No. 17-1140(L), 17-1136, 17-1137, 17-1189

IN THE
UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices, and Products Liability Litigation (NO II) MDL 2502

PLAINTIFFS APPEALING CASE MANAGEMENT ORDER 100,
Plaintiffs-Appellants,

v.

PFIZER, INCORPORATED; MCKESSON CORPORATION; GREENSTONE, LLC; PFIZER INTERNATIONAL LLC,
Defendants-Appellees.

Appeal from United States District Court
for the District of South Carolina (Charleston)
Case Nos. 2:14-mn-02502-RMG, 2:14-cv-01879-RMG

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* SUPPORTING DEFENDANTS-APPELLEES

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

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INTEREST OF *AMICUS CURIAE*

The Chamber of Commerce of the United States of America is the largest business federation in the world. 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. This appeal—involving questions about the admissibility of scientific and other expert evidence—is one of those cases.

With unfortunate frequency, the Chamber's members must defend themselves against lawsuits in which an expert witness proposes results-oriented testimony unmoored from a scientifically valid methodology. 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, gave Plaintiffs several opportunities to prove that the proposed expert testimony was admissible, and exercised its broad discretion

to hold that the proposed testimony failed Rule 702's standards (and in one respect also failed Rule 403's requirements). This Court should affirm those holdings under the deferential abuse-of-discretion standard. Clear evidentiary rules and appellate-review standards promote the certainty and predictability that the business community depends on 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 counsel or party made a monetary contribution intended to fund the preparing or submitting of this brief. No person other than the Chamber, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to this filing.

INTRODUCTION

Judging by Plaintiffs' opening brief, you would think that this Court must decide in the first instance whether proposed scientific testimony is admissible. It doesn't. This appeal does not require the Court to break new ground, to find facts about whether Lipitor causes diabetes, or otherwise to dive back into the science that the District Court reviewed at length. As the Supreme Court explained in *Joiner*, the deferential "abuse-of-discretion standard" governs Plaintiffs' appeal from the District Court's order excluding proposed 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"); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001). Under that standard, this Court will not disturb a district court's decision to exclude testimony unless the "'court has a definite and firm conviction that the court below committed a clear error of judgment . . . .'" *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (citation omitted); *accord Zellers v. NexTech Ne., LLC*, 533 F. App'x 192, 195–96, 199–200 (4th Cir. 2013).

Judged under that standard, this appeal is straightforward, and the Court must affirm the District Court's order excluding Dr. Nicholas Jewell's statistical testimony and Dr. Sonal Singh's dose-dependent general-causation testimony about doses less

than 80 mg.[2] *See Roche v. Lincoln Prop. Co.*, 175 F. App'x 597, 602 (4th Cir. 2006) (in two-page discussion, affirming the exclusion of causation testimony); *Newman v. Motorola Inc.*, 78 F. App'x 292, 294 (4th Cir. 2003) (in two-page opinion, affirming the exclusion of flawed causation testimony). "The district court thoroughly analyzed the facts and legal principles respecting [the experts'] proffered testimony in" "well-reasoned" opinions (*Roche*, 175 F. App'x at 602), so this Court should "conclude that the district court did not abuse its discretion . . . [and] affirm on the reasoning of the district court." *Newman*, 78 F. App'x at 294.

Plaintiffs ignore the abuse-of-discretion standard. They ask this Court to find new facts in place of those that the District Court found. So far as the District Court's decision excluding Dr. Jewell's and Dr. Singh's testimony is concerned, they fail to show—or even argue for—an abuse of discretion. Their silence about *Joiner* speaks volumes about the real implications of this appeal: If Plaintiffs convince this Court to undertake the *de novo*-ish review that they urge instead of the abuse-of-discretion review that the Supreme Court has established, then federal courts of appeals will see a spike in appeals attacking basic factual findings grounded in a comprehensive record.

[2] For brevity's sake, the Chamber limits its arguments to Drs. Jewell's and Singh's testimony. The Chamber also agrees with Appellees' arguments about Dr. Murphy's testimony.

In repackaging their appeal as *de novo*-like review, the Plaintiffs fail to grapple with the many fatal flaws in Dr. Jewell's and Dr. Singh's methodology that justified excluding their testimony. Instead, they attack the District Court's fact-finding as "mischaracterizations" of the record (Jewell) and an improper "bright-line requirement of statistical significance" (Singh). Appellants' Br. 31. Those arguments are wrong on the facts and are really just another attack on the abuse-of-discretion standard. On top of that, Plaintiffs forfeited any challenge to the District Court's separate conclusion that Rule 403 barred Dr. Jewell's New Drug Application testimony because it could mislead the jury. That unchallenged ruling independently requires affirmance.

