No. 17-___

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether, as the Second Circuit held in direct conflict with three other courts of appeal, a district court may under the Federal Rules of Evidence preclude a defendant from presenting evidence and conducting cross examination regarding possible alternative causes of a plaintiff's injuries on the ground that the defendant has not proved that they are an actual cause of the plaintiff's injuries.

2. Whether a plaintiff's claims against a cigarette manufacturer for strict liability and negligence are preempted by federal statutes manifesting Congress' intent that cigarettes continue to be lawfully sold in the United States, where the plaintiff put before the jury a theory under which selling any cigarette would result in liability?

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

The plaintiff below was Barbara A. Izzarelli.

The defendant below was petitioner R.J. Reynolds Tobacco Company. R.J. Reynolds Tobacco Company is a wholly owned subsidiary of R.J. Reynolds Tobacco Holdings, Inc.

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PETITION FOR A WRIT OF CERTIORARI

The Second Circuit stayed its mandate in this case to allow this Court to decide whether to grant certiorari to address two important and recurring questions. The first question potentially impacts every case in which causation is at issue: May a district court preclude a defendant from cross-examining a plaintiff's experts and from presenting evidence of possible alternative causes of a plaintiff's injury on the ground that the defendant has not affirmatively proved that those alternative causes in fact caused the plaintiff's injury. The Second Circuit's ruling affirming the district court's preclusion orders here gave rise to a direct split with the Eleventh Circuit, which held, in *Aycock v. R.J. Reynolds Tobacco Co.*, 769 F.3d 1063 (CA11 2014), that it is reversible error for a district court to preclude a defendant from presenting such alternative causation evidence because it "place[s] the burden of proof as to causation on the wrong party." *Id.* at 1070

This question is well-framed by this case. There is no contention that the possible alternative causes, or "risk factors," at issue are junk science, nor were they excluded on that basis. They are widely noted in the medical literature, accepted by both the National Cancer Institute and the American Cancer Society as potential causes of plaintiff's injury (larynx cancer), and defendant's proffered experts are eminent in their fields. There is also no question that plaintiff herself exhibited these risk factors for her injury. Any doctor investigating the etiology of a patient's larynx cancer would have questioned whether these conditions—including severe gastroesophageal reflux that ulcerated plaintiff's throat—were a po-

tential factor. The district court, however, prevented the jury from hearing *any* of this evidence of potential alternative causes, even going so far as to require Reynolds to "white out" from a National Cancer Institute pamphlet any mention of possible causes of larynx cancer *other than* smoking. The district court reasoned that the defendant—who did not bear the burden of proof on causation—had not affirmatively proved that these widely accepted risk factors for larynx cancer are established to a medical certainty as a cause of plaintiff's injury. As discussed further below, the conflict here is direct: evidence of potential causes, or "risk factors," for an injury is admissible to rebut a plaintiff's proof of causation in the First, Eighth, and Eleventh Circuits, but it may be excluded in the Second Circuit.

The second question presented by this petition affects thousands of pending tort cases—and untold numbers of yet-to-be-filed actions—seeking to impose liability for the sale of cigarettes: Whether a series of federal statutes that regulate tobacco products and manifest Congress' intent that cigarettes continue to be sold in the U.S. preempt state-law tort claims resting on theories that would allow imposition of liability for the sale of any cigarette.

This issue, too, is starkly presented here. The Second Circuit acknowledged, in an initial opinion, that plaintiff's own experts opined that nothing specific to the Salems cigarettes she smoked caused her cancer and that their opinions "would not change if she smoked a different brand"; "any cigarettes would have had the same effect." *Izzarelli v. R.J. Reynolds Tobacco Co.*, 731 F.3d 164, 167 (CA2 2013). The Court of Appeals thereafter held, however, that

plaintiff overcame the federal preemption issue in this case simply by relying on a theory that the "particular blend" of "addictive and carcinogenic ingredients" in Salems could make them "defective" as a matter of Connecticut law. But *every* cigarette has a "particular blend" of nicotine and tar that could be said to distinguish it from all other brands. And so the Second Circuit's ruling permits a State to skirt the preemptive effect of federal law easily through a series of lawsuits that would pick off one brand of cigarettes at a time.

The Court should grant this petition to resolve each of these far-reaching and important questions of federal law.

OPINIONS BELOW

The decision of the United States District Court for the District of Connecticut denying Petitioner R.J. Reynolds Tobacco Company's motion to dismiss is published at 117 F. Supp. 2d 167. The District Court's order awarding punitive damages is reported at 767 F. Supp. 2d 324. The District Court's order awarding offer-of-judgment interest is reported at 767 F. Supp. 2d 335. The District Court's order denying Reynolds' motion for judgment as a matter of law or, alternatively, a new trial, is reported at 806 F. Supp. 2d 516.

The opinion of the United States Court of Appeals for the Second Circuit certifying a question of law to the Connecticut Supreme Court is published at 731 F.3d 164. The Connecticut Supreme Court's opinion answering the certified question is published at 136 A.3d 1232, 321 Conn. 172. The order of the United States Court of Appeals for the Second Cir-

cuit affirming the judgment of the district court as to liability is unpublished, but available online at 2017 WL 2889482.

JURISDICTION

The judgment of the United States Court of Appeals for the Second Circuit for which review is sought was entered on July 7, 2017. On August 30, 2017, the Second Circuit denied the petition for rehearing or rehearing en banc timely filed by Petitioner R.J. Reynolds Tobacco Company. Reynolds timely filed this petition. Because Reynolds seeks review of a case decided by a federal court of appeals, the Court has jurisdiction under 28 U.S.C. § 1254.

PROVISIONS INVOLVED

Rule 401 of the Federal Rules of Evidence provides:

> Evidence is relevant if:
>
> (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and
>
> (b) the fact is of consequence in determining the action.

