No. 17-802

IN THE

Supreme Court of the United States

R. J. REYNOLDS TOBACCO COMPANY,
Petitioner,

v.

BARBARA A. IZZARELLI,
Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

REPLY BRIEF FOR PETITIONER

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES (continued)

Page(s)

REPLY BRIEF

I. The Split Among the Circuits Could Not Be Clearer.

a. There are no issues of fact presented by this petition, and plaintiff's efforts to avoid review by characterizing the dispute as factual are specious. It has never been in controversy that plaintiff had a number of well-documented risk factors for laryngeal cancer, throat ulceration from reflux disease, genetic predisposition, certain drug use, and throat abuse among them. (Pet.App.56a). It has never been in controversy that these risk factors are established in peer-reviewed literature or that medical practitioners routinely advise their patients, where possible, to modify their conduct to avoid them to reduce their chances of developing laryngeal cancer. (A-461-503). The issue is purely legal, and it divides the circuits: Must a defendant demonstrate, to a reasonable degree of medical probability, that such risk factors are established causes of the disease before the defendant can cross-examine plaintiff's experts with regard to them, or can offer medical literature regarding them, or can offer its own experts to testify regarding them.

This is a constantly recurring question. It arises in pharmaceutical litigation (*see, e.g.*, *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2018 WL 305503, at *2 (N.D. Ill. Jan. 6, 2018)), medical malpractice litigation (*e.g.*, *Clark ex rel. Clark v. Heidrick*, 150 F.3d 912, 915 (8th Cir. 1998)), product liability litigation (*e.g.*, *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prod.*

Liab. Litig., 978 F. Supp. 2d 1053, 1072 (C.D. Cal. 2013)), and a wide range of other cases. As pointed out in our petition, three circuits hold that defendant has no such burden as a predicate to cross examination or the presentation of evidence; indeed, in those circuits invoking such an obstacle would be a clear error of law. In the present case, however, the district court, affirmed by the Second Circuit, placed precisely this burden on the defendant, holding, *inter alia*:

> If you want to cross somebody with a risk factor, you're not permitted to do that unless that risk factor has been shown to be a general cause of laryngeal cancer.

(Resp.App.27a). Satisfaction of this burden was seen by the district court as necessary to establish relevance. *See* Pet.App.74a; *see also* Resp.App.25a. Satisfaction of this burden was seen by the Second Circuit as necessary to avoid confusion and prejudice. *See* Pet.App.7a. The issue is one of admissibility and arises purely under federal law; state law is not in controversy.

The split with the First, Eighth, and Eleventh Circuits could not be clearer, and in view of it, it should be no wonder that the Second Circuit stayed its mandate.

b. The courts below applied a legal standard for admissibility to defendants *identical* to the substantive test a plaintiff must satisfy to establish a prima facie case.

Plaintiff does not acknowledge, and consequently does not defend, the central holdings of the decisions below; plaintiff does not defend on relevance

grounds. Plaintiff further concedes that defendants do not have a burden of establishing causation (Opp. 20), but, flailing, characterizes the preclusionary order here as arising from a different "burden" of "establishing the admissibility requirements set by this Court in *Daubert*." *Id*. Suffice it to say, *Daubert* does not address precluding cross-examination. Nor does it anywhere address or authorize redacting risk factors from a National Cancer Society pamphlet to remove references to established risk factors other than the one asserted by the plaintiff. Nor did the Second Circuit even refer to *Daubert* or any case applying *Daubert's* standard in reaching its decision. Nor did the district court predicate its preclusion on the basis of any *Daubert* factor. Never did the district court address whether the testimony "fit," was generally accepted, was based on peer-reviewed literature, or was subject to testing,[1] and it was incontrovertible that the proffered testimony met each of those standards.

c. The defendants' experts were prepared to offer reliable, generally accepted opinions that Plaintiff's exhibited risk factors are possible causes of larynx cancer. The eminence of Reynolds' experts was

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[1] Post-hoc, and without addressing *Daubert* factors, the district court characterized its preclusion as based on *Daubert*, but at the time of its ruling, the district court precluded Reynolds from offering its risk-factor evidence on the ground that it was not *relevant*:

> [T]o make it relevant and certainly to make it admissible under 403, you have to say, you have to have somebody say here's the ultimate cause.