The Court should confirm that abuse-of-discretion review does not permit Plaintiffs to relitigate from scratch the District Court's factual findings and should affirm the exclusion of Dr. Jewell's and Dr. Singh's proposed testimony.

ARGUMENT

I. THE COURT SHOULD REJECT EFFORTS (LIKE THOSE HERE) TO RECAST FACTUAL FINDINGS ABOUT PROPOSED EXPERT TESTIMONY AS LEGAL ERRORS.

A. Plaintiffs have not shown—and don't even argue for—an abuse of discretion.

Plaintiffs have not carried their burden of showing that the District Court abused its discretion in excluding Dr. Jewell's and Dr. Singh's testimony. In fact, they haven't argued "abuse of discretion" in any meaningful way. Those words don't appear in Plaintiffs' Statement of Issues. Although Plaintiffs acknowledge the abuse-of-discretion standard (as they must) in their Standard of Review, they wrap their challenges to the District Court's factual findings in the language of "legal error." *See, e.g.*, Appellants' Br. at 57 ("The district court compounded its legal error by requiring that Dr. Singh's causation opinions be supported by at least one statistically significant study *for every dose of Lipitor*.") (emphasis in original). Plaintiffs invite this Court to re-review the entire record underlying the experts' statistical analyses, and they re-argue statistical significance with new evidence not presented to the District Court—as if this Court were reviewing matters *de novo*. It is not.

The Supreme Court in *Joiner* confirmed that abuse of discretion is the proper standard for judging evidentiary rulings (including those admitting or excluding expert testimony) on appeal. 522 U.S. at 143. In that case, the district court excluded general-causation testimony because it was unreliable, but the Eleventh Circuit reversed and

admitted the testimony based on its own review of the record. The Supreme Court reversed the Eleventh Circuit's decision because the circuit court "failed to give the trial court the deference that is the hallmark of abuse-of-discretion review." *Id.* (citation omitted).

Two years later, in *Kumho Tire*, the Supreme Court again reversed an Eleventh Circuit decision overriding a district court's order excluding expert testimony. In doing so, the Supreme Court "instruct[ed]" appellate courts "to provide district courts with 'broad latitude' or 'considerable leeway,' both as to the method used to decide whether to admit expert testimony and to the decision whether to admit or exclude the testimony." *Marsh v. W.R. Grace & Co.*, 80 F. App'x 883, 886 (4th Cir. 2003) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 142, 156 (1999)).

Heeding the Supreme Court's teaching, this Court has repeatedly confirmed that "[w]e will find an abuse of discretion only where the district court's 'conclusion is guided by erroneous legal principles, or rests upon a clearly erroneous factual finding,' or if, after considering all of the evidence, the reviewing court possesses a 'definite and firm conviction that the court below committed a clear error of judgment in the conclusion it reached upon a weighing of the relevant factors.'" *Roche*, 175 F. App'x at 602 (quoting *Westberry*, 178 F.3d at 261). The Court has taken that deferential approach when district courts are in a better position to judge the issue or evidence at hand:

> The purpose of standards of review is to focus reviewing courts upon their proper role when passing on the conduct of other decisions-makers. Standards of review are thus an elemental expression of the judicial restraint, which, in their deferential varieties, safeguard the superior vantage points of those entrusted with primary decisional responsibility.

Evans v. Eaton Corp. Long Term Disability Plan, 514 F.3d 315, 320–21 (4th Cir. 2008); *see also United States v. Mitchell*, 365 F.3d 215, 233–34 (3d Cir. 2004) ("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.").

There is perhaps no issue on which the district court has a better vantage point than finding facts on a complicated record. *See Anderson v. City of Bessemer City*, 470 U.S. 564, 574–75 (1985) (the abuse-of-discretion deference reflects both the district court's superior vantage point and the need to avoid duplicating the fact-finding process on appeal). That is why the Supreme Court has directed that

> [i]f the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently. Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.

