Nos. 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

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PLAINTIFFS APPEALING CASE MANAGEMENT ORDER 100; JUANITA HEMPSTEAD; PLAINTIFFS APPEALING CASE MANAGEMENT ORDER 99; PLAINTIFFS APPEALING CASE MANAGEMENT ORDER 109,

Plaintiffs-Appellants,

v.

PFIZER, INCORPORATED; MCKESSON CORPORATION; GREENSTONE, LLC; PFIZER INTERNATIONAL LLC,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of South Carolina (Charleston Division)
Nos. 2:14-mn-02502-RMG; 2:14-cv-01879-RMG (Hon. Richard M. Gergel)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES, URGING AFFIRMANCE

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July 7, 2017

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT
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I certify that on July 7, 2017 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by serving a true and correct copy at the addresses listed below:

/s/ Cory L. Andrews (signature) July 7, 2017 (date)

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IDENTITY AND INTEREST OF *AMICUS CURIAE*[1]

Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, limited government, and the rule of law. WLF regularly calls on courts to prevent "junk science" from ever reaching the jury by faithfully policing the admissibility of expert evidence. To that end, WLF has long appeared as *amicus curiae* in cases in support of the principle that trial courts must exclude expert evidence that lacks sufficient indicia of reliability. *See, e.g., Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

In addition, WLF's Legal Studies Division, the publishing arm of WLF, regularly publishes articles on the reliability threshold for expert testimony. *See, e.g.*, Victor E. Schwartz, In re Zoloft *MDL Judge's Rejection of Causation Testimony Provides Helpful Lessons for Bench and Bar*, WLF Legal Backgrounder (May 13, 2016); Evan M. Tager & Carl J. Summers, *Seventh Circuit Affirms that Unreliable Methodology Renders Expert Testimony on Causation Excludable*,

[1] Pursuant to Federal Rule of Appellate Procedure 29(c), *amicus* WLF states that no counsel for any party authored this brief in whole or in part, and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties have consented to the filing of this brief.

WLF Legal Opinion Letter (November 6, 2015).

WLF believes that the quality of decision-making in the federal courts largely depends on the willingness of federal judges to take seriously their responsibility as gatekeepers, to ensure that unreliable "scientific" expert evidence is not presented to the finder of fact. When judges disregard that obligation by, for example, deciding that the reliability of an expert's opinion goes to weight rather than admissibility, they undermine the civil justice system's ability to produce a fair and just result.

In this case, after extensive supplemental briefing and five days of oral argument, the district court found that plaintiffs' expert evidence was inconsistent with well-accepted scientific standards and therefore inadmissible. Having given Plaintiffs multiple opportunities to establish either general causation at doses of Lipitor less than 80 mg *or* specific causation at any dose, the district court appropriately granted summary judgment to Defendants. Because Judge Gergel carefully and responsibly applied the correct legal standard under *Daubert*, this Court should affirm the well-reasoned judgment below.

STATEMENT OF THE CASE

The facts of this case are set out in greater detail in the parties' briefs. WLF wishes to highlight several facts of relevance to the issues on which this brief

focuses.

Lipitor is a leading FDA-approved "statin" used to treat high cholesterol and to help reduce the risk of stroke, heart attack, and other cardiovascular injuries. In the United States, Lipitor is prescribed in only four distinct therapeutic doses: 10 mg, 20 mg, 40 mg, and 80 mg. This appeal arises from a Multi-District Litigation (MDL) consolidating lawsuits against Defendants on behalf of more than 3,000 plaintiffs who allege that their physician-prescribed use of Lipitor caused them to develop Type-2 diabetes.

Under reliable scientific methods, epidemiological studies generally cannot be used to establish that Lipitor is "associated" with diabetes in the absence of replicated, statistically significant epidemiological findings that adequately control for confounding factors and biases. But as the record below demonstrates, neither the 2003 Anglo Scandinavian Cardiac Outcomes Trial (ASCOT) nor Dr. Eliano Navarese's 2013 meta-analysis of five randomized clinical trials reported a statistically significant association between Lipitor and diabetes.

Even when established, mere "association" is necessary but insufficient to prove causation. Once a true association has been clearly established, scientists still must try to infer a causal relationship from that association by consulting widely accepted criteria. Given the lack of evidence of any true association between

Lipitor and diabetes—much less any evidence of causation—Pfizer moved under *Daubert* and Rule 702 to exclude Plaintiffs' expert evidence.

