**No. 16–2247**

**IN THE**
# UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation

JENNIFER ADAMS, *et al.*,
*Plaintiffs-Appellants,*

v.

WOLTERS KLUWER HEALTH INC., *et al.*,
*Defendants-Appellees*

Appeal from United States District Court
for the Eastern District of Pennsylvania
Case No. 12-md-2342

## BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES, URGING AFFIRMANCE

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## RULE 26.1 CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent company, and no publicly held company holds ten percent or greater ownership in the organization.

## TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**Page(s)**

## Cases

**Other Authorities**

## INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States of America is the world's largest business federation. Boasting over 300,000 members, the Chamber represents the interests of more than three million companies and professional organizations of every size, in every sector, and from every region of the country. To that end, the Chamber regularly files *amicus curiae* briefs in cases of concern to the Nation's business community. Those cases often involve questions about the admissibility of scientific or other expert evidence.

With great frequency, the Chamber's members must defend themselves against lawsuits in which an expert witness proposes a novel theory that has no scientifically valid methodology underpinning it. The Chamber's members thus have a strong interest in ensuring that district courts properly apply the Federal Rules of Evidence to "fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points toward the right substances and does not destroy the wrong ones." *General Elec. Co. v. Joiner*, 522 U.S. 136, 148-49 (1997) (Breyer, J., concurring).

The District Court here fulfilled its gatekeeping duty. It reviewed lengthy briefing and numerous scientific studies, received evidence in a *Daubert* hearing that lasted several days, and exercised its broad discretion to hold that the proposed expert testimony failed not only Rule 702's exacting standards but also Rule 403's requirements because the proposed testimony would mislead and confuse the jury. This Court should affirm those holdings under the

deferential abuse-of-discretion standard. Clear evidentiary rules and clear appellate-review standards promote the certainty and predictability on which the business community depends to navigate the landscape of high-stakes tort litigation.[1]

[1] In accordance with Federal Rule of Appellate Procedure Rule 29(c)(5), the Chamber certifies that no party or party's counsel authored this brief in whole or in part and that no person except the Chamber and its counsel funded the brief. All parties have consented to this filing.

## INTRODUCTION

This appeal does not require the Court to break new legal ground, to engage in its own fact-finding about whether Zoloft causes the alleged injuries, or to otherwise dive back into the science that the District Court reviewed. Rather, as the U.S. Supreme Court clarified in its landmark *Joiner* decision, the deferential "abuse-of-discretion standard" governs an appeal seeking review of the exclusion of expert testimony. *General Elec. Co. v. Joiner*, 522 U.S. 136, 143, 145 (1997) (affirming district court's finding that certain "epidemiological studies . . . were not a sufficient basis for the [excluded] experts' opinions"). Under that standard, this Court "will not disturb a district court's decision to exclude testimony unless [it is] left with a definite and firm conviction that the court below committed a clear error of judgment." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 293 (3d Cir. 2012) (internal quotation marks omitted).

Judged under that standard, this appeal is straightforward and the Court must affirm the District Court's decision to exclude Dr. Nicholas Jewell's general-causation opinion. *Compare Magistrini v. One Hour Martinizing Dry Cleaning*, 68 F. App'x 356, 357 (3d Cir. 2003) (affirming in two-page opinion the exclusion of similarly flawed causation testimony). The District Court "properly conducted the *Daubert* hearing, applied the correct legal standard, and made no clearly erroneous findings of fact." *Id.* There was no abuse of discretion.

Plaintiffs attempt to evade the abuse-of-discretion standard by recasting the District Court's factual findings as "legal errors"—an argument that the District Court itself explained was factually wrong. The plaintiffs have failed to

show—or even argue for—an abuse of discretion. Their conspicuous silence on *Joiner* speaks volumes about the real implications of this appeal: If the plaintiffs prevail, the courtroom doors will be blown open by a flood of appeals repackaging basic fact-findings about the scientific method as "legal errors." Such an outcome threatens to erode the incentive for district courts to engage in the type of thorough, gatekeeping *Daubert* proceeding that the District Court undertook below.