Id. at 573–74 (citing *United States v. Yellow Cab Co.*, 338 U.S. 338, 342 (1949)). Accordingly, when a district court bases its decision "upon factual predicates

established, on conflicting evidence, by the fact-finding process," this Court will not "disregard critical fact-findings" but will give those underlying findings "deference." *Plyler v. Evatt*, 846 F.2d 208, 217–18 (4th Cir. 1988). In other words, when a district court weighs competing evidence and relies on factual findings to exclude expert testimony, this Court will not second-guess it.[3]

That is the practice in this Circuit. In *Newman v. Motorola Inc.*, for instance, the district court excluded the general-causation testimony of an epidemiologist who, like Dr. Singh, relied on studies that failed to show "any statistically significant increased risk" for the relevant outcome. 218 F. Supp. 2d 769, 778 (D. Md. 2002), *aff'd*, 78 F. App'x 292 (2003). In a short, per-curiam opinion, this Court "affirm[ed] on the reasoning of the district court." *Newman*, 78 F. App'x at 294. Similar decisions abound. *See Roche*, 175 F. App'x at 602; *Bourne ex rel. Bourne v. E.I. DuPont de Nemours & Co.*, 85 F. App'x 964, 967 (4th Cir. 2004); *Marsh*, 80 F. App'x at 886; *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 68 F. App'x 356, 357 (3d Cir. 2003) ("Given the District Court's careful analysis, no purpose will be served by this court undertaking a redundant discussion simply to reach the same result.").

Here, the District Court carefully reviewed Dr. Jewell's and Dr. Singh's proffered testimony and concluded (after several rounds of briefing and supplemental reports) that the testimony failed Rule 702's requirements. Applying Rule 702 to the

[3] Of course, neither does the appellate court "rubber stamp" the district court's order. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999).

letter, the District Court found that Dr. Jewell's testimony suffered from many methodological flaws. The District Court found that "Dr. Jewell's analysis of the NDA data and ASCOT data was results driven, that Dr. Jewell's methodology and selection of relevant evidence changed based on the results they produced, and that Dr. Jewell chose to ignore and exclude from his report his own analyses that did not support his ultimate opinions." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices, & Prods. Liab. Litig.*, 145 F. Supp. 3d 573, 594 (D.S.C. 2015). Plaintiffs cannot undo the District Court's careful analysis merely by repeating the word "mischaracterization," presenting their side of the record, and inviting this Court to decide the issue anew. The District Court's decision is not "clearly erroneous" simply because the Court disagreed with Plaintiffs. *Anderson*, 470 U.S. at 574–75.

As for Dr. Singh, the District Court found that "Plaintiffs have failed to demonstrate that Dr. Singh's reliance on non-statistically significant 'trends' is accepted in his field, that non-statistically significant findings have served as the basis for any epidemiologist's causation opinion in peer-reviewed literature, or that standards exist for controlling the technique's operation. . . . These *Daubert* factors all suggest a lack of reliability." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices, & Prods. Liab. Litig.*, 174 F. Supp. 3d 911, 926 (D.S.C. 2016). There is nothing clearly erroneous about those findings. Plaintiffs cannot evade them by claiming that the District Court improperly adopted a "bright-line rule" of statistical significance. As the Third Circuit recently remarked in rejecting the identical argument, the District

Court "was not creating a legal standard, but merely making a factual finding." *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 794 (3d Cir. 2017). The District Court explained that the record showed that Dr. Singh's non-statistically-significant methodology was not scientifically accepted in his field. And Plaintiffs do not confront the District Court's additional finding that Dr. Singh's own testimony "demonstrates that studies without statistical significance are insufficient to support a causation opinion." *In re Lipitor*, 174 F. Supp. 3d at 926.

In any event, even if the District Court had imposed a legal rule requiring statistically significant, replicated epidemiology in this setting, that would not have been error. Numerous courts—including the Supreme Court in *Joiner*—have excluded general-causation experts who based their opinions on epidemiologic data that "was not statistically significant." 522 U.S. at 145; *accord Newman*, 78 F. App'x at 294. Indeed, it is remarkable that Plaintiffs offered expert testimony that they confess is based on data that are not statistically significant.

The District Court's factual findings were grounded in the record; the Plaintiffs do not show otherwise. They do not argue abuse of discretion at all. This Court must affirm the District Court's ruling.

II. AT ANY RATE, THIS COURT CAN AFFIRM THE DISTRICT COURT'S ORDER EXCLUDING DR. JEWELL'S PROPOSED NDA TESTIMONY FOR THE INDEPENDENT REASON THAT IT FAILS RULE 403.