Rule 402 of the Federal Rules of Evidence provides:

> Relevant evidence is admissible unless any of the following provides otherwise:
>
> - the United States Constitution;
> - a federal statute;
> - these rules; or

- other rules prescribed by the Supreme Court.

Irrelevant Evidence is not admissible.

Rule 403 of the Federal Rules of Evidence provides:

> The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

The Supremacy Clause of the Constitution provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI, § VI, cl. 2.

STATEMENT OF THE CASE

Plaintiff Barbara A. Izzarelli brought this diversity action against Reynolds under the Connecticut Products Liability Act, Conn. Gen. Stat. § 52-572m *et seq*. *See* 28 U.S.C. § 1332. Plaintiff claimed that the Salem King cigarettes she smoked were defectively designed, and that they caused her laryngeal cancer, with which she was diagnosed in 1996, at age 36—and from which she has survived for now more than twenty years. A-92-94[A1]. After a trial, the jury re-

turned general verdicts for Ms. Izzarelli on her claims for strict liability and negligence. A-899-908. In the final, amended judgment, the United States District Court for the District of Connecticut awarded Ms. Izzarelli a total of $28 million in damages, including: an award of compensatory damages in the amount of $7,982,250 (after reduction under Connecticut's comparative fault statute); an award of punitive damages in the amount of $3,970,289.87; and $16,127,086.40 in offer-of-judgment interest. A-2184. The Second Circuit affirmed that judgment. In the process, the Second Circuit both created a circuit split on a recurring question of evidentiary law, *see infra* at __-__, and answered an important federal question of preemption in a way that conflicts with this Court's precedent, *see infra* at __-__, and presents an issue similar to that posed by the pending petition for certiorari in *R. J. Reynolds Tobacco Co. v. Graham*, No. 17-415.

1. Proceedings In The District Court.

The massive judgment in this individual smoker case is premised on two erroneous rulings—either of which warrants this Court's review.

a. Like products-liability plaintiffs everywhere, Plaintiff had to carry the burden of proving to the jury that an alleged defect in the product proximately caused her injury (here, laryngeal cancer). *See Metro. Prop. & Cas. Ins. Co. v. Deere & Co.*, 25 A.3d 571, 579(Conn. 2011); *Theodore v. Lifeline Sys. Co.*, 163 A.3d 654, 664-65 (Conn. App. 2017). Therefore, as with many products-liability cases, evidence that tended to rebut Plaintiff's theory of causation—in other words, to cast doubt on it—was critical to Reynolds' defense.

In the district court, Reynolds repeatedly tried to introduce just this sort of evidence to rebut Plaintiff's theory that smoking cigarettes caused her laryngeal cancer. Among other things, Reynolds offered the testimony of three experts—and related documentary evidence—that Plaintiff exhibited several well-documented risk factors, aside from smoking, which were possible alternative causes for Plaintiff's laryngeal cancer. Those risk factors exhibited in Plaintiff's medical history and records included: human papilloma virus ("HPV"), a long history of severe gastroesophagal reflux that ulcerated plaintiff's throat, genetic predisposition to cancer, and habitual and heavy use of marijuana and cocaine. *See, e.g.*, A-469-72[A2], A-486-90[A3], A-495-502[A4]. Each of Reynolds' proffered experts explained that a series of peer-reviewed articles provided a basis for their opinions that the factors in question were not merely statistically correlated to, but were possible causes of, larynx cancer. *See* A-471-72; A-493-502; A-485-490. Moreover, Reynolds' experts were all prepared to testify that Plaintiff's other risk factors "have to be considered as potential causes" of her laryngeal cancer. *See* A-468, 473, [A5]A-480-82, 490[A6], A-498-502[A7].

There is a great deal of literature evaluating the risks of laryngeal cancer from smoking. Above the age of 50, there is an ascending curve of risk. But there is no study showing any correlation between laryngeal cancer and smoking in individuals as young as plaintiff when she was diagnosed (at age 36). There are, however, studies showing increased risk of laryngeal cancer in young people from other conditions and exposures, including conditions and exposures exhibited by the plaintiff.

Indeed, Reynolds' experts submitted sworn declarations that, on this record, smoking could be *ruled out* as a cause of Plaintiff's laryngeal cancer. *See* A-481[A8] ("Plaintiff cannot show that cigarette smoking was the cause of her laryngeal cancer."). According to one of those experts, "the totality of the evidence points to a non-tobacco etiology for Mrs. Izzarelli's laryngeal cancer," such as one of "her multiple [non-smoking] risk factors." A-473[A9]. Another of the experts would have opined, if the district court had not excluded the testimony, that "Ms. Izarrelli's cancer was not caused by or contributed to by smoking. She is too young and the epidemiology does not support smoking as a cause.... [One] of her multiple risk factors would be the likely cause." A-502[A10].

This unanimity is unsurprising. As all three defense experts were prepared to testify, no study has shown that a 36-year-old female smoker (which was Plaintiff's age at diagnosis) is at increased risk of laryngeal cancer as compared to a non-smoker—regardless of the length of the person's smoking history. A-468[A11]; A-494[A12], A-480-82[A13]. Moreover, as all three experts would have explained, any positive association of smoking and this cancer in older people cannot be used to infer causation in someone as young as Plaintiff was at the time of her diagnosis, because laryngeal cancer is a "disease of aging" and primarily "elderly men." A-468[A14], A-493[A15], A-480-82[A16].

In addition to this expert testimony to rebut Plaintiff's theory of causation, Reynolds also sought to introduce a pamphlet, published by the National Cancer Institute, stating that those "with certain risk factors are more likely to get" laryngeal cancer.