In repackaging their appeal as *de novo*(ish) review, the plaintiffs fail to grapple with the many fatal flaws in Dr. Jewell's "methodology" that justified excluding his testimony, instead repeating their mantra that Jewell used a "generally accepted" methodology. Lacking record support, that is merely a discarded shibboleth from the long-lost kingdom of *Frye*. Moreover, the plaintiffs forfeited any challenge to the District Court's separate conclusion that Rule 403 barred Jewell's testimony because it could mislead the jury. That unchallenged ruling independently requires affirmance.

The Court should affirm the exclusion of Dr. Jewell's testimony and the grant of summary judgment.

## ARGUMENT

### I. THE COURT SHOULD REJECT EFFORTS, AS HERE, TO RECAST *DAUBERT* TRIAL FACTUAL FINDINGS AS LEGAL ERRORS.

#### A. The plaintiffs fail to show—or even argue for—an abuse of discretion.

The plaintiffs have not carried their burden of showing that the District Court abused its discretion in excluding Dr. Jewell's testimony. In fact, they haven't argued abuse of discretion in any meaningful way. Those words don't appear in the plaintiffs' Statement of Issues. Instead, the plaintiffs claim that "the district court committed legal error" and that their designated expert's opinions "should be admitted"—as if this Court were conducting a *de novo* review. It is not.

The Supreme Court in *Joiner* confirmed that abuse of discretion is the proper standard for judging evidentiary rulings, including the exclusion of expert testimony. 522 U.S. at 143. In *Joiner*, the Eleventh Circuit had erred because "it failed to give the trial court the deference that is the hallmark of abuse-of-discretion review." *Id.* (citation omitted).

Tacking closely to the Supreme Court's teaching, this Court has repeatedly confirmed that "[u]nder the deferential abuse of discretion standard, we will not disturb a district court's decision to exclude testimony unless we are left with a definite and firm conviction that the court below committed a clear error of judgment." *ZF Meritor,* 696 F.3d at 293 (internal quotation marks

omitted). The Court has explained "the rationale for using a deferential standard of review":

> Deferential review is employed not because the court being reviewed labored to produce a long opinion–there are lengthy but incorrect opinions just as there are brief but sagacious ones. Rather, deferential review is used when the matter under review was decided by someone who is thought to have a better vantage point than we on the Court of Appeals to assess the matter.

*United States v. Mitchell*, 365 F.3d 215, 233–34 (3d Cir. 2004) (citations omitted).

Accordingly, when a district court shows great care and thought in excluding expert testimony, this Court will not second-guess it. In *Magistrini v. One Hour Martinizing Dry Cleaning*, for instance, the district court excluded causation testimony from designated experts who, like Dr. Jewell, proposed an alleged "weight of the evidence" methodology and over-interpreted a large collection of epidemiologic data. *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 601 (D.N.J. 2002), *aff'd* 68 F. App'x 356 (3d Cir. 2003). This Court affirmed in a short opinion, explaining that "[t]he District Court has carefully and completely explained its reasons for excluding the testimony of Appellant's causation expert . . . ." *Magistrini*, 68 F. App'x at 357. "Given the District Court's careful analysis," this Court continued, "no purpose will be served by this court undertaking a redundant discussion simply to reach the same result." *Id.* Similar decisions abound. *See, e.g.*, *Wade-Greaux v. Whitehall Labs., Inc.*, 46 F.3d 1120 (3d Cir. 1994) (table); *Rupert v. Ford Motor Co.*, 640 F. App'x 205, 208 (3d Cir. 2016) ("Therefore, we affirm for essentially the same

reasons set forth by the district court in its reasoned consideration of this issue."); *Henry v. St. Croix Alumina, LLC*, 572 F. App'x 114, 118 (3d Cir. 2014) ("In sum, the District Court performed an exhaustive and able analysis of the proposed expert testimony, and determined that it was inadmissible. We agree with the reasoning and conclusions of the District Court, and affirm its evidentiary rulings.").