Apart from permitting limited testimony on the effects of Lipitor 80 mg from two experts, Judge Gergel excluded all seven of Plaintiffs' experts. On appeal, Plaintiffs contest the exclusion of only three experts: (1) Dr. Nicholas Jewell, a statistician who opined on whether a statistical association exists between Lipitor and diabetes; (2) Dr. Sonal Singh, an Associate Professor of Medicine at the University of Massachusetts Medical School who opined on general causation; and (3) Dr. Elizabeth Murphy, a Professor of Medicine at the University of California, San Francisco, who opined on specific causation in the first case set for trial, the *Hempstead* case.

Without the testimony of Drs. Jewell, Singh, or Murphy—or any other expert—Plaintiffs could not possibly satisfy their threshold burden of establishing causation. Seeking to efficiently resolve the entire MDL, Judge Gergel (with the assent of Plaintiffs' lead counsel) ordered Plaintiffs to show cause why summary judgment should not be granted to Pfizer. CMO-65. When after five months "not a single Plaintiff came forward" to show cause, CMO-82:8, Pfizer moved for summary judgment as to general causation in all cases below 80 mg (and as to specific causation in all cases).

In opposing summary judgment, Plaintiffs argued (for the first time in this protracted litigation) that they need not rely on expert evidence to establish general causation but instead could avoid summary judgment through purported "admissions" found in certain Pfizer e-mails and other company documents. Pls.Br.27-28. After affording Plaintiffs two additional opportunities to establish causation, CMO-82:6-8, Judge Gergel ultimately rejected Plaintiffs' eleventh-hour attempt to avoid summary judgment with non-expert evidence.

After more than three years of MDL proceedings, including two exhaustively briefed and argued *Daubert* hearings on three experts, the district court granted summary judgment in favor of Defendants. *See* CMO-97:12-33; CMO-99:16-42; CMO-100:19-61. Plaintiffs appeal from the district court's exclusion of Drs. Jewell, Singh, and Murphy and the resulting grant of summary judgment.

SUMMARY OF ARGUMENT

Evidence that is scientifically unreliable is no evidence at all. Consistent with *Daubert* and Rule 702, this Court uniformly requires the proponent of expert testimony to establish (through independent proof) that the basis for that expert's causation opinion—*i.e.*, either the principle of causation itself or each step in any proposed causal theory—is scientifically reliable. As the district court found in

carefully exercising its gatekeeping responsibility in this case, plaintiffs' expert evidence that Lipitor causes Type-2 diabetes simply cannot meet that basic test. Not only did plaintiffs' experts fail to rely on replicated, statistically significant, dose-specific data showing a true association between Lipitor and diabetes, but they also failed to account for alternative explanations for their causation opinions. Because the district court acted well within its discretion in rejecting those opinions as unreliable, this Court should affirm the judgment below.

Affirmance is also required to ensure that reliability remains a threshold question for the court, not the jury. It is not enough for Plaintiffs to invoke "cross-examination" as a cure-all while leaving any dispute about reliability to the "weight" a jury decides to give that testimony. But unreliable evidence is entitled to *no* weight and thus should never reach the jury. Although cross-examination has its benefits, it cannot help jurors readily distinguish valid expert conclusions from junk science, nor can it supplant the court's duty to ensure "that expert evidence is sufficiently relevant and reliable when it is submitted to the jury." *Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017). That rarified task falls only on the court's shoulders, and in this case Judge Gergel performed his role as gatekeeper with painstaking care. Given Plaintiffs' lack of sufficient admissible evidence of causation, Defendants were entitled to summary judgment.

Nor did the district court err in refusing to allow Plaintiffs to avoid summary judgment by relying solely on non-expert evidence in the form of alleged party admissions. Even if admissible under the Federal Rules of Evidence, those alleged admissions do not constitute expert testimony and thus, under the relevant substantive law, fail to raise a genuine issue of material fact regarding causation. Likewise, the district court's grant of summary judgment against all plaintiffs on the issue of specific causation was also correct. No plaintiff came forward with evidence of specific causation (or even with a request for discovery on specific causation), despite the district court's numerous directives to every plaintiff (in the form of show-cause orders) to provide notice to the court if they could proffer the necessary evidence for proving specific causation.

Finally, in seeking reversal, Plaintiffs invite the Court to disregard *Daubert* by significantly relaxing a product-liability plaintiff's burden to establish reliability. But doing so would not only sweep aside more than two decades of Supreme Court precedent, it would also trigger detrimental consequences that would reverberate well beyond this case. Permitting flimsy, unscientific expert evidence of a purported "association" to serve as the basis for imposing massive tort liability on drug manufacturers would undoubtedly disincentivize the continued development of lifesaving drugs. Absent clearly enforced thresholds for

the reliability of expert evidence on causation, drug manufacturers facing unwarranted liability would be forced either to raise prices significantly or to exit the market altogether—reducing access to vitally important, FDA-approved therapies. In such a litigious climate, it is the patients who rely on such lifesaving drugs who would suffer the most.