In excluding Dr. Jewell's NDA testimony, the District Court did not abuse its discretion, and this Court should not invite future plaintiffs to attack district courts' well-supported factual findings by recasting the District Court's factual findings as legal errors. The Court also should not invite future plaintiffs to ignore on appeal a district court's evidentiary rulings (beyond Rule 702) that independently support excluding expert testimony. *See Grayson O Co. v. Agadir Int'l LLC*, 856 F.3d 307, 316 (4th Cir. 2017) (declining to address issues not addressed in opening brief). Here, Plaintiffs do not challenge the District Court's separate holding that Dr. Jewell's NDA testimony is inadmissible under Rule 403. That separate ruling independently requires affirmance.

Rule 403 is "a necessary, independent inquiry" separate from Rule 702. *Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1055 (4th Cir. 1986). "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); *accord Casey v. Geek Squad® Subsidiary Best Buy Stores, L.P.*, 823 F. Supp. 2d 334, 347–48 (D. Md. 2011) (excluding expert testimony under Rule 702 and Rule 403).

In *Daubert* itself, the Supreme Court explained that district courts should also vet proposed expert testimony under Rule 403. The *Daubert* Court "emphasized that a district court evaluating the admission of expert testimony under Rule 702 should also consider other applicable rules of evidence, including Rule 403, which authorizes the exclusion of relevant evidence whose probative value is substantially outweighed by its danger of unfair prejudice." *United States v. Prince-Oyibo*, 320 F.3d 494, 504 (4th Cir. 2003) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993)). 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." *Daubert*, 509 U.S. at 595 (internal quotation marks omitted).

The District Court excluded Dr. Jewell's NDA testimony under both Rule 702 and Rule 403. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices, & Prods. Liab. Litig*, No. 2:14-mdl-02502, 2016 WL 827067, at *5 (D.S.C. Feb. 29, 2016). According to the District Court, Dr. Jewell's NDA testimony failed Rule 403's requirements because the "testimony's probative value is substantially outweighed by its danger to confuse and mislead the jury." *Id.* One reason for the potential confusion: Dr. Jewell relied on a calculation that improperly combined glucose increases from placebo and atorvastatin-experimental groups to suggest that atorvastatin caused all the increases, which would be "highly misleading." 2016 WL 827067, at *4; *see also* 145 F. Supp. 3d

at 587 ("Dr. Jewell's opinion regarding the average increase in glucose is misleading and results driven."). Rule 403 gave the District Court an independent basis to exclude Dr. Jewel's NDA testimony.[4]

Plaintiffs did not challenge the District Court's 403 ruling in their opening appellate brief, so they have waived any such argument in this appeal. "A party waives an argument by failing to present it in its opening brief." *Grayson O Co.*, 856 F.3d at 316. A "passing shot at the issue" in a brief is not enough. *Id.* "As a rule that 'all the federal courts of appeals employ,' waiver 'makes excellent sense.'" *Brown v. Nucor Corp.*, 785 F.3d 895, 923 (4th Cir. 2015) (quoting *Joseph v. United States*, -- U.S. --, 135 S. Ct. 705, 705 (2014) (Kagan, J., respecting denial of certiorari)). "Judges are not mind-readers, so parties must spell out their issues clearly, highlighting the relevant facts and analyzing on-point authority." *Rodriguez v. Municipality of San Juan*, 659 F.3d 168, 175 (1st Cir. 2011).

Plaintiffs don't give Rule 403 even a passing shot. 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 the exclusion of the NDA testimony.

[4] The admissibility of Dr. Jewell's later NDA opinions depends on the fate of his initial NDA opinion. The District Court explained that excluding Dr. Jewell's initial NDA testimony made that expert's supplemental NDA testimony "irrelevant and moot." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices, & Prods. Liab. Litig*, No. 2:14-mdl-02502, 2016 WL 827067, at *5 (D.S.C. Feb. 29, 2016). Plaintiffs have not argued otherwise.

CONCLUSION

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

Dated: July 7, 2017

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CERTIFICATE OF COMPLIANCE

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 3,330 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.

Dated: July 7, 2017

/s/ Brian D. Boone
Brian D. Boone

CERTIFICATE OF SERVICE

I certify that, on July 7, 2017, I electronically filed this brief with the Clerk of the Court for the United States Court of Appeals for the Fourth 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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