A-2169. The pamphlet defined "risk factors" for laryngeal cancer as "anything that increases your chance of developing this disease." *Id.* And the pamphlet listed some of those risk factors, including: advanced age, male gender, African-American race, alcohol use, poor diet, certain viruses, and gastroesophagal reflux. *See id.* Finally, Reynolds sought to cross-examine Plaintiff's experts concerning the possible alternative causes of laryngeal cancer that Plaintiff herself exhibited.

The district court rebuffed each of these efforts to rebut Plaintiff's proof of causation. The district court held Reynolds' experts to a "reasonable medical probability" standard and, applying that standard, ruled that their proffered testimony was *irrelevant* for two reasons. SPA-26. First, the district court reasoned that Reynolds' "experts could not testify that any of the identified risk factors were [sic] medically established to be a general cause of larynx cancer," notwithstanding that those risk factors are statistically associated with laryngeal cancer. *Id.* Second, the district court stated that Reynolds' experts did not offer to testify to a reasonable medical probability that any of the non-smoking risk factors exhibited by Plaintiff in fact caused Plaintiff's laryngeal cancer. *See* SPA 25-30[A17]. In the district court's words, it barred Reynolds from presenting "evidence of conditions not scientifically-established to cause larynx cancer generally or to have caused [Plaintiff's] cancer specifically." SPA-26.

The district court similarly forced Reynolds to redact the publicly available pamphlet from the National Cancer Institute so that none of the risk factors featured on it and exhibited by Plaintiff, except

for smoking, were visible to the jury, because, the Court concluded, there was no record evidence showing that those risk factors caused Plaintiff's laryngeal cancer. *See* A-885-87[A18]; A-2039-40[A19]. On the same rationale, the district court forbade Reynolds from cross-examining Plaintiff's experts as to whether they had ruled out—or even *considered*—possible non-smoking causes of Plaintiff's cancer. *See* Pet.App.72a-82a.

The only exception the district court made was for HPV, as it allowed Reynolds to submit evidence and cross-examine Plaintiff's experts on whether HPV was a *general* cause of laryngeal cancer. *See* SPA-27[A20]. Yet, even as to this factor, the court prohibited Reynolds from offering evidence that HPV may have been a specific cause of *Plaintiff's* laryngeal cancer. *See* SPA-28-29. The district court barred Reynolds' experts from testifying that a test—the "p16" test—revealed that Plaintiff's tumor contained antibodies for a specific type of HPV linked to laryngeal cancer, on the ground that such testimony was "irrelevant" because a second test—an "in situ" test—was negative for HPV.[1] SPA-29. According to the district court, the in situ test prevented Reynolds from "meet[ing] its burden" of proving that HPV caused Plaintiff's cancer and therefore rendered "irrelevant" evidence and testimony that Plaintiff's laryngeal cancer may have been caused by HPV, and not smoking. SPA-29; *see also id.* ("Indeed, the rec-

[1] The record shows that the in situ test results in false negatives in anywhere from 10% to more than 50% of cases. *See* A-469-70; A-485; A-498.

ord generated by the motions in limine made clear that [Reynolds] had no intention of proving that HPV caused [Plaintiff's] injuries.").

In making each of these evidentiary rulings, the district court effectively shifted the burden to Reynolds, the defendant, to affirmatively prove to a medical certainty that something other than smoking caused Plaintiff's laryngeal cancer. And, in doing so, the district court crippled Reynolds' ability to defend itself. The jury heard the opinion of Plaintiff's experts that smoking caused her laryngeal cancer. Meanwhile, Reynolds was barred from casting any doubt on that theory through evidence of, or even cross-examination concerning, potential alternative causes of Plaintiff's laryngeal cancer.

b. To prevail on her strict-liability and negligence claims of design defect, Plaintiff had to prove that some defect in the cigarettes she smoked proximately caused her laryngeal cancer. *See Metro. Prop. & Cas. Ins. Co.*, 25 A.3d at 579; *Theodore*, 163 A.3d at 664-65. At trial, Plaintiff sometimes argued to the jury that the "defect" in Salems was a reduced nicotine level that caused smokers to smoke more cigarettes to sustain their addiction. *See Izzarelli v. R.J. Reynolds Tobacco Co.*, 731 F.3d 164, 166-67 (2d Cir. 2013).

In attempting to prove her case, Plaintiff relied on the testimony of several experts. But, time after time, her very own experts gave uncontroverted testimony that there was no "defect" unique to Salems that caused her cancer. Instead, Plaintiff's experts testified that her injury was attributable to substances—nicotine and tar—present in *all* cigarettes, and that Salems were no more dangerous than ciga-

rettes of any other brand. For instance, one of Plaintiff's experts asserted that "the brand of cigarette that she smoked made no difference" to his opinion, because he "would have had the same opinion" with respect to "any cigarettes that had tobacco in it." A-831[A21]. A second Plaintiff's expert "admit[ted]" that he "didn't pay attention" to the brand Plaintiff smoked because that detail "didn't matter" to his causation opinion, as cigarettes "are all dangerous." A-762[A22]. And a third expert for Plaintiff testified that he was "not aware of any significant difference in the potential of nicotine in one cigarette or another to cause, so that one cause is more likely to cause addiction. They all do it." A-770.[A23] A fourth expert for Plaintiff admitted that there was nothing that "makes Salems more addictive" than other brands. A-749. Finally, Reynolds' Vice President of Cigarette Product Development (Dr. James Figlar), who testified for both Plaintiff and Defendant, explained that Reynolds has done nothing to make Salems more dangerous than other cigarettes on the market. A-857.