ARGUMENT

I. THE DISTRICT COURT ACTED WELL WITHIN ITS DISCRETION IN REJECTING PLAINTIFFS' UNRELIABLE EXPERT OPINIONS

A district judge enjoys "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper v. Smith & Nephew*, 259 F.3d 194, 200 (4th Cir. 2001) (internal quotation marks and citation omitted). Judge Gergel's decision to exclude Plaintiffs' unreliable expert evidence is entitled to review under an abuse-of-discretion standard, which "grants the trial judge broad latitude" and "applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusions." *Kumho Tire Co.*, 526 U.S. at 152-53.

Under this highly deferential standard, "this Court may not substitute its judgment for that of the district court." *United States v. Mason*, 52 F.3d 1286, 1289 (4th Cir. 1995). Rather, a district court "abuses its discretion in excluding expert testimony only if its 'conclusion is guided by erroneous legal principles, or rests

upon a clearly erroneous factual finding.'" *Nettles v. Procter & Gamble Mfg. Co.*, 33 F.App'x 670, 671 (4th Cir. 2002) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). Plaintiffs cannot possibly satisfy that high burden on appeal.

A. Dr. Nicholas Jewell

Plaintiffs contend that the district court abused its discretion in excluding the expert opinion of Dr. Nicholas Jewell, a statistician who purported to re-analyze Pfizer's own clinical data to find a statistical association between Lipitor and diabetes.[2] Having failed in his initial report to even account for the 2003 ASCOT study—a randomized, placebo-controlled clinical trial that found no statistically significant association between Lipitor 10 mg and diabetes—Dr. Jewell obtained leave to supplement his report to account for the ASCOT data.

In contrast to ASCOT's blinded endpoint adjudication process—whereby a committee of independent physicians reviewed the clinical trial data to help screen out any cases of preexisting diabetes and to otherwise ensure accurate, unbiased

[2] Even if shown, a mere "association" between Lipitor and diabetes is insufficient to prove causation. Rather, only after a true association has been clearly established may scientists then attempt to infer a causal relationship from that association. *See, e.g., Ambrosini v. Labarraque*, 101 F.3d 129, 136 (D.C. Cir. 1996). Not only did Dr. Jewell never attempt to establish such causation, but Plaintiffs conceded below that he was not a causation expert and would "not be offering a causation opinion." CMO-54:34.

results—Dr. Jewell opted to re-analyze only unadjudicated, raw data. CMO-54:26. When pressed on cross examination to justify his methodology, Dr. Jewell could not adequately explain why ASCOT's more reliable, adjudicated data should be discounted in favor of less reliable, unadjudicated data.

Dr. Jewell's rejection of ASCOT's adjudicated data "without any reasons to suspect an error in that data" raised "serious questions" in Judge Gergel's mind "as to the reliability of Dr. Jewell's determinations." CMO-54:30-31. A statistician lacking any clinical expertise in medicine or diabetes, Dr. Jewell nonetheless chose to rely solely on unadjudicated data "that conveniently resulted in a statistically significant finding." CMO-54:31-32. This was "the very definition of cherry picking data to reach a pre-determined conclusion." CMO-54:32. Because Dr. Jewell "formed an opinion first, sought statistical evidence that would support his opinion, and ignored his own analyses and methods that produced contrary results," Judge Gergel excluded nearly all of his testimony. CMO-54:35.

Accordingly, Judge Gergel did not abuse his broad discretion by "boring in on the precise state of scientific knowledge in this case." *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999); *Rodriguez v. Striker Corp.*, 680 F.3d 568, 572 (6th Cir. 2012) ("[C]ourts have a duty to inspect the reasoning of qualified experts.") (quotation and citation omitted). As the Third Circuit recently observed

in affirming Dr. Jewell's exclusion under *Daubert* in a similar case, "[t]here is sufficient reason to find Dr. Jewell's testimony was unreliable." *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 858 F.3d 787, 800 (3d Cir. 2017).

B. Dr. Sonal Singh

The "gold standard" for establishing epidemiological causation is a double-blind, randomized, controlled trial study. Yet the Navarese 2013 meta-analysis—the only published meta-analysis of all available dose-specific Lipitor data from five randomized clinical trials—found *no* statistically significant association between Lipitor and diabetes. Not only did the Navarese analysis conclude that the risk of diabetes for Lipitor 10 mg is statistically indistinguishable from a placebo, but that analysis echoed the findings of the 2003 ASCOT study.

