time-to-first-event analysis the risk of hospitalization for heart failure was higher in the [saxagliptin] group (estimated Hazard Ratio: 1.27, 95% CI: 1.07, 1.51).

R.749-2, Prescribing Information at 3, PageID 17379.

II.

SAVOR's HHF finding sparked this multi-district litigation. Plaintiffs sued defendants in federal courts across the country, asserting claims for strict product liability, negligence, failure to warn, breach of warranty of merchantability, and breach of express and implied warranties, all stemming from heart failure allegedly caused by saxagliptin. In February 2018, the Judicial Panel on Multidistrict Litigation consolidated 41 actions pending in 23 districts (as well as 43 potential tag-along actions in 26 districts), transferring them to the Eastern District of Kentucky as MDL 2809.[1]

The district court ordered phased discovery, with the first phase dedicated to the issue of general causation: whether saxagliptin "is capable of causing any person to develop heart failure or other conditions alleged by the plaintiffs such as congestive heart failure, myocardial

[1] Another 13 actions filed in California state court were managed by a California Judicial Council coordination proceeding (JCCP), which followed the MDL's discovery plan and schedule. *See Onglyza Prod. Cases*, 307 Cal. Rptr. 3d 480, 484 (Ct. App. 2023).

infarction and/or cardiovascular injury." R.179, Case Management Order No. 1 at 1, PageID 1049.

Plaintiffs presented a single general causation expert: Dr. Parag Goyal. Dr. Goyal, a cardiology professor at Weill Cornell Medicine was to testify that "it is more likely than not that saxagliptin is capable of causing heart failure." R.633-10, Goyal Report at 14, PageID 12297.

Defendants moved to exclude Dr. Goyal, arguing that he: (1) unreliably based his causation finding on SAVOR alone while ignoring all subsequent human data, (2) unreliably used animal data, and (3) unreliably applied the Bradford Hill criteria.[2]

The district court conducted a *Daubert* hearing on Dr. Goyal's testimony on August 10, 2021, before granting defendants' motion to exclude Dr. Goyal's testimony on January 5, 2022.[3]

After Dr. Goyal's exclusion, defendants moved for summary judgment, arguing that Dr. Goyal's exclusion meant that plaintiffs now lacked admissible evidence raising a triable issue of material fact on general causation. Plaintiffs opposed this motion, contending other evidence in the record was sufficient to create a disputed material fact as to general causation. Meanwhile, plaintiffs moved to modify the scheduling order to allow them another ninety days to identify a replacement general causation expert for Dr. Goyal.

On August 2, 2022, the district court denied plaintiffs' motion for more time to identify a substitute general causation expert, concluding they could not show "good cause" to modify a scheduling order as required by Federal Rule of Civil Procedure 16(b)(4).

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[2]Bradford Hill is a scientific framework used to analyze whether an association between two variables is causal, named after epidemiologist Sir Austin Bradford Hill. *See* Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc'y Med. 295 (1965). Bradford Hill identifies nine relevant factors: (1) strength of association, (2) consistency of association, (3) specificity, (4) temporal relationship, (5) biological gradient, (6) biological plausibility, (7) coherence, (8) experiment, and (9) analogy. *Id.* at 295–99. Dr. Goyal arrived at his opinion that saxagliptin could cause heart failure after applying the Bradford Hill criteria.

[3]This was a joint hearing with the California JCCP court. *See Onglyza Prod. Cases*, 307 Cal. Rptr. 3d at 485. The California court likewise excluded Dr. Goyal's expert testimony under its own *Sargon* standard for expert testimony. *See id.* (citing *Sargon Enters., Inc. v. Univ. of S. Cal.*, 288 P.3d 1237 (Cal. 2012)). Dr. Goyal's exclusion was affirmed on appeal. *Id.* at 487–92.

In the same order, the district court granted defendants' motion for summary judgment, concluding that plaintiffs failed to produce admissible expert testimony that saxagliptin can cause heart failure.

Plaintiffs timely appealed, arguing the district court erred thrice: (1) by excluding Dr. Goyal, (2) by granting summary judgment, and (3) by refusing to grant plaintiffs more time to find a substitute general causation expert.

III.