In short, the jury was presented with uncontroverted testimony from at least five witnesses, including four experts called by Plaintiff alone, that Plaintiff's injury was caused by the same harmful characteristics—nicotine and tar—shared by *all* tobacco-burning cigarettes. And they heard Dr. Grunberg, one of Plaintiff's experts, specifically fault Reynolds for failing to produce an "unnatural and altered cigarette" without the nicotine that occurs naturally in tobacco—which equates to faulting Reynolds for selling cigarettes at all. A-736, 739 (testifying that Dr. Grunberg's imagined a cigarette is not sold "any-

where in the world"); T.1413, 2302 (Plaintiff's expert Dr. Cummings testifying that adoption of the proposed design would fundamentally alter the product and that "people will probably not use" the product).

Plaintiff's closing argument crystallized the point for the jury: counsel asserted that cigarettes are unreasonably dangerous because they are addictive and carcinogenic and faulted Reynolds for failing to eliminate nicotine and tar altogether from all of its cigarette brands. *See* A-895-96. Over Reynolds' objection, the jury was then given a "risk-utility" instruction that invited the jury to determine for itself whether cigarettes in general—as a product category and not any specific brand—are unreasonably dangerous and should not be sold in the State of Connecticut.

Having heard that testimony and argument and having been given that instruction, the jury returned a general verdict for Plaintiff on her strict-liability and negligence claims. A-901-02. Reynolds moved for judgment as a matter of law or a new trial. In doing so, Reynolds argued that the jury found Reynolds liable based on purported defects common to all cigarettes, and that its verdict therefore was preempted by federal law allowing the manufacture and sale of cigarettes. The district court rejected this argument, reasoning that "a finding of liability on the basis of Salem cigarettes does not amount to a ban on all cigarettes," but instead "reflects, at most, a finding that, at the time [Plaintiff] smoked Salems, the nicotine delivery system and tar content of Salem[s] were unreasonably dangerous." SPA-497.

2. Proceedings in the Second Circuit.

As relevant to this petition, the United States Court of Appeals for the Second Circuit affirmed the district court's judgment. *See* Pet.App.12a-13a[A24].

a. In addressing the district court's exclusion of Reynolds' alternative causation evidence, the Second Circuit recast the district court's decision. Specifically, the Second Circuit did not directly address the district court's evidentiary rulings on their own terms—i.e., as determinations of irrelevancy based on a ruling that the relevant risk factors were not shown to have caused Plaintiff's laryngeal cancer. Instead, the Second Circuit stated that it was affirming a district court "find[ing]" that the district court never made: that "whatever relevance" Reynolds' alternative causation evidence had was "substantially outweighed by the danger of confusion and unfair prejudice." Pet.App.7a[A25]. Having thus remade the district court's decision, the Second Circuit reasoned that the district court did not abuse its discretion in excluding the evidence under Rule 403 of the Federal Rules of Evidence because Reynolds had failed to prove that Plaintiff's risk factors had been "shown to cause laryngeal cancer." *Id.*[A26].

The Second Circuit similarly concluded that "it was not error" for the district court to "rule that the positive p16 test [for HPV antibodies] was irrelevant." *Id.*. In reaching that conclusion the Second Circuit echoed the district court's reasoning that the negative in situ test prevented Reynolds from proving that Plaintiff's cancer was caused by HPV and, therefore, precluded Reynolds from offering evidence and testimony concerning that possibility.

As described in more detail below, in ruling on the exclusion of Reynolds' evidence of alternative causes, the Second Circuit opened up a division among the Courts of Appeals by departing from the approach taken by three other Circuits in addressing the same issue.

b. The Second Circuit issued two opinions in this case: one certifying a question of state law to the Connecticut Supreme Court, and one affirming the district court's liability judgment after the Connecticut Supreme Court answered the certified question. *See Izarelli*, 731 F.3d at 169; Pet.App.12a-13a. The Second Circuit's two opinions gave differing accounts of the record concerning Reynolds' preemption argument.

In its first opinion, the Second Circuit recognized that "Reynolds elicited testimony that [Plaintiff's] cancer was not specific to Salems; the opinions of Izzarelli's experts would not change if she smoked a different brand." *Izzarelli*, 731 F.3d at 167. But, in its second opinion, the Second Circuit rejected Reynolds' preemption argument on the ground that Plaintiff's "theory at trial was that Salem[s]…—with their particular blend of addictive and carcinogenic ingredients—are unreasonably dangerous, not that cigarettes in general are." Pet.App.12a. The Second Circuit added that the jury received "proper[] instruct[ions] that … Reynolds could not be held liable merely because Salem[s] … contained nicotine and carcinogens." *Id.*.

c. On September 20, 2017, the Second Circuit stayed its mandate pending this Court's disposition of Reynolds' petition for certiorari. CA2 Dkt. 293. In doing so, the Second Circuit recognized that Reyn-

olds' petition presents a "substantial question," Fed. R. App. P. 41(d)(2)(A), such that there is a "reasonable probability that four justices will vote to grant certiorari and a reasonable possibility or 'fair prospect' that five justices will vote to reverse the circuit court's judgment." 20A-341 MOORE'S FEDERAL PRACTICE-CIVIL § 341.14[2] (2015); *see also Maryland v. King*, 133 S. Ct. 1, 2 (2012) (Roberts, C.J., in chambers) (same); *Books v. City of Elkhart*, 239 F.3d 826, 828 (7th Cir. 2001) (Ripple, J., in chambers) (same).

REASONS FOR GRANTING THE PETITION

I. The Court Should Resolve The Circuit Split Concerning Application Of The Rules Of Evidence To Evidence Of Possible Alternative Causes.

In its decision in this case, the Second Circuit created a circuit split concerning an important and recurring issue: How should the admissibility of alternative causation evidence be determined under the Federal Rules of Evidence? Not only that, but the Second Circuit committed error in the process. The Court should grant certiorari to resolve this issue. *See* Supreme Ct. R. 10(a).