Attempting to prove otherwise, Plaintiffs proffered the expert testimony of Dr. Sonal Singh, an epidemiologist who opined that Lipitor causes diabetes because "statins are associated with diabetes." CMO-68:13. Although Judge Gergel permitted Dr. Singh to testify concerning Lipitor 80 mg, he excluded Dr. Singh's testimony concerning Lipitor 10 mg as unreliable. CMO-68:39. In particular, Judge Gergel found that Dr. Singh did not reliably apply the epidemiological method, which generally requires a statistically significant

association be established through studies. CMO-100:13. As even Plaintiffs concede, "such studies do not exist for Lipitor 10 mg." CMO-68:15-16; CMO-100:13. And absent any reliable evidence of causation at 10 mg, as Judge Gergel explained, "Dr. Singh, by his own testimony, is unable to offer a causation opinion regarding Lipitor 20 mg or Lipitor 40 mg." CMO-68:23-24.

On appeal, Plaintiffs argue that the district court erred in excluding Dr. Singh's causation opinions because "[d]ose-specific evidence is not required." Pls.Br.58. But that contention ignores the first tenet of toxicology: "the dose makes the poison." Federal Judicial Center, *Reference Manual on Scientific Evidence* 636 (3d ed. 2011). The basic concept of a necessary dose dates back to the sixteenth century when Paracelsus, the "father of toxicology," observed: "All substances are poisonous; there is none which is not a poison. The right dose differentiates poison from a remedy." *Casarett & Doull's Toxicology: The Basic Science of Poisons* 5 (Curtis D. Klaassen ed., 7th ed. 2008).

As one leading expert has observed, "Dose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." David L. Eaton, *Scientific Judgment and Toxic Torts—A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & Pol'y 5, 11 (2003). Indeed, an "expert who avoids or neglects this principle [of the dose-response relationship]

without justification casts suspicion on the reliability of his methodology." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1242 (11th Cir. 2005). That is why this Court has consistently required experts seeking to prove causation to "demonstrate the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure." *Westberry*, 178 F.3d at 263.

At the very least, proof of causation requires the ability to quantify the dose-specific level of exposure to a drug that is allegedly toxic or dangerous. Yet even after being invited to submit supplemental reports to establish dose-specific associations, Dr. Singh was unable to demonstrate *any* level of Lipitor below 80 mg that causes diabetes generally. Without such a showing, Dr. Singh could not possibly satisfy *Daubert*'s basic reliability threshold for proving causation in this case, where "the parties know a plaintiff's dosage level and know the dosage levels at issue in particular studies." CMO-49:9. Accordingly, Judge Gergel did not abuse his broad discretion in concluding that Dr. Singh's opinion departed from well-accepted scientific methodologies for proving causation.

C. Dr. Elizabeth Murphy

The district court also excluded—as unreliable under *Daubert*—Dr. Elizabeth Murphy's opinion on specific causation in the first case set for trial for failure to account for other possible alternative causes for Ms. Hempstead's

diabetes (*i.e.*, weight gain, BMI, family history, hypertension, etc.). CMO-55:26. When pressed by the district court, Dr. Murphy "could not identify any organizations or peer-reviewed texts" that endorsed her *sui generis* methodology. CMO-55:11-12. On appeal, Plaintiffs contend that, by finding Dr. Murphy's opinion unreliable and therefore inadmissible, "the district court usurped the role of the jury to decide the weight to be given to Dr. Murphy's opinions." Pls.Br.77. According to Plaintiffs, "criticisms of the expert's application of [a given] methodology to the facts should be ventilated through cross-examination and resolved by the jury." Pls.Br.5. Such arguments are wholly without merit after *Daubert*.

Under *Daubert*, reliability is a threshold question for the court, not for the jury, and Rule 702 demands that district courts reject expert testimony that is not based on "sufficient facts or data," or is not the product of "reliable principles and methods," or where the proffered witness has not "reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. The Plaintiffs' dismissive approach to reliability thus obscures the fact that Judge Gergel's criticisms of Dr. Murphy's methodology went directly to the guideposts established by *Daubert* and Rule 702: whether her opinion was based on sufficient facts, whether she reliably applied principles and methods to the facts of the case, and whether she accounted

for alternative explanations in forming her opinion. *See Daubert*, 502 U.S. at 593-94; Fed. R. Evid. 702.