Here, the District Court's careful review of Dr. Jewell's proffered general-causation testimony is typical of the review that this Court has routinely affirmed. Indeed, the District Court went through the Rule 702 analysis *twice*—once with Dr. Bérard, the plaintiffs' first proposed-but-ultimately-rejected general-causation expert and then again with Dr. Jewell. Both times, the District Court held multi-day *Daubert* hearings to evaluate the experts, their methodologies, and their materials.[2]

Applying Rule 702 by the book, the District Court held that the plaintiffs did not show that Dr. Jewell's testimony was admissible because it suffered from many methodological flaws. Dr. Jewell

- "failed to consistently apply the scientific methods he articulated,"
- "deviated from or downplayed certain well-established principles of his field,"
- "inconsistently applied methods and standards to the data so as to support his a priori opinion," and

[2] Plaintiffs have "elected" not to appeal the District Court's articulate and well-supported exclusion of Dr. Bérard's similar general-causation testimony. (Appellants' Br. at 24).

- "failed to address adequately all of the available epidemiological studies, particularly more recent studies that did not replicate the results in earlier studies, even though these studies included and expanded upon the populations in the earlier studies."

J.A. 32. Those factual findings were grounded in the record; the Plaintiffs do not contend otherwise. They do not argue abuse of discretion at all. Accordingly, this Court must affirm the District Court's ruling.

### B. The District Court committed no "legal errors."

The Plaintiffs have no argument that the District Court abused its discretion, so they try to recast the District Court's factual findings as "legal error[s]." Appellants' Br. at 2. The plaintiffs claim that the District Court based its decision on legal rulings that (1) expert opinions "must be supported by 'repeated, consistent, statistically significant human epidemiological findings'" (*id.* at 30), and (2) that "a positive, but statistically non-significant association cannot be used to infer causation" (*id.* at 36).

The District Court did not announce new legal rules; it made factual findings. The District Court explained as much to the plaintiffs when they made the identical arguments below after the District Court excluded Dr. Bérard's testimony:

> Contrary to the PSC's contention, the Court did not hold that there is a 'legal requirement of repeated or replicated statistically significant epidemiological findings in order to establish general causation,' nor did it rely on any such holding made by another court. Rather, the Court set forth its factual finding that *epidemiologists*, such as Dr. Bérard, who are examining potential teratogens generally will not draw causal conclusions in the absence of replicated statistically significant

> epidemiological findings and application of the Bradford–Hill criteria.

*In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, No. 12-md-2342, 2015 WL 314149, at *2 (E.D. Pa. Jan. 23, 2015).

In any event, even if the District Court had imposed a legal rule demanding a statistically significant, replicated epidemiology, that would not have been error, either. Numerous courts—including the Supreme Court in *Joiner*—have excluded general-causation experts who attempted to base their opinions on epidemiologic data that "was not statistically significant." 522 U.S. at 145. It is somewhat remarkable that plaintiffs seek to admit expert testimony that they brazenly confess is based on data that are neither statistically significant nor replicated. The Court should be wary about the plaintiffs' proposed *de novo*-type legal standard that would invite district courts to abdicate their Rule 702 obligations to screen dubious science from federal courtrooms and federal juries.

### C. The plaintiffs rely on generalities; they don't defend Dr. Jewell's specific "methodology" or its application.

The plaintiffs' arguments evince a fundamental misunderstanding of Rule 702, which, if adopted, would undermine the Supreme Court's decision decades ago to retire the *Frye* standard. As the Supreme Court clarified, it is not enough for *lawyers* to assert that an alleged methodology is "generally accepted." Instead, to survive Rule 702's exacting standard, the proffering party must prove by a preponderance of the evidence that the proposed expert has sufficient facts or data, that the expert has used reliable principles and methods

and that the expert has reliably applied the principles and methods to the facts of the case. FED. R. EVID. 702 (b)-(d). Yet the plaintiffs' brief is full of assertions that belong to the bygone *Frye* era:

- "Dr. Jewell's 'weight of the evidence' methodology has been generally accepted by the scientific community for decades . . ." Appellants' Br. at 4.
- "Where an expert employs a well-accepted methodology, as Dr. Jewell did here, criticisms of the expert should be ventilated through cross-examination and resolved by the jury." *Id.* at 5.
- "Where, as here, an expert applies a well-accepted methodology, challenges to the expert's opinions are appropriately vetted through vigorous cross-examination at trial and resolution by the jury." *Id.* at 29.
- "Dr. Jewell's causation opinion is based on the well-accepted weight-of-the-evidence methodology using the Bradford-Hill criteria." *Id* at 43.
- "Dr. Jewell's methodology therefore unquestionably is accepted as sound by the scientific community." *Id.*