A. The Second Circuit's Decision In This Case Opened Up A Circuit Split On An Important And Recurring Question Of Law.

In affirming the district court's ruling excluding Reynolds' evidence of possible alternative causes of Plaintiff's injury, the Second Circuit created a split among the federal courts of appeals. And it did so not in some obscure corner of the law, but on a centrally important and frequently arising issue of causation.

The Second Circuit's exclusion of Reynolds' evidence was based on that Court's understanding of how Rules 401, 402, and 403 of the Federal Rules of Evidence apply to alternative causation evidence. Specifically, the Second Circuit concluded that (1) the evidence was irrelevant because the alternative causes were not "scientifically-established" to cause laryngeal cancer or have caused Plaintiff's laryngeal cancer (F.R.E. 401, 402); and (2) Reynolds' evidence threatened "confusion and unfair prejudice" that "substantially outweighed … whatever relevance" that evidence had (F.R.E. 403). *See* Pet.App.7a; SPA-26; A-507-13; A-885-87. Both of those conclusions are predicated on the view that the admissibility of causation rebuttal evidence turns on whether the defendant has proved that the specific risk factor is "scientifically[ ] established" to cause the disease or injury in question and to have caused the plaintiff's disease or injury.[2]

The Second Circuit's understanding of how the Federal Rules of Evidence apply to alternative causation evidence is diametrically opposed to the understanding of other federal courts of appeals. Indeed, the Eleventh Circuit adopted a directly contra-

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[2] The Second Circuit's conclusion relating to relevance under Rules 401 and 402 obviously rests on that view. And the conclusion relating to "confusion and unfair prejudice" rests on it too, as that approach would require the district court to weigh the purported confusion and prejudice against the evidence's relevance. The Second Circuit made this assessment using a standard that required Reynolds to prove that the potential alternative causes were "scientifically[ ] established." The Second Circuit's prejudice analysis thus depends on the relevance analysis—and stands or falls with it. *See* Pet.App.7a.

ry position in a case materially indistinguishable from this one: *Aycock v. R.J. Reynolds Tobacco Co.*, 769 F.3d 1063 (11th Cir. 2014).

The plaintiff in *Aycock* brought a products liability action against Reynolds on the theory that her husband's cancer and death had been caused by smoking cigarettes. *Id.* at 1066-67. In response, Reynolds proffered expert testimony that "even though the precise cause of death could not be determined," the decedent's alcohol use "could have contributed to whatever disease caused his death." *Id.* at 1071. In other words, Reynolds offered evidence of a risk factor in order to cast doubt on the plaintiff's theory of causation. The district court excluded this evidence on the ground that Reynolds had not established "alternative causes … to a reasonable medical certainty" and thus failed to "prove that [the decedent's] death was caused by something other than smoking." *Id.* at 1070. According to the district court, the alcohol was one of "multiple risk factors," which meant that the cause of death "cannot be determined." *Id.* at 1067.

The Eleventh Circuit reversed. *See id.* at 1072. As the Eleventh Circuit explained, in applying Rules 401, 402, and 403 of the Federal Rules of Evidence, "courts treat evidence produced by plaintiffs to prove causation differently than they treat evidence produced by defendants to rebut causation." *Id.* at 1069. And courts do so for good reason: While plaintiffs bear the burden to *prove* causation, defendants do not. Thus, by "forcing Reynolds to prove that [the decedent's] death was caused by something other than smoking," the district court in *Aycock* had "placed the burden of proof as to causation on the

wrong party." *Id.* at 1070. Because the plaintiff "bore the burden of proving that cigarette smoking more likely than not caused [her husband's] death, and his alcohol use increased the likelihood that his death was caused" by something else, the excluded evidence was "highly relevant and could have been used to rebut the plaintiff's case." *Id.* at 1071. Thus, the Eleventh Circuit held, Reynolds' risk-factor evidence was relevant and admissible under Rules 401 and 402 of the Federal Rules of Evidence.

The Eleventh Circuit then applied Rule 403, balancing the probative value of Reynolds' risk-factor evidence against the risk of prejudice. As the Eleventh Circuit noted, the defendant's risk-factor evidence was "directly relevant" to a key element of the plaintiff's claims, because it "could have caused or made him more susceptible to the illness causing his death." *Id.* at 1072. Such evidence should not be excluded under Rule 403, because its admission is "not unfairly prejudicial" in light of its probative value. *Id.* Thus, "[w]here, as here, the plaintiff bears the burden of proving causation and the defendant is unable to challenge fully the plaintiff's causative theory because of a court's evidentiary ruling, the decision to exclude that evidence should not stand." *Id.* at 1070.

The upshot of all of this is that the Eleventh Circuit applies Rules 401, 402, and 403 to risk-factor or alternative-causation evidence in a way that is directly contrary to the Second Circuit's application of the very same rules to the very same type of evidence. And the Eleventh Circuit is not alone in doing so. In *Wilder v. Eberhart*, 977 F.2d 673 (1st Cir. 1992), for instance, the First Circuit reversed the

district court's exclusion of a defendant's expert testimony concerning "other 'possible' causes of [an] esophageal injury" on the ground that the testimony "could not be expressed in terms of 'probability.'" *Id.* at 675. The First Circuit reasoned that a defendant "need not prove another cause" in order to introduce evidence of potential alternative causes; instead, the defendant may introduce any "credible evidence which tends to discredit or rebut the plaintiff's evidence" on causation." *Id.* at 676. Similarly, in *Allen v. Brown Clinic, P.L.L.P.*, 531 F.3d 568 (8th Cir. 2008), the Eighth Circuit affirmed a district court's decision *not* to exclude a defendant's expert testimony concerning "alternative 'possible' causes," despite the plaintiff's protestations that the expert "failed to offer an opinion as to the actual cause of the" injury. *Id.* at 574. As the Eighth Circuit explained, a defendant's expert on causation need only "undermine the plaintiff's proffered testimony regarding proximate cause," and the plaintiff's argument to the contrary sought to impermissibly "shift[ ] the burden of proof." *Id.*

In sum, the Second Circuit's decision in this case opened up a three-to-one split among the circuits. And that circuit split concerns a critically important question that can arise in any of the many cases in which causation is at issue. The Court should grant this petition to conclusively resolve how courts should apply the Federal Rules of Evidence to a defendant's evidence of possible alternative causes.