Daubert clarified that "*any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994). "This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *Ibid.* Indeed, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. As for how much "weight" a jury should give such evidence, there is only one acceptable answer: *none*. Such "[i]nadmissible evidence contributes nothing to a 'legally sufficient evidentiary basis'" for a jury verdict. *Weisgram v. Marley Co.*, 528 U.S. 440, 454 (2000) (internal citation omitted).

Nor is it enough to invoke the "cross-examination" of expert testimony while leaving any dispute about reliability to the "weight" a jury decides to give that testimony. While cross-examination has its benefits, it is no panacea; it cannot readily distinguish valid expert opinions from junk science, and thus it cannot take

the court's place in determining an expert's reliability in the first instance. As Professor Jules Epstein has explained:

> This treatment of cross-examination as the palliative of choice has its flaws, not merely in its expectation that cross-examination without other resources can fairly respond to an expert witness. The mythic status of cross-examination in this regard actually impedes accurate fact-finding because leading questions are not always an appropriate or sufficient tool for truth finding. Courts have not acknowledged these limitations.

Jules Epstein, *Cross-Examination: Seemingly Ubiquitous, Purportedly Omnipotent, and "At Risk,"* 14 Widener L. Rev. 427, 437 (2009) (internal citations omitted). Consistent with this view, the Court has recently recognized that the mere "fact that an expert witness was 'subject to a thorough and extensive examination' does not ensure the reliability of the expert's testimony; such testimony must still be assessed *before* it is presented to the jury." *Nease*, 848 F.3d at 231 (emphasis added) (citation omitted).

Urging admission of Dr. Murphy's unreliable expert testimony on appeal, Plaintiffs contend that a jury can somehow muddle through the relevant science with the aid of competing expert evidence and cross-examination. But dismissing key, demonstrable, and objective flaws in expert evidence as going to the "weight" of that evidence inevitably leaves jurors with the rarified task of resolving the basic

reliability of a given expert's testimony. Jurors cannot and should not be expected to make those sorts of reliability determinations.

Indeed, legal scholars have long insisted that "cross-examination does little to affect jury appraisals of expert testimony." Christopher B. Mueller, Daubert *Asks the Right Questions: Now Appellate Courts Should Help Find the Right Answers*, 33 Seton Hall L. Rev. 987, 993 (2003). To the contrary, studies have revealed jurors' commonly held assumption that, because the trial judge admitted the expert evidence, it must have passed at least some minimal level of scrutiny. *See, e.g.*, N.J. Schweitzer & Michael J. Saks, *The Gatekeeper Effect: The Impact of Judges' Admissibility Decisions on the Persuasiveness of Expert Testimony*, 15 Psychol. Pub. Pol'y & L. 1, 7 (2009).

The only way to ensure that a jury does not give too much weight to unreliable evidence is not to admit it in the first place. "The basic calipers that jurors use to evaluate testimony—their own life experience—are of little value when jurors evaluate whether an expert is telling the truth." Victor E. Schwartz & Cary Silverman, *The Draining of* Daubert *and the Recidivism of Junk Science in Federal and State Courts*, 35 Hofstra L. Rev. 217, 220 (2006). Thus, any questions about the "factual basis, data, principles, [or] methods" of expert testimony—or "their application"—require the trial judge to determine whether that testimony is

reliable *before* sending it to the jury. *Kumho Tire Co.*, 526 U.S. at 149 (emphasis added). Because that is precisely what Judge Gergel did in this case, he did not abuse his broad discretion in doing so.

II. IN THE ABSENCE OF EXPERT EVIDENCE, PLAINTIFFS FAILED TO RAISE A GENUINE ISSUE OF MATERIAL FACT REGARDING CAUSATION

Although Plaintiffs allege that their physician-prescribed use of Lipitor caused them to develop Type-2 diabetes, they could not create a jury question on that issue. The district court exhaustively canvassed the substantive law of all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands on proof required to establish causation. CMO-100:24-38. Based on that canvas, it determined, "All jurisdictions require expert testimony [to meet one's burden of proving causation] at least where the issues are medically complex and outside common knowledge and lay experience." *Id*. at 24. In light of that determination, Judge Gergel properly granted summary judgment against all Plaintiffs once he determined that the expert testimony of Drs. Jewell, Singh, and Murphy was inadmissible.

In the absence of expert evidence, Plaintiffs cannot create a jury question on general causation by pointing to alleged admissions by Pfizer. Those alleged admissions, while arguably admissible under the Federal Rules of Evidence, do not constitute expert testimony and thus fail to raise a genuine issue of material fact

regarding causation. The district court's grant of summary judgment against all plaintiffs on the issue of specific causation was similarly unobjectionable. No plaintiff came forward with evidence of specific causation (or even with a request for discovery on specific causation) following the decision to exclude Dr. Murphy's testimony (CMO-55), despite the district court's numerous directives to every plaintiff (in the form of show-cause orders) calling on them to provide notice to the court if they alleged facts serving to distinguish their cases from CMO-55.