The plaintiffs even claim that when an expert invokes a generally accepted methodology, a district court may exclude the expert's testimony only in "extreme circumstance[s]" (Appellants' Br. at 44), which of course ignores Rule 702's requirement of "*reliable* principles and methods," not generally accepted ones. FED. R. EVID. 702 (emphasis added).[3] Eventually, plaintiffs upend their own applecart, admitting—as they must—that "as a matter of law,

[3] Appellants also ignore the three traditional *Daubert* factors beyond general acceptance: testing, peer review, and error rate. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-94 (1993).

general acceptance . . . is not the legal standard under *Daubert* and Rule 702." Appellants' Br. at 56-57.

It is not enough for the plaintiffs to assert generically that Dr. Jewell used a "generally accepted" methodology such as Bradford Hill or "weight of the evidence."[4] *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999) ("the question before the trial court [is] specific, not general"). In *Kumho Tire*, the Supreme Court explained that "the specific issue before the court was not the reasonableness *in general* of [the expert's methodology]." 526 U.S. at 153. It "was the reasonableness of using such an approach, along with [the expert's] particular method of analyzing the data thereby obtained, to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant*." 526 U.S. at 153-54; *accord Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999) ("such general rules must . . . be applied fact-specifically in each case"). The District Court understood and correctly applied Rule 702 as interpreted by the Supreme Court.

Claiming generally that an expert—whether Dr. Jewell or any other expert—relied on "epidemiology" gets plaintiffs nowhere. *Joiner*, 522 U.S. at 144 ("Of course, whether animal studies can ever be a proper foundation for an expert's opinion was not the issue. The issue was whether *these* experts' opinions were sufficiently supported by the animal studies on which they purported to rely.").

[4] Dr. Jewell did not claim below that he used "weight of the evidence." That is a creation of appellate counsel.

Those kinds of generalities do not satisfy Rule 702; a district court gatekeeper must inquire more deeply. "The reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion . . . ." *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 355 (5th Cir. 2007) (internal quotation marks omitted). Under that standard, "*any* step that renders the analysis unreliable renders the expert's testimony inadmissible. *This is true whether the step completely changes a reliable methodology or merely misapplies that methodology*." FED. R. EVID. 702, advisory committee's note (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)).[5]

This Court should not open the gate to experts who, like Dr. Jewell, fail to use methodologies generally accepted in the expert's field, fail to apply the methods that the experts claim to use, and fail to present sufficient scientific data. Fact-based rulings cannot be overcome by rote invocation, on appeal, of generic labels like "weight of the evidence" and "Bradford-Hill."

## II. THE COURT SHOULD ENFORCE ITS RULES REQUIRING AFFIRMANCE ON ALL SUFFICIENT GROUNDS NOT EXPLICITLY RAISED AND ARGUED ON APPEAL.

In excluding Dr. Jewell's testimony, the District Court did not abuse its discretion and this Court should not invite future plaintiffs to recharacterize district courts' factual findings as "legal errors." The Court also should not

[5] The Plaintiffs fail to cite this Court's seminal *Paoli II* decision and instead cite only the pre-*Daubert Paoli I*.

invite future plaintiffs to ignore on appeal district court evidentiary rulings—beyond Rule 702—that independently support the exclusion of expert testimony. *See Kost v. Kozakiewicz*, 1 F.3d 176, 182 (3d Cir. 1993) (declining to address issues not addressed in opening brief); *accord Simmons v. City of Philadelphia*, 947 F.2d 1042, 1065 (3d Cir. 1991). Here, plaintiffs do not even challenge the District Court's separate holding that Dr. Jewell's testimony is inadmissible under Rule 403. That separate ruling independently requires affirmance.