B. This Petition Is A Good Vehicle For Settling How The Rules Of Evidence Apply To Evidence Of Possible Alternative Causes.

This petition presents this Court with a good vehicle to settle the circuit split concerning application of the Rules of Evidence to a defendant's evidence of possible alternative causes. To begin, neither the Second Circuit nor the district court articulated alternative bases, beyond those discussed above, for excluding Reynolds' evidence. Alternative holdings, then, will neither obstruct the Court's resolution of the question presented nor render the Court's effort to resolve that question in this case wasted.

Moreover, the exclusion of Reynolds' evidence of possible alternative causes clearly was not harmless. *See, e.g.*, *Malek v. Federal Ins. Co.*, 994 F.2d 49, 55 (2d Cir. 1993) (error is not harmless "'[i]f one cannot say, with fair assurance that the judgment was not substantially swayed by the error'" (quoting *Kotteakos v. United States*, 328 U.S. 750, 765 (1946)). In preventing Reynolds from cross-examining Plaintiff's expert witnesses about Plaintiff's risk factors for laryngeal cancer, the district court left the jury in the dark about whether and, if so, how Plaintiff's experts ruled out possible causes of Plaintiff's laryngeal cancer other than smoking in arriving at their conclusion that cigarettes were the cause.

More fundamentally, the district court's evidentiary rulings misled the jury into the false belief that smoking cigarettes was the *only* risk factor for laryngeal cancer that plaintiff had and thus the *only* possible cause for her cancer. In short, the district court prevented Reynolds from presenting—and the jury from considering—evidence challenging Plaintiff's

theory of causation, a necessary element of Plaintiff's claims for which Plaintiff bore the burden of proof. Thus, if there was error in the exclusion of Reynolds' risk-factor evidence, it was certainly not harmless. *See, e.g.*, *Malek*, 994 F.2d at 55 (errors held not harmless where they concerned issue central to the case for which beneficiary of the error bore the burden).

And there was error. Under Rule 401 of the Federal Rules of Evidence, evidence is relevant—and thus admissible under Rule 402—if it has "any tendency to make a fact more or less probable than it would be without the evidence." Evidence of Plaintiff's long-term exposure to a variety of well-documented risk factors for laryngeal cancer—e.g., severe gastroesophageal reflux that ulcerated her throat—makes it less probable that cigarette smoking caused her laryngeal cancer. *See Aycock*, 769 F.3d at 1071 (excluded risk-factor evidence "increased the likelihood" that something other than smoking caused the smoker's illness).

The lower courts reached their conclusions to the contrary only by erroneously requiring Reynolds to affirmatively *prove* an alternative cause before being allowed to use it to rebut Plaintiff's theory of causation or cross-examining Plaintiffs' experts about it. The district court made the basis of its rulings clear as day: "[I]f [Reynolds] want[s] to suggest that there is an alternative cause, it's [Reynolds'] burden to come forward with record evidence that would permit a jury to find that." *See*[A27] *also* SPA-26 (excluding Reynolds' expert testimony on the ground that the possible alternative causes were "not scientifically-established to cause larynx cancer generally or to

have caused [Plaintiff's] cancer specifically"); A-509 (preventing Reynolds from cross-examining Plaintiff's experts because Reynolds did not "have an expert who says these, this or that or those risk factors were causative"); A-885 (redaction of National Cancer Institute pamphlet was based on these "earlier rulings"). Similarly, the district court barred Reynolds from introducing testimony and evidence—including a test result—concerning HPV's possible causal relation to Plaintiff's laryngeal cancer because, in the district court's view, the record as a whole prevented Reynolds from *proving* that HPV caused Plaintiff's laryngeal cancer. *See* SPA-29 (reasoning that Reynolds "failed to meet its burden" because its experts "could not opine that HPV was a specific cause of [Plaintiff's] cancers," such that Reynolds' alternative-cause evidence concerning HPV was "entirely irrelevant"); *see also id.* ("Indeed, the record generated by the motions in limine made clear that [Reynolds] had no intention of proving that HPV caused [Plaintiff's] injuries."). The Second Circuit's affirmance was based on an adoption of the district court's views. *See* Pet.App.7a (concluding that Reynolds did not "show[]" that risk factors "cause laryngeal cancer"); *id.* (concluding that Reynolds' evidence concerning HPV "was irrelevant" because Plaintiff's evidence proved that she did not have HPV).

The lower courts erred by impermissibly shifting the burden of proof to a defendant. *See Aycock*, 769 F.3d at 1070 (By "forcing Reynolds to prove that [the] death was caused by something other than smoking," the district court "placed the burden of proof as to causation on the wrong party."). Indeed, precisely

because products liability-plaintiffs, in Connecticut and elsewhere, bear the burden to prove that a product caused their injury, *Metro Prop. & Cas. Ins. Co.*, 25 A.3d at 579, evidence that tends to "rebut the plaintiff's case" for causation—including evidence of other possible causes—is "highly relevant" under Rules 401 and 402, *Aycock*, 769 F.3d at 1071.