(Pet.App.74a).

unquestionable. One was the former Director of Risk Assessment for the National Academy of Sciences/National Research Council. (A-478). Another is the Chairman of Pathology at the University of Nevada. (A-462). They were prepared to testify that plaintiff exhibited a number of well-documented risk factors for laryngeal cancer, all of which were potential causes of her disease; that the exposures were all well-established risk factors in the medical literature; that the evidence was not speculative; and that the totality of the evidence pointed to a non-tobacco etiology for plaintiff's cancer. (A-461-503). Indeed, they were prepared to testify that the statistical risk of laryngeal cancer in a 36-year-old woman from several of these risk factors was appreciably higher than the statistical risk from smoking. (A-473, A-502).

Unlike tobacco, plaintiff's other risk factors had not been the subject of multiple, large prospective or retrospective studies. (A-485-86). In some cases, as with street drugs, such tests could not be conducted, as they would be unethical. In others, tests were not necessary, as the medical community assumed causality and warned the public to avoid the risks; indeed, that was exactly the purpose of the redacted NCI pamphlet. The defendant's experts, being careful scientists, testified that because of the lack of long-term testing, causation had not been established to a reasonable degree of certainty for those risk factors, but in light of the strong statistical link between those risk factors and laryngeal cancer, they were a more likely cause of plaintiff's disease than smoking. (A-490). This view of risk factors as presumptively causal is consistent with standard medical literature. *See, e.g.*, DICTIONARY OF EPIDEMIOLO-

GY 251 (6th ed. 2014) ("risk factor" is "[a] factor that is causally related to a change in the RISK of a relevant health process, outcome, or condition").

As strong and well-documented as this evidence was to undermine plaintiff's theory of etiology, the jury was precluded from hearing any of it. So sweeping was the preclusionary ruling that white-out was applied to delete all reference to non-tobacco risk factors in medical texts. Reynolds not only received a ruling in variance with all other circuits, but was denied a fair trial.

d. The split in Circuits is pellucid. Plaintiff's argument that the difference among the Circuits arises from differences in "state law rules imposing different burdens on plaintiffs and defendants to prove or disprove medical causation," (Opp. 26), was not raised below, is insincere, and baseless. *At no point in her brief does plaintiff even cite to Connecticut law on the "burdens on plaintiffs and defendants to prove medical causation."* To the contrary, plaintiff acknowledges that plaintiff had the burden of proof on causation (Opp. 20), as is uniform throughout the United States. The question of evidentiary preclusion raised here is purely federal, whether under Rule 401, Rule 403 or *Daubert*.

As the Eleventh Circuit made clear in *Aycock,* while a plaintiff must prove causation, a defendant is treated differently. Relying on the First Circuit, the Eleventh Circuit stated that "the defendant 'need not prove another cause' but 'only has to convince the trier of fact that the alleged negligence was not the legal cause of the injury." Nor was any distinction

made between general and specific causation.[2] *Aycock v. R.J. Reynolds Tobacco Co.,* 769 F.3d 1063, 1070 (11th Cir. 2014) (quoting *Wilder v. Eberhart*, 977 F.2d 673, 676 (1st Cir. 1992) (error to preclude defendant's evidence because it was stated in terms of "mere possibility" instead of "probability" because that approach improperly shifted the burden of proof)).

In the First, Eighth, and Eleventh Circuits, it is prejudicial error to require a defendant to show that a possible alternative cause has been demonstrated to a reasonable degree of certainty before presenting such a rebuttal case. *See Aycock*, 769 F.3d at 1069-70.

The split could not be clearer.