A. Pfizer's Alleged Admissions Are an Inadequate Substitute for Expert Testimony on General Causation

Defendants' brief explains in detail why Plaintiffs, in the absence of expert testimony, cannot avoid entry of summary judgment on general causation. Defs.Br.69-82. WLF will not repeat that explanation here. Rather, WLF writes separately to focus on several points that merit special emphasis.

1. Plaintiffs' reliance on Federal Rule of Evidence 801(d)(2) is misplaced. The rule provides that a statement is not hearsay (and thus not inadmissible on that ground) when it is offered against a party and is "the party's own statement, in either an individual or representative capacity." Fed. R. Evid. 801(d)(2)(A). Plaintiffs contend that the four statements on which they rely—an e-mail written by Dr. DeMicco and three statements that appeared on Lipitor labeling—are admissible under Rule 801(d)(2), and that it is up to a jury to determine whether

the statements are sufficient to establish general causation. Plaintiffs further contend that to the extent that state substantive law is to the contrary, it is preempted by federal law. Pls.Br.64-70.

But the district court did not disagree with Plaintiffs' contention that the four alleged admissions were admissible evidence. Rather, the court properly focused on whether, under Fed. R. Civ. P. 56(a), Plaintiffs' proffered evidence was sufficient to create a "genuine dispute" on the issue of general causation. In light of its exhaustively documented finding that the laws of *every* State require expert testimony to support a general-causation claim when (as here) "the issues are medically complex and outside common knowledge and lay experience," CMO-100:24, the court properly concluded that the alleged admissions did not suffice to defeat Pfizer's summary judgment motion. There is therefore no conflict between that state substantive law and Rule 801(d)(2). The latter governs the admissibility of non-expert evidence in a federal court proceeding, but it has no bearing on whether the evidence, once admitted, is sufficient to create a genuine dispute regarding a material fact.

2. Plaintiffs seek to rely on the dearth of case law stating explicitly that alleged admissions by a defendant regarding causation can *never* be an adequate substitute for expert testimony. But Plaintiffs' argument overlooks the voluminous

case law, from every State, holding that expert testimony on general causation is *required* in cases of this sort. *See, e.g., Lewis v. Johnson & Johnson*, 601 F.App'x 205, 211 (4th Cir. 2015) (applying Texas law and stating, "Texas courts have regarded expert testimony on causation as *particularly vital*" in cases involving complex "medical diagnoses.") (emphasis added). It is Plaintiffs who seek to create an exception to that requirement, yet they have failed to cite a single case that supports the "admissions" exception they espouse.

As one federal court has explained, States are highly unlikely to recognize such an exception, because isolated statements by the defendant are unlikely "to be comparable to expert testimony in terms of reliability." *In re Mirena IUD Products Liability Litig.*, 202 F.Supp.3d 304, 320 (S.D.N.Y. 2016), *appeal pending*, No. 16-2890(L) (2d Cir. 2016). The court added, "It is hard to imagine a case where Plaintiffs' counsel could not find an expert who could make [a general causation finding] using a reliable methodology, yet a patchwork of snippets of Defendants' employees' statements would do the trick." *Ibid*.

3. Plaintiffs have misconstrued the cases on which they rely. For example, they cite *Westberry v. Gislaved Gummi AB* for their assertion that "this Court held that a defendant's admissions were sufficient to prove general causation." Pls.Br.67. Wrong. *Westberry* never considered whether a defendant's admissions

could serve as a substitute for expert testimony; rather, the Court concluded that the district court did not abuse its discretion in *admitting expert testimony* that the plaintiff's illness was caused by exposure to the defendant's product. 178 F.3d at 260-66. Moreover, Plaintiffs inaccurately contend that the *Westberry* expert's sole basis for finding general causation was a statement in a Material Safety Data Sheet (MSDS) distributed by the defendant. Yet the *Westberry* defendant's objection to the admissibility of the testimony took no issue with the expert's reliance on the MSDS statement to conclude that the defendant's product was capable of irritating the plaintiff's sinuses. *Id.* at 264 (stating that "it was *undisputed* that inhalation of high levels of talc irritates mucous membranes") (emphasis added). In sharp contrast, Pfizer here disputes that the alleged admissions are evidence of a causal relationship between use of Lipitor and Type-2 diabetes, and Plaintiffs have proffered no admissible expert testimony to support their general causation claim.

