No. 15-600

In the
Supreme Court of the United States

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., F/K/A JANSSEN PHARMACEUTICAL, INC., AND/OR JANSSEN, L.P.,

Petitioner,

v.

SOUTH CAROLINA EX REL. ALAN WILSON, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF SOUTH CAROLINA,

Respondent.

On Petition for Writ of Certiorari to the Supreme Court of South Carolina

REPLY BRIEF FOR PETITIONER

WALTER DELLINGER
STEPHEN D. BRODY
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, DC 20006
(202) 383-5300

PAUL D. CLEMENT
Counsel of Record
JEFFREY M. HARRIS
SUBASH S. IYER
BANCROFT PLLC
500 New Jersey Avenue, NW
Seventh Floor
Washington, DC 20001
(202) 234-0090
pclement@bancroftpllc.com

(Additional Counsel Listed on Inside Cover)

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CHARLES C. LIFLAND
O'MELVENY & MYERS LLP
400 South Hope Street
Los Angeles, CA 90071
(213) 430-6000

GREGG W. MACKUSE
CHANDA A. MILLER
DRINKER BIDDLE & REATH LLP
One Logan Square
Suite 2000
Philadelphia, PA 19103
(215) 998-2700

Counsel for Petitioner

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REPLY BRIEF FOR PETITIONER

The South Carolina state courts imposed a $124 million penalty on Janssen for making statements that were neither found to be knowingly false nor shown to have caused any actual harm or injury. That penalty violates the First Amendment, intrudes upon the federal government's exclusive regulatory authority, and is excessive under any conceivable constitutional standard. Given the immense pressure to settle when a company is faced with an amorphous allegation of "unfair" practices (backed by practically limitless liability given the State's claimed flexibility to define a sanctionable "violation"), this case presents a rare and important opportunity for this Court to address the constitutional issues implicated by such proceedings.

In its brief in opposition, Respondent barely addresses the merits of these issues. In particular, Respondent spends little more than a page attempting to explain how a nine-figure civil penalty in the absence of any showing of injury, harm, or reliance can be squared with the Excessive Fines Clause. Like the South Carolina Supreme Court, Respondent asserts (at 18) that this staggering fine is not unconstitutionally excessive because it was "within the $5,000 per violation allowed by SCUTPA." Of course, the total penalty was not $5,000 but $124 million, and the difference reflects not a legislative judgment but the standardless ability of state officials and courts to define the relevant "violation." Respondent's plea for deference to the South Carolina legislature thus rings hollow, and provides no basis for allowing this penalty to evade

constitutional scrutiny under the Excessive Fines Clause.

Respondent also asserts that this Court lacks jurisdiction over the First Amendment and preemption issues because the South Carolina Supreme Court stated that those arguments were not properly preserved under state law. But a procedural ruling by a state court is not an "adequate" basis to foreclose this Court's review unless that ruling has fair support in the record and involves a procedural rule that is firmly established and regularly followed. Neither criterion is met here. The South Carolina Supreme Court's *sua sponte* findings of forfeiture rested on a novel and untenable theory of preservation, were flatly contradicted by the record, and did not prevent the courts below from reaching the merits of both the First Amendment and preemption issues. Any purported finding of forfeiture was plainly not "adequate" to insulate the lower courts' profoundly flawed judgment from this Court's review.

I. Respondent's Brief Defense Of The Decision Below Fails.

A. The massive civil penalty in this case violates the First Amendment because the South Carolina courts punished Janssen for the content of its speech even though the jury had not found that this speech contained a knowing or reckless falsehood. Pet.18-22.

Respondent asserts (at 14) that the decision below "[does] not conflict with this Court's First Amendment jurisprudence." But Respondent does not even cite, much less attempt to distinguish, the two key precedents from this Court. In *Illinois ex rel. Madigan v. Telemarketing Associates*, 538 U.S. 600 (2003), this

Court discussed the critical safeguards that were needed to ensure that a state-law fraud claim did not unduly chill protected speech. The Court found that the statute in question "provide[d] sufficient breathing room for protected speech" because the state needed to prove that "the defendant made a false representation of a material fact *knowing that the representation was false*," and "made the representation with the intent to mislead the listener, and succeeded in doing so." *Id.* at 620 (emphasis added). The Court then reaffirmed in *United States v. Alvarez*, 132 S. Ct. 2537 (2012), that even false speech is generally protected unless it contains "a knowing or reckless falsehood." *Id.* at 2545 (plurality op.); *see also id.* at 2552-53 (Breyer, J., concurring in judgment). Respondent does not dispute that the trial court rejected a proposed First Amendment instruction that would have required a showing of knowing falsity. R.2938, 7665.

Respondent further contends (at 14) that "there was ample evidence in the record to support a determination that petitioner's representations in marketing and promoting Risperdal were false, deceptive, or misleading." But whatever evidence might be in the record, that is not the "determination" the jury was asked to make. All the jury found was that Janssen's statements were "unfair or deceptive" under SCUTPA, which can include statements the jury deems "immoral," "unethical," "oppressive," or offensive to public policy. R.7665. Even if the government has the power to regulate communications "likely to deceive the public," *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563-64 (1980), it does not follow that a state can penalize any speech it deems "unethical" or

"immoral." A finding of liability and massive civil penalty based on that amorphous legal standard is antithetical to the First Amendment and would have the inevitable result of chilling protected speech.

B. Respondent's SCUTPA claim is also preempted because its sole purpose is to *punish* Janssen for its FDA-regulated conduct, thereby encroaching upon regulatory and enforcement authority that belongs exclusively to the federal government. Pet.22-28. Even though Janssen used the same Risperdal label throughout the country, and even though the conduct in question had no special nexus to South Carolina, Respondent asserts the extraordinary power to second-guess the FDA's approval of that label and punish Janssen for its purported transgressions. *Contra* 21 U.S.C. §337(a) (exclusive federal enforcement authority over FDCA, except as provided in §337(b)); *id.* §337(b) (allowing state enforcement of twelve FDCA provisions related to food labeling). Moreover, the courts below penalized Janssen for purported misstatements in the November 2003 letter to healthcare providers even though Janssen had already addressed that issue to the FDA's satisfaction and the FDA considered the matter "closed." R.7315. The FDCA preempts Respondent's attempts to penalize federally-regulated conduct in a manner inconsistent with the FDA's expert judgment and regulatory approach.

Respondent contends (