II. The Recurring Question Whether a State May Ban Cigarettes Categorically Through its Tort Law or Otherwise is Squarely, and Ineluctably, Presented

a. Plaintiff's opposition evades the central issues raised by our petition. It does not contain a single reference to the jury instruction that frames the issue:

> Under Connecticut law [in balancing the risks and utility of a product] the plaintiff does not need to prove that there was a feasible safer alternative design that the de-

[2] Plaintiff's attempt to distinguish *Aycock* on the ground that the risk factor there was alcohol (Opp. 26) is baffling. In the present case, alcohol was also a risk factor, (Opp. 14 n.9), and evidence of it was precluded.

> fense could have used in order for your (sic) to find that the product is defective.

(A-890-91). Nor does it even mention that the jury entered a general verdict.

Instead, plaintiff argues that she presented alternative designs at trial. She did. She variously argued at times at trial that Salem's nicotine was too *high* (*see* Opp. 34-35), at other times that nicotine was too *low* (*see* Opp. 9) (should not have lowered nicotine to 1.3 mg.), or that Reynolds should have blended other tobaccos (*see* Pet.App.31a, 34a-35a). Perhaps the jury found on one of those bases. Perhaps not. It is settled, however, that when a trial court instructs a jury on multiple alternative grounds, any one of which is legally invalid, and the jury thereafter renders a general verdict, it is presumed for purposes of appeal that the jury found liability on the invalid ground. *E.g.*, *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 384 (1991), and cases cited at Pet. 23. Here the point is even further sharpened, as plaintiff's unifying theme throughout trial was that the risks of cigarettes exceed their benefits, a theme reinforced by plaintiff's experts' opinions that their conclusions would have been the same regardless of cigarette design. *See* Pet.App.21a.

Virtually all states apply the risk-utility test for product liability, but the states are split on whether plaintiffs must prove a safer, feasible alternative design as a predicate to liability. Approximately half, including Connecticut, do not require proof of a safer

alternate design.[3] The difference is monumental: the requirement that a plaintiff prove a safer alternate design puts the product's *design* on trial; in the absence of an alternative design requirement, the risk-utility test puts the generic *category* on trial, a point forcefully emphasized by Reporters of the *Restatement (Third) of Torts*. Aaron Twerski & James A. Henderson, Jr., *Manufacturer's Liability for Defective Product Designs: The Triumph of Risk Utility*, 74 BROOK. L. REV. 1061, 1069-70 (2009).

The jury instruction in the present case, allowing the jury to impose liability even if there were no feasible alternate design, challenges the sale of cigarettes categorically; liability on that basis would enforce a state-created duty not to sell cigarettes. The ultimate question of federal preemption – can a state ban the sale of cigarettes – is thus presented in crystalline form.

Plaintiff's principal rejoinder is diversionary. She speculates that the jury rested its verdict on evidence of a safer design and argues that two courts have found that the jury was presented with evidence of alternate designs that could have supported their verdicts, precluding a further factual review. These arguments, willfully silent on the jury instruction allowing liability without a superior design, are in

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[3] *See* Mike McWilliams & Margaret Smith, *An Overview of the Legal Standard Regarding Product Liability Design Defect Claims and a Fifty State Survey on the Applicable Law in Each Jurisdiction*, 82 DEF. COUNS. J. 80 (2015) (listing 20 states that do not require proof of an alternate design).

diametric opposition to this Court's jurisprudence on general verdicts.