B. The District Court Properly Entered Summary Judgment Against All Plaintiffs on Specific Causation

Federal law authorizes the judicial panel on multidistrict litigation to transfer related federal cases to a single federal court "for coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407(a). It is universally recognized that transferee courts are authorized, at their discretion, to rule on summary judgment motions. *See* Federal Judicial Center, *Manual for Complex Litigation* § 22.36 (4th

ed. 2004) ("An MDL transferee judge has authority to dispose of cases on the merits—for example, by ruling on motions for summary judgment."). Plaintiffs have failed to demonstrate that the district court abused its discretion in addressing summary judgment on specific causation.

1. Plaintiffs cannot plausibly contend that they were not provided an adequate opportunity to contest the motion for summary judgment on specific causation. CMO-100 provides a detailed accounting of the numerous show-cause orders informing counsel for all plaintiffs that the court would be addressing specific causation and directing them to notify the court if they alleged facts serving to distinguish their cases from CMO-55 (which determined that Dr. Murphy's proffered expert testimony was inadmissible to establish specific causation in the *Hempstead* case). Despite the court's repeated extensions of time for the provision of such notice, and despite the fact that plaintiffs were asked to provide only a bare notice (*i.e.*, the parties were to be provided adequate additional time to conduct discovery and develop expert testimony before a ruling on summary judgment would be issued), no plaintiff sought to avail herself of the opportunity. CMO-100:4-9. Even then, the district court provided plaintiffs still more opportunities to submit evidence that purported to preclude entry of summary

judgment on specific causation. CMO-100:9-11 (citing CMO-82 and Dkt. No. 1695).

2. Congress authorized MDL transfers under § 1407 to, *inter alia*, "reduce litigation cost, and save the time and effort of the parties, the attorneys, the witnesses, and the courts." *Gelboim v. Bank of America Corp.*, 135 S. Ct. 897, 903 (2015). The district court acted well within its discretion in determining that "just and efficient conduct" of the MDL proceedings required it to address the specific causation claims of all plaintiffs, CMO-100:60, particularly given the absence of any response to the show-cause orders.

3. Plaintiffs' real complaint is not that individual plaintiffs were denied an adequate opportunity to assert specific causation, but that the court's prior rulings excluding expert witnesses deprived them of sufficient financial incentive to do so:

> [T]he court put thousands of individual plaintiffs in the untenable position of having to go through full-blown fact and expert discovery on a case-specific issue even though the court had all but doomed their cases through its erroneous general causation rulings and the erroneous exclusion of Dr. Murphy's opinions in *Hempstead*.

Pls.Br.84. But that complaint in effect asserts that Plaintiffs have a right to interlocutory review of the evidentiary rulings before being required to defend summary judgment motions. That assertion is in considerable tension with 28

U.S.C. § 1291, which states that federal appeals courts are empowered to review only "final decisions of the district courts."

The Supreme Court has repeatedly refused to create exceptions to the final-order doctrine based on assertions that denying interlocutory appeal would deprive plaintiffs of all financial incentives to continue with the litigation. For example, the Court last month reiterated its rejection of the "death knell" doctrine, under which plaintiffs asserted a right to interlocutory appeal from denial of class certification orders whenever denial rendered it economically infeasible for them to continue on a non-class basis. *Microsoft v. Baker*, 137 S. Ct. 1702 (2017). Similarly, Plaintiffs have no right to insist that individual specific-causation rulings be delayed until after their appeal from the *Daubert* rulings.

III. RELAXING THE RELIABILITY THRESHOLD FOR EXPERT EVIDENCE OF CAUSATION WOULD DISINCENTIVIZE DRUG RESEARCH AND DEVELOPMENT, SIGNIFICANTLY HARMING PUBLIC HEALTH

As the record demonstrates, physicians routinely rely on Lipitor as a first-line "statin" therapy to help reduce the risk of stroke, heart attack, and other cardiovascular injuries in patients with high cholesterol. At the same time, the cumulative body of scientific evidence does not demonstrate that Lipitor causes Type-2 diabetes. From a public-health vantage, then, vindicating the district court's broad discretion in exercising its gatekeeping duty to exclude plaintiffs' unreliable expert evidence is vitally important. As Justice Breyer has recognized:

> [M]odern life, including good health as well as economic well-being, depends upon the use of artificial or manufactured substances, such as chemicals. And it may, therefore, prove particularly important to see that judges 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.

Joiner, 522 U.S. at 148-49 (Breyer, J. concurring); *see also Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 678 (6th Cir. 2010) (explaining that "allowing the law to get ahead of science" would "stifle innovation unnecessarily").

Many assumptions about risks of harm from taking certain drugs have been exaggerated and are overwhelmingly wrong. *McClain*, 401 F.3d at 1243 ("[S]imply because a person takes drugs and then suffers an injury does not show causation."). And yet, there are literally thousands of product-liability suits pending throughout the country—in both state and federal courts—against the manufacturers of pharmaceutical products. Lay juries are naturally sympathetic to plaintiffs who appear to have suffered harm while using prescription drugs, and the temptation is great to indulge the *post hoc ergo propter hoc* fallacy, especially when manufacturer liability can be imposed on the basis of a "scientific" expert's say-so. Given the sheer number of such cases, rigorous gatekeeping is essential to ensure that "the powerful engine of tort liability" does not do more harm than good. *Joiner*, 522 U.S. at 149 (Breyer, J. concurring).

Absent clearly enforced thresholds for the reliability of expert evidence on causation, drug manufacturers will be left with little guidance about how to structure their conduct in advance to avoid debilitating liability. Permitting flimsy, unscientific "expert" opinions to serve as the basis for vexatious litigation imposing massive tort liability on drug manufacturers would create a strong incentive for the pharmaceutical industry to discontinue developing lifesaving, innovative drugs. *See, e.g.*, *Browning Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part) (observing that "the threat of … enormous awards" has convinced prescription drug manufacturers "that it is better to avoid uncertain liability than to introduce a new pill"); *Carlin v. Superior Court*, 920 P.2d 1347, 1361 (Cal. 1996) ("[T]he imposition of excessive liability on prescription drug manufacturers may discourage the development and availability of life-sustaining and lifesaving drugs."); Margaret Gilhooley, *Innovative Drugs, Products Liability, Regulatory Compliance, and Patient Choice*, 24 Seton Hall L. Rev. 1481, 1483 (1994) ("[M]edical experts have expressed concern that uncertain liability standards, coupled with litigation costs, may discourage useful drug innovation.").

For many manufacturers, the easiest way to prevent unwarranted litigation may be to avoid market participation altogether. Indeed, leading scientific organizations—such as the National Academy of Sciences (NAS) and the

American Association for the Advancement of Science (AAAS)—have warned that permitting experts to present novel causation theories in a court of law "can unwittingly inject bad science into broader decisions affecting society (for example, by encouraging meritless litigation against the producers of products that in fact are safe, or, even worse, by causing the abandonment of products that might prevent injuries)." Br. for the Am. Ass'n for the Advancement of Science and the Nat'l Academy of Sciences as *Amici Curiae* in Support of Respondent, *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993) (No. 92-102), *available at* 1993 WL 13006381, at *23.

Drug manufacturers that opt to remain in the marketplace will nonetheless be forced to pass ever-increasing operating costs along to consumers in the form of significantly higher prices. *See, e.g.*, *Brown v. Superior Court*, 751 P.2d 470, 478 (Cal. 1988) (warning that "the consuming public … will pay a higher price for the product to reflect the increased expense of insurance to the manufacturer resulting from its greater exposure to liability"); S. Rep. No. 105-32, at 3 (1997) ("Increased product liability costs are reflected in dramatic increases in liability insurance costs. Over the last forty years, general liability insurance costs have increased at over four times the rate of growth of the national economy.").

If, as Plaintiffs here urge, liability could be imposed where the data does not show that Lipitor causes Type-2 diabetes, the resulting "product price may reflect

external costs not associated with the risks of the medication [and] distort the cost-benefit calculus faced by each consumer." Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 Harv. L. Rev. 773, 781 (1990). Not only would that be fundamentally unfair to manufacturers, but it would prove disastrous for the public health.

CONCLUSION

For the foregoing reasons, *amicus* Washington Legal Foundation respectfully requests that the Court affirm the well-reasoned judgment below.

Respectfully submitted,

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COMBINED CERTIFICATIONS

I certify that:

1. This brief complies with the type-volume limitations of Fed. R. App. 29(a)(5) and Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,282 words, excluding those parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in double spaced, proportionally spaced serif typeface using Microsoft Office Word 2010 in 14-point Times New Roman font.

Dated: July 7, 2017

/s/ Cory L. Andrews
Cory L. Andrews

CERTIFICATE OF SERVICE

Pursuant to Fed. R. App. P. 25(d), I certify that on July 7, 2017, I filed the foregoing *amicus curiae* brief with the Clerk of the Court via the Fourth Circuit's CM/ECF system. All parties to this case are represented by counsel who are registered CM/ECF users and will be served electronically by the CM/ECF system.

/s/ Cory L. Andrews
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