Rule 403 is a separate basis for excluding expert testimony: "Even if the evidence offered by the expert witness satisfies Rule 702, it may still be excluded if its 'probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury.'" *Saldana v. Kmart Corp.*, 260 F.3d 228, 232–33 (3d Cir. 2001) (quoting Fed. R. Evid. 403). In *Daubert* itself, the Supreme Court explained that district courts should also vet proposed expert testimony under Rule 403: "Finally, Rule 403 permits the exclusion of relevant evidence . . ." 509 U.S. at 595. Rule 403 is an integral part of the *Daubert* analysis because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses." *Id.* (internal quotation marks omitted).

The District Court excluded Dr. Jewell's testimony under both Rule 702 and Rule 403. J.A. 82 ("the Court will exclude his testimony at trial under

Federal Rules of Evidence 403 and 702, and the principles outlined in *Daubert*"). According to the District Court, Dr. Jewell's testimony not only failed Rule 702 but also was "likely to confuse or mislead the jury." *Id.* One reason for the potential confusion: Dr. Jewell improperly relied on Pfizer company documents, which "would potentially be misleading to a jury." J.A. 32; *see also id.* at 24. Rule 403 gave the District Court a sufficient independent basis to exclude Dr. Jewel's testimony.

The Plaintiffs did not challenge the District Court's 403 ruling in their opening appellate brief, so they have forfeited their right to attack that holding. "[A]ppellants are required to set forth the issues raised on appeal and to present an argument in support of those issues in their opening brief." *Kost*, 1 F.3d at 182. Even "a passing reference to an issue in a brief will not suffice to bring that issue before this court on appeal." *Simmons*, 947 F.2d at 1066 (citing *Lunderstadt v. Colafella*, 885 F.2d 66 (3d Cir.1989)). "There is good reason for this [rule]. Brief, casual references to arguments do not put the opposing party on adequate notice of the issue, nor do they develop it sufficiently to aid our review." *NLRB v. FedEx Freight, Inc.*, No. 15-cv-2585, —— F.3d ——, ——, 2016 WL 4191498, at *11 (3d Cir. Aug. 9, 2016) (Jordan, J., concurring); *accord Rodriguez v. Municipality of San Juan*, 659 F.3d 168, 175 (1st Cir. 2011) ("Judges are not mind-readers, so parties must spell out their issues clearly, highlighting the relevant facts and analyzing on-point authority.").

The Plaintiffs don't give Rule 403 even a passing reference. They spill much ink on epidemiological data and statistical significance but do not

mention "403" or even talk obliquely about that separate holding. The 403 ruling—unchallenged on appeal—provides a sufficient basis to affirm summary judgment.

## CONCLUSION

There was no abuse of discretion. And the Plaintiffs have forfeited any Rule 403 argument. This Court should affirm the District Court's exclusion of Dr. Jewell's testimony and the grant of summary judgment.

Dated: October 18, 2016

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## COMBINED CERTIFICATIONS

1. **Bar Membership**—I certify that Brian D. Boone and David Venderbush, counsel for *Amicus Curiae* The Chamber of Commerce of the United States of America, are members in good standing of the United States Court of Appeals for the Third Circuit's bar.

2. **Word Count/Typeface Requirements**—I certify that this brief complies with Federal Rule of Appellate Procedure 32(a)(7)(B)'s type-volume limitation because it contains 3,373 words, excluding the parts exempted by Rule 32(a)(7)(B)(iii). This brief also complies with Rule 32(a)(5)'s typeface requirements and Rule 32(a)(6)'s type-style requirements because we have prepared the brief in proportionately spaced typeface using Microsoft Word in 14-point Garamond font.

3. **Identical Compliance of Briefs**—I certify that the text of the electronically filed version of this brief is identical to the hard copies filed with the Court.

4. **Virus Check**—I certify that I ran Symantec Endpoint Protection Version 12 on the electronic version of brief before filing it. The anti-virus program detected no virus.

Dated: October 18, 2016

/s/ Brian D. Boone
Brian D. Boone

## CERTIFICATE OF SERVICE

I certify that, on October 18, 2016, I electronically filed this brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit. I filed the brief using the CM/ECF filing system, which will send notification of the filing to counsel of record in the case, all of whom are registered on the CM/ECF system.

/s/ Brian D. Boone
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