Nor did the Second Circuit fix matters by reframing the issue in terms of Rule 403. The district court made no such ruling. And, in any event, the Second Circuit's application of Rule 403 rested on its erroneous conclusion that Reynolds' risk factor evidence had minimal relevance because Reynolds had not "shown" that the risk factors "cause laryngeal cancer." Pet.App.7a. That the Second Circuit (like the district court) identified no specific risk of prejudice or confusion confirms as much.

More fundamentally, though, the Second Circuit's application of Rule 403 would amount to error.[3] This alternative causation evidence could be prejudicial only if one argues—essentially as a matter of law—that the jury would be confused if the plaintiff's experts had been cross-examined with relevant, peer reviewed, generally accepted medical literature con-

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[3] On this record, that assumption is incorrect. Even if Plaintiff's illegal drug use in the abstract posed a risk of prejudice, other risk factors—like reflux disease or genetic predisposition—plainly did not. In any event, Reynolds' risk-factor evidence concerning drug use could not have prejudiced Plaintiff here, because Plaintiff and Reynolds had both already put evidence concerning her illegal drug use (and reflux disease, for that matter) before the jury. *See* Tr. 1091, 1185-1201, 1219-34, 2137-42.

cerning possible causes of larynx cancer. As the Eleventh Circuit held in *Aycock*, the probative value of a defendant's risk-factor rebuttal evidence is "high" because it "relate[s] directly" to a key issue going to an element of the plaintiff's claims. 769 F.3d at 1072. Risk-factor evidence therefore generally should not be excluded under Rule 403 because its admission is "not *unfairly* prejudicial" in light of its high probative value. *Id.* (emphasis added). Stated differently, "[w]here, as here, the plaintiff bears the burden of proving causation and the defendant is unable to challenge fully the plaintiff's causative theory because of a court's evidentiary ruling, the decision to exclude that evidence should not stand." *Id.* at 1070. The Second Circuit's contrary approach to Rule 403 is erroneous.

II. The Court Should Reiterate Or Clarify The Preemptive Effect Of Federal Tobacco Legislation.

There is a second question presented by this case that separately warrants either granting certiorari here or holding the petition in this case pending the Court's determination of the petition for certiorari in *R.J. Reynolds Tobacco Co. v. Graham*, No. 17-415. The Second Circuit's decision affirming the judgment in this case conflicts with this Court's decisions discerning the preemptive effect of federal statutes regulating tobacco. *See* S. Ct. Rule 10(c). Specifically, the Second Circuit affirmed a judgment that rests on a duty not to sell cigarettes, despite this Court's recognition of Congress' enacted intent that cigarettes continue to be sold in the United States. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 137, 140 (2000). The Court should grant this petition

to (re-)settle the preemptive effect of federal tobacco statutes—a timely issue impacting thousands of cases currently pending.

A. The Second Circuit Answered An Important Question of Federal Preemption In A Way That Conflicts With Precedent Of This Court.

The jury here found Reynolds liable based on a theory that would allow imposition of liability based on sales of any and all cigarettes. As the Second Circuit observed in its first decision in this case, Plaintiff's own experts testified without contradiction that there was nothing specific to the Salem brand she smoked that caused her cancer or caused her to be addicted to cigarettes. *See Izzarelli*, 731 F.3d at 167. According to Plaintiff's own experts' uncontradicted testimony, then, smoking any tobacco-burning cigarette would have caused Plaintiff's injuries. *See id.* For that very reason, one of Plaintiff's experts faulted Reynolds for failing to make and sell a new kind of "altered" and "unnatural" cigarette without nicotine, which is to fault Reynolds for selling cigarettes, as they have always been known. A-736, 739. And in her closing argument Plaintiff's counsel asked the jury to hold Reynolds liable because cigarettes are addictive and carcinogenic and, thus, unreasonably dangerous. *See* A-895-96. On that record, the jury's verdict imposed liability for the simple act of selling cigarettes—that is, for violating a de facto duty not to sell cigarettes.

For that reason, the jury's verdict runs head first into a preemption problem under the Supremacy Clause. U.S. Const., Art. VI, cl. 2. Conflict preemption bars the imposition of state-law tort liability

based on conduct that Congress has specifically authorized. *See*, *e.g.*, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873–74 (2000) (explaining that federal law impliedly preempts state laws that "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (internal quotation marks omitted)). And, as this Court recognized in *Brown & Williamson*, 529 U.S. 120, Congress has, through a web of "tobacco-specific legislation … enacted over the past" fifty-plus years, manifested its intention that cigarettes remain available on the market. *Id.* at 137, 139-40, 143. Through this finely-woven tapestry of statutes, Congress has "foreclosed the removal of tobacco products from the market"—and it has done so despite awareness of their health risks and addictiveness. *Id.* at 137, 140.[4]

A State therefore may not impose tort liability based on the inherent risks of cigarettes. That is just what Plaintiff argued to the jury in this case, and the judgment for Plaintiff thus runs afoul of the preemptive effect of federal law as recognized in *Brown & Williamson*. In other words, the judgment rests on a theory that conflicts with Congress' goal of ensuring

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[4] *See*, *e.g.*, Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965); Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970); Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175; Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984); Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30 (1986); Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. No. 102-321, 106 Stat. 394 (1992).

that cigarettes "remain on the market" and "continue to be sold." *Brown & Williamson*, 529 U.S. at 139. And that problem does not disappear simply because Plaintiff purported to focus on the unreasonable dangerousness of Salems, and not "cigarettes in general," or because the district court instructed the jury that liability could not be imposed "merely because Salem[s] … contained nicotine and carcinogens." Op. at 9.[5] Indeed, on this record, a reasonable jury could only have imposed liability on a (preempted) basis applicable to all cigarettes, given the repeated and uncontroverted testimony from Plaintiff's own experts that nothing "specific" to Salems caused her injury.[6] *Izarelli*, 731 F.3d at 167.