Plaintiff's only other argument implies that a different instruction, that "cigarettes are not defective merely because nicotine and/or carcinogenic substances may be inherent in the tobacco," somehow negated the instruction allowing liability in the absence of a superior design (Opp. 30). That argument does not get very far. If two instructions are in conflict and one is prejudicial, the jury is assumed for purposes of the appeal to have relied on the prejudicial instruction. *See, e.g.*, *Francis v. Franklin,* 471 U.S. 307, 320-24 nn. 8-9 (1985); *NewCSI Inc. v. Staffing 360 Sols., Inc.,* 865 F.3d 251, 263 (5th Cir 2017). But in any event, the jury could have found cigarettes categorically unreasonably dangerous regardless of the presence of nicotine and carcinogens in the tobacco from which they are made. Plaintiff made a broadside attack on cigarettes generically at trial, hardly limited to the issues of nicotine and cancer. She put on testimony of a variety of diseases caused by cigarettes – heart disease, vascular disease, COPD – unrelated to carcinogens. (*See, e.g.*, A-850). She offered testimony that cigarettes kill 400,000 American a year (*id.*), most unrelated to cancer. And she offered testimony that (because all cigarettes were equally dangerous) if Salem had 9% of the market, it was responsible for 9% of the deaths. (*Id.*) In short, the jury heard evidence and argument that the problem with Salem was that it was a cigarette; and that cigarettes are too dangerous to be sold. This case presents on a pin the question whether states can ban the sale of cigarettes as a category, a question that arises in every state that

applies the risk-utility test without requiring plaintiff to prove a safer alternate design.

b. Plaintiff makes three arguments to defeat preemption: (1) that a long line of appellate cases holds that states may ban the sale of cigarettes (Opp. 35-36); (2) that *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), dealt only with the FDA's jurisdiction, and not preemption (Opp. 36); and (3) that the Tobacco Control Act of 2009 allowed states to ban cigarettes (Opp. 37). Each of those arguments is wrong.

First, plaintiff's cited appellate dispositions are not as described, but disparate. Several simply hold that specific design claims are not preempted. *See, e.g.*, *Thompson v. Brown & Williamson Corp.,* 207 S.W.3d 76, 95-96 (Miss. Ct. App. 2006); *Major v. R.J. Reynolds Tobacco Co.*, 222 Cal. Rptr. 3d 563, 574 (Cal. Ct. App. 2017). A welter of other cases, as noted in the petition (28-29 n.10), dismiss product liability claims on preemption grounds. The recurring and unsettled nature of the question begs this Court's definitive resolution.

Second, it is sophistry to argue that *FDA v. Brown & Williamson* did not rule on preemption. The case certainly held that the FDA did not have jurisdiction over cigarettes, but that was only because if the FDA took jurisdiction it would have been required under the FDCA at the time to ban cigarettes because of their dangers. This Court held that such action was precluded because Congress had preempted any categorical cigarette bans. *See* 529 U.S. at 137 ("Congress, however, has foreclosed the removal of tobacco products from the market"). The Court's holding on

preemption was the *sine qua non* of *Brown & Williamson*.

Further, preemption of categorical *state* bans on the sale of cigarettes rests not only on all the grounds in *Brown & Williamson*, which apply equally to agencies and the states, but also on the Cigarette Labelling and Advertising Act, 15 U.S.C. § 1334(b), which provides:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

"Promotion" under § 1334(b) refers to the "furtherance" of the "*sale*" of cigarettes through "advertising, publicity or discounting." *23-34 94th St. Grocery Corp. USA v. NY City Bd. of Health,* 685 F.3d 174, 182 (2d Cir. 2012). Promotion "obviously" includes, among many other things, the "[d]istribution of coupons and free samples." *Id.* It similarly includes other means to "maximize the opportunity for purchase." *Id.* If a state cannot ban promotion – and it is expressly preempted from doing so – it perforce cannot ban the sale. Whether viewed as express or conflict preemption, Congress has plainly prohibited states from categorical bans on the sale of cigarettes, a point further accentuated by Congress's many references to the protection of interstate commerce in cigarettes. *See, e.g.*, 15 U.S.C. § 1331(2).

Finally, plaintiff's reference to the Tobacco Control Act of 2009 is misleading, to say the least. First, Plaintiff's references are to provisions regarding

smokeless tobacco, not cigarettes. Second, as to cigarettes, the Act expressly preserves preemption of states from regulating the content of promotion, 15 U.S.C. § 1334(c). Third, this case involves sales of cigarettes exclusively before 2006, and the Tobacco Control Act, which is prospective by its terms (15 U.S.C. § 1334(c)), was enacted in 2009. It is a quintessential red herring.

CONCLUSION

The Court should grant the petition.

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