We review the district court's decision to exclude Dr. Goyal's expert testimony for abuse of discretion. *See United States v. LaVictor*, 848 F.3d 428, 440 (6th Cir. 2017). Federal Rule of Evidence 702 entrusts district courts with a "gatekeeping role" to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). Before admitting expert testimony, the district court needed to ensure that Dr. Goyal's testimony was (a) helpful to the trier of fact, (b) "based on sufficient facts or data," and (c) "the product of reliable principles and methods" that (d) have been "reliably applied" to the "facts of the case." Fed. R. Evid. 702 (2011) (amended 2023).[4]

The party proffering the expert (here plaintiffs) bears the burden of showing by a preponderance of the evidence that the expert satisfies Rule 702. *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 478 (6th Cir. 2008). "The task for the district court in deciding whether an expert's opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529–30 (6th Cir. 2008).

[4]On December 1, 2023, two changes to Rule 702 went into effect. First, language was added to clarify that the proponent bears the burden of showing the expert testimony more likely than not complies with the rule. Second, 702(d) was rephrased to emphasize that an expert opinion must "reflect[] a reliable application" of the expert's methodology. We employ the old rule because it was still in force at the time of the district court's decision (January 5, 2022). *See In re Cooper Tire & Rubber Co.*, 568 F.3d 1180, 1186 n.4 (10th Cir. 2009). But the district court's reasoning aligns with the updated Rule 702, since it placed the burden of showing that Dr. Goyal was admissible on plaintiffs. And our decision here would be the same under either version of the Rule.

A.

First, Dr. Goyal's reliance on SAVOR, to the exclusion of all other studies involving human data, was unreliable.

As Dr. Goyal conceded, no clinical study beyond SAVOR has found a statistically significant association between saxagliptin and heart failure. Instead, four post-SAVOR observational studies, collectively following 175,000 saxagliptin users, found no association. Dr. Goyal conceded that these observational studies were "reasonably designed" and that "the number of patients" was "a strength." R.710, Tr. of Dr. Goyal's *Daubert* Hearing at 90–91, PageID 16078–79. Even so, Dr. Goyal's report failed to engage with these studies, dismissing them as "generally limited due to issues related to confounding." R.633-10, Goyal Report at 9, PageID 12292. But Dr. Goyal identified no specific issues or confounders in the observational studies. Dr. Goyal's failure "to adequately account for contrary evidence is not reliable or scientifically sound." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 174 F. Supp. 3d 911, 932 (D.S.C. 2016).

Yet, despite admitting that basing causation on a single study is improper, Dr. Goyal still found causation based only on SAVOR. Indeed, Dr. Goyal stated that SAVOR's findings "should be interpreted as cause-and-effect unless there is compelling evidence to prove otherwise." R.633-10, Goyal Report at 8, PageID 12291. But Dr. Goyal's conclusion that SAVOR shows causation in the absence of "compelling evidence" showing otherwise reverses the burden of proof. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (Exclusion is proper for "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."). And SAVOR is no smoking gun: the study only observed "higher incidence of hospitalization among patients treated with saxagliptin," not a causal link between the two. Scirica, *supra,* 369 New Eng. J. Med. at 1324. SAVOR's authors cautioned that there "are presently no known mechanisms" by which saxagliptin "could precipitate heart failure," Benjamin M. Scirica et al., *Heart Failure, Saxagliptin, and Diabetes Mellitus: Observations from the SAVOR-TIMI 53 Randomized Trial,* 130 Circulation: Am. Heart Ass'n J. 1579, 1585 (2014), and that the observed association "may have resulted in a false positive," Scirica et al., *supra,* 369 New Eng. J. Med. at 1324.

So Dr. Goyal drew "unauthorized conclusions from limited data—conclusions the authors of the study d[id] not make," betraying a "lack of scientific rigor." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1248 (11th Cir. 2005). By ignoring all other human studies, besides SAVOR, without an adequate explanation, Dr. Goyal failed to base his opinion on "sufficient facts or data." Fed. R. Evid. 702(b).

Plaintiffs raise two main arguments on appeal. Neither is persuasive. First, plaintiffs claim that the district court "erroneously concluded that a study—including an RCT—must be replicated to be reliable." Appellant Br. at 21.[5] Not so. The district court did not exclude Dr. Goyal based on a per se rule against studies that still haven't been replicated. Indeed, the district court clarified that Dr. Goyal's views on replication came into play because "there are multiple studies on the issue of whether saxagliptin can cause heart failure." R.740, Experts Order at 31 n.3, PageID 17089. And the court concluded that Dr. Goyal acted unreliably by agreeing on the importance of replication but, without explanation, ignoring all human studies beyond SAVOR.

Second, plaintiffs claim that the district court "improperly concluded that Dr. Goyal could not make a causation finding based on an epidemiological study . . . that does not itself make a causal determination." Appellant Br. at 21 (citing *In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 9 F.4th 768, 779 (8th Cir. 2021)).[6] Again, not so. The district court did not fault Dr. Goyal for considering an epidemiological study. It faulted him for basing his opinion on SAVOR's finding without adequately explaining how he inferred a causal relationship from SAVOR, an epidemiological study that did not come to a conclusion about causation.

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[5]Along these lines, plaintiffs dedicate pages of their briefing defending RCTs like SAVOR as "the gold standard" for assessing causation, rather than "junk science" subject to exclusion. Appellant Br. at 24–28; Reply Br. at 7–10. But the district court never questioned the reliability of SAVOR itself. Instead, the court focused on *how* Dr. Goyal used SAVOR in forming his general causation opinion. So do we, rendering plaintiffs' defense of RCTs like SAVOR beside the point.

[6]The Eighth Circuit in *Bair Hugger* found that it is not "*per se* unreliable for an expert to draw an inference of causation from an epidemiological study that disclaimed proving causation." 9 F.4th at 779. But the court cautioned that epidemiology studies only allow "experts to find associations, which by themselves do not entail causation"—experts must still do "the work to bridge the gap between association and causation." *Id.* (internal quotation marks omitted). Unlike Dr. Goyal, the experts there did not rest their opinion on only an epidemiological study, but also identified plausible causal mechanisms to explain the observed association and created models to test their theories. *Id.* at 785–86, 788.

According to the district court, Dr. Goyal's sin was methodological inconsistency, not reliance on an un-replicated epidemiological study.

The district court did not abuse its discretion in concluding that Dr. Goyal's reliance on SAVOR to prove causation, disregarding all other human studies, was unreliable.

B.

Second, Dr. Goyal's use of animal data was unreliable because he has no expertise in interpreting animal studies.

Dr. Goyal conceded multiple times he is unqualified to analyze animal studies. He specifically conceded he was unqualified to conclude either that the animals in the studies he cited "actually had heart failure" or whether "saxagliptin is capable of causing heart failure in animals." R.710, Hearing Tr. at 148, PageID 16136. Further, Dr. Goyal admitted to ignoring multiple peer-reviewed animal studies dispelling a causal link between saxagliptin and heart failure. And, since none of the studies diagnosed animals with heart failure, Dr. Goyal simply claimed that particular animals showed *symptoms* of heart failure, such as anemia or congestion. Since Dr. Goyal was admittedly unqualified to make these diagnoses, the district court did not err in finding Dr. Goyal's use of animal studies unreliable.

C.

Third, Dr. Goyal did not reliably apply Bradford Hill.

Courts must ensure both that expert opinions are "the product of reliable principles and methods," and that these methods have been "reliably applied" to the "facts of the case." Fed. R. Evid. 702 (2011) (amended 2023). Bradford Hill is undeniably a reliable methodology. *See, e.g.*, *Milward v. Acuity Specialty Prods. Grp, Inc.*, 639 F.3d 11, 17–18 (1st Cir. 2011). Indeed, as plaintiffs point out, defendants' experts used the same methodology. But the district court had an independent duty to ensure that all experts "reliably applied" Bradford Hill. Fed. R. Evid. 702(d) (2011) (amended 2023); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (Courts must "make certain that an expert . . . employs in the courtroom the same level of

intellectual rigor that characterizes the practice of an expert in the relevant field."). And the court had multiple grounds to find that Dr. Goyal had not reliably applied Bradford Hill.

On the one hand, Dr. Goyal cherry-picked data to bolster his case. When considering the analogy factor, Dr. Goyal looked at thiazolidinedione (TZD) drugs (a different kind of second-line diabetes medication), rather than DPP-4 inhibitors (the class of drugs to which saxagliptin belongs). Dr. Goyal explained this unconventional choice simply by claiming that TZDs "provide[] an appropriate analogy" because they have been shown to "worsen heart failure." R.633-10, Goyal Report at 14, PageID 12297. This cherry-picking "undermines principles of the scientific method and is a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 634 (4th Cir. 2018).

On the other hand, Dr. Goyal inconsistently applied several Bradford Hill factors. For instance, Dr. Goyal's report claimed that two of the factors (specificity and biological gradient) were satisfied, but he later testified that they were not. These changes in Dr. Goyal's Bradford Hill analysis—neither explained nor justified—cast doubt on the reliability of his testimony.

Plaintiffs don't defend Dr. Goyal's application of Bradford Hill per se. Instead, they contend that exclusion was improper because a "jury, not the trial judge, must evaluate and weigh conflicting expert testimony." Appellant Br. at 33 (internal quotation marks omitted). To be sure, "competing expert opinions present the classic battle of the experts and it is up to a jury to evaluate what weight and credibility each expert opinion deserves." *Phillips v. Cohen*, 400 F.3d 388, 399 (6th Cir. 2005) (internal quotation marks omitted). And "cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. But district courts may allow juries to evaluate and weigh *only* relevant and reliable expert testimony. *See Sardis v. Overhead Door Corp.*, 10 F.4th 268, 284 (4th Cir. 2021) (citing

Daubert, 509 U.S. at 589). Since Dr. Goyal's opinion is unreliable, the district court properly exercised its "gatekeeping role." *Daubert*, 509 U.S. at 597.[7]

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In sum, the district court had three good reasons to find Dr. Goyal's testimony unreliable: (1) improper reliance on SAVOR to the exclusion of all other human studies, (2) unqualified analysis of animal studies, and (3) cherry-picking and inconsistent consideration of the Bradford Hill factors. So we conclude that excluding Dr. Goyal was not an abuse of its discretion.

IV.

Plaintiffs claim that, even if Dr. Goyal were properly excluded, summary judgment was improper because "there is extensive other evidence from which a jury could properly determine that saxagliptin can cause heart failure." Appellant Br. at 19.

We review a district court's grant of summary judgment de novo. *Baggs v. Eagle-Pitcher Indus., Inc.*, 957 F.2d 268, 271 (6th Cir. 1992). Summary judgment is appropriate only where "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.

As a preliminary point, plaintiffs claim that the district court erred by finding they cannot establish general causation *without* expert testimony. Instead, plaintiffs argue that "[j]uries are permitted to decide issues of causation without guidance from experts." Appellant Br. at 40.

The district court concluded that, as an MDL, the issue was governed by "the substantive state law of the transferor state." R.769, Summary Judgment Order at 14, PageID 18470; *see, e.g.*, *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 194 F.R.D. 484, 490 (D.N.J. 2000).[8] So the court reviewed the law of all fifty states, concluding that all states require "the

[7]Indeed, Rule 702's recent amendments, *see supra* n.5, were drafted to correct some court decisions incorrectly holding "that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility." Fed. R. Evid. 702 advisory committee's note to 2023 amendments.

[8]Since both parties agreed, we see no need to revisit this choice-of-law issue. *See AtriCure, Inc. v. Meng*, 12 F.4th 516, 525 (6th Cir. 2021).

plaintiff in cases involving complex issues of medical causation to present expert testimony on the subject." R.769, Summary Judgment Order at 14, PageID 18470 (citing R.746-2, Jurisdiction Survey of the Laws on Causation in Product Liability Actions).

The district court does not stand alone: other district courts have agreed that all jurisdictions require expert testimony to show general causation, "at least where the issues are medically complex and outside common knowledge and lay experience." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig.*, 227 F. Supp. 3d 452, 469–78 (D.S.C. 2017) (collecting cases); *see also In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 387 F. Supp. 3d 323, 341 (S.D.N.Y. 2019) ("It is well established that 'expert testimony is required to establish causation' where the issue of causation is 'beyond the knowledge of lay jurors.'") (quoting *Wills v. Amerada Hess Corp.*, 379 F.3d 32, 46 (2d Cir. 2004)). Indeed, we often apply such a requirement in our diversity cases. *See, e.g.*, *Nocilla v. Bridges*, No. 23-3184, 2023 WL 7550019, at *4 (6th Cir. Nov. 14, 2023) (applying Ohio's requirement "that a plaintiff must present scientific or medical evidence if an untrained layperson would not have the expertise necessary to decide whether a defendant's actions could cause a plaintiff's injury").

While plaintiffs contest this requirement, they identify no state without a requirement of expert testimony to establish general causation in complex medical cases. Instead, plaintiffs resort to selectively quoting cases. Most important is a decision of this circuit, which plaintiffs claim affirmed a district court's finding that causation could be shown "based simply on the warning language in product inserts." Appellant Br. at 40–41 (citing *Meridia Prods. Liab. Litig. v. Abbott Lab'ys*, 447 F.3d 861, 866 (6th Cir. 2006)). But plaintiffs incorrectly characterize the district court opinion: it merely "assume[d] *arguendo* that no states' laws erect" a requirement of expert testimony to establish general causation, because "[r]egardless, the Court ends up in the same place: summary judgment for Defendants." *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 802 (N.D. Ohio 2004). Plaintiffs' string citation to four state-court cases is similarly inapposite and misleading.

So we conclude that the district court did not err in finding that all jurisdictions require expert testimony to show general causation in complex medical cases such as this MDL. Dr. Goyal's exclusion warranted the district court's grant of summary judgment to defendants.

V.

For their third and final issue on appeal, plaintiffs argue that the district court abused its discretion when it refused to grant them leave to identify a new general causation expert.

District courts may modify scheduling orders "only for good cause." Fed. R. Civ. P. 16(b)(4). We review district courts' decisions whether to modify scheduling orders for abuse of discretion. *Leary v. Daeschner*, 349 F.3d 888, 909 (6th Cir. 2003). And we give district courts "wide discretion to manage their own dockets and to decide issues which have consumed considerable resources." *Reed v. Rhodes*, 179 F.3d 453, 471 (6th Cir. 1999).

We have specified that district courts should measure "good cause" mainly by reference to two factors. "[T]he moving party's diligence in attempting to meet the case management order's requirements" is the "primary measure," but "possible prejudice to the party opposing the modification" is also relevant. *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 625 (6th Cir. 2002). Both factors cut against plaintiffs.

First, plaintiffs' diligence in attempting to meet the scheduling order. Plaintiffs are right that they "were diligent and timely in identifying Dr. Goyal." Appellant Br. at 57. But that misses the point. As the district court noted, "plaintiffs do not really request an *extension* of deadlines," since expert discovery and motions were already done when they filed their motion. R.769, Summary Judgment Order at 10, PageID 18466. Instead, plaintiffs are asking to reopen expert discovery. And plaintiffs cannot explain why they have failed to identify other, reliable, general causation experts—despite years of expert discovery. *See* R.769, Summary Judgment Order at 11–12, PageID 18467–68; Appellant Br. at 55–59. So plaintiffs were not diligent in identifying a *reliable* general causation expert.

Second, prejudice to defendants. Plaintiffs claim that granting their motion would cause defendants "no prejudice" because of the "minimal amount of delay." Appellant Br. at 58. But

granting plaintiffs' request would essentially restart expert discovery, requiring depositions, briefing, hearings, and motions on plaintiffs' new expert. This would delay the MDL's resolution for years—just consider that plaintiffs requested three months to simply identify an expert. So granting the motion would likely impose significant costs on defendants in the form of substantial legal expenses and years of delay. *See Com. Benefits Grp., Inc. v. McKesson Corp.*, 326 F. App'x 369, 377–78 (6th Cir. 2009) ("[A]ny further delay in discovery would have resulted in additional time and expense incurred by both the parties and the court and would have unfairly prejudiced defendants.").

We conclude the district court did not abuse its discretion by denying plaintiffs' request for more time to identify a general causation expert to replace Dr. Goyal. The court properly refused to reward plaintiffs for their failure to identify a reliable general causation expert by imposing significant costs on defendants. To find otherwise would set a precedent that parties may drag out litigation by identifying "only one expert witness on a crucial issue who is later excluded." R.769, Summary Judgment Order at 11, PageID 18467.

VI.

For these reasons, we AFFIRM.