Moreover, the Supremacy Clause would make reversal the proper course *even if* there were some

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[5] For reasons stated in the text, the jury instructions are irrelevant to the question of whether this petition should be granted. That said, the Second Circuit's description of those instructions is misleading. On the strict liability claim, for example, the district court instructed that "cigarettes are not defective merely because" nicotine or tar "may be inherent in the *tobacco* from which [they] are manufactured." A890 (emphasis added). That instruction leaves open the possibility—touted by Plaintiff and her experts—that finished *cigarettes* are defective because the nicotine and tar has not been removed.

[6] That is particularly true given the district court's instruction on product defects. The district court instructed the jury that it could find Salems defective by determining that "the benefits of the challenged design … outweigh the risks of the product," without regard to whether "there was a feasible safer alternative design." A-890-91. This instruction invited the jury to impose liability on the basis of a finding that the benefits of cigarettes outweigh their risks, in contravention of federal law.

possibility that the jury did not impose liability on a theory applicable to all cigarettes. That result follows from this Court's decisions adopting and applying the common law rule that reversal is required in a civil case if a general verdict may have rested on an invalid theory of liability. *See, e.g.*, *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 384 (1991); *Sunkist Growers, Inc. v. Winckler & Smith Citrus Prods. Co.*, 370 U.S. 19, 29-30 (1962); *United New York & New Jersey Sandy Hook Pilots Ass'n v. Halecki*, 358 U.S. 613, 618-19 (1959); *see also, e.g.*, *Cramer v. United States*, 325 U.S. 1, 36 n.45 (1945) (reversal required in criminal case where general verdict might rest on theory violative of the constitution).

Any argument that the jury imposed liability based on Salem's "particular blend" of nicotine and tar does not dispense with the preemption problem with this judgment. Pet.App.11a. That theory would allow Connecticut (and other States) to remove all cigarettes from the market by letting plaintiffs pick off one brand at a time. After all, every commercially-available cigarette brand contains a "particular blend" of nicotine and tar that could be said to distinguish it from other brands.

In sum, States should not be permitted to impose tort liability for the sale of cigarettes based on the very substances—nicotine and tar—that make a cigarette a cigarette. Doing so conflicts with the federal statutes manifesting Congress' intent that cigarettes continue to be sold and, thus, with the Supremacy Clause. *See Brown & Williamson*, 529 U.S. at 139. Connecticut did just that through the jury's verdict in this case. For that reason, the Second Circuit's

decision affirming the judgment based on that verdict conflicts with this Court's precedent on an important issue of federal law.

B. The Preemption Question Presented In This Petition Is Oft-Arising, Timely, And Important.

The Court should grant this petition to answer the oft-arising preemption question it presents. While many of the courts faced with the question have recognized that federal law preempts state tort claims premised on inherent dangers of tobacco and cigarettes,[7] others have not. Indeed, the *en banc* United States Court of Appeals for the Eleventh Circuit recently reversed a prior panel decision in holding, over an exhaustive dissent, that federal law does not preempt the strict-liability and negligence findings made by the jury in the massive class action decertified in *Engle v. Liggett Group, Inc.*, 945 So. 2d 1246 (Fla. 2006)—despite the fact that those findings may rest on a determination that all cigarettes are defective. *See Graham v. R.J. Reynolds Tobacco Co.*,

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[7] *See, e.g.*, *Pooshs v. Philip Morris USA, Inc.*, 904 F. Supp. 2d 1009, 1025-26 (N.D. Cal. 2012); *De Jesus Rivera v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 148, 154-55 (D.P.R. 2005); *Prado Alvarez v. R.J. Reynolds Tobacco Co.*, 313 F. Supp. 2d 61, 72-73 (D.P.R. 2004), *aff'd by* 405 F.3d 36 (1st Cir. 2005); *Johnson ex rel. Estate of Johnson v. Brown & Williamson Tobacco Corp.*, 345 F. Supp. 2d 16, 21-22 (D. Mass. 2004); *Mash v. Brown & Williamson Tobacco Corp.*, No. 4:03CV0485, 2004 WL 3316246, at *4-6 (E.D. Mo. 2004); *Jeter ex rel. Estate of Smith v. Brown & Williamson Tobacco Corp.*, 294 F. Supp. 2d 681, 685-86 (W.D. Pa. 2003), *aff'd by* 113 F. App'x 465 (3d Cir. 2004); *Insolia v. Philip Morris Inc.*, 128 F. Supp. 2d 1220, 1224 (W.D. Wis. 2000).

857 F.3d 1169, 1186-91 (11th Cir. 2017) (en banc), *petition for certiorari pending*, No. 17-415 (filed Sept. 15, 2017). The Florida Supreme Court recently held likewise earlier this year. *See R.J. Reynolds Tobacco Co. v. Marotta*, 214 So. 3d 590, 600-01, 605 (Fla. 2017).

Those *Engle*-progeny decisions underscore just how often the issue arises and just how important it is. There are more than 3,500 cases pending arising out of the *Engle* decision, each of which seeks millions of dollars in damages. That is on top of the non-*Engle* cases such as this one.

The Court should grant this petition to resolve with finality the important preemption question it presents. Moreover, the Court should decide this case alongside *Graham*, which presents an additional and *Engle*-specific question concerning due process. Alternatively, if the Court does not review the issues presented by this petition but grants certiorari to review the preemption issue presented in *Graham*, Reynolds respectfully submits that this petition should be held pending disposition of the petition in *Graham*. *See, e.g.*, *Flores v. United States*, 137 S. Ct. 2211 (2017) (granting, vacating, and remanding following decision in another case addressing issues implicated in petition).

CONCLUSION

For the foregoing reasons, this Court should grant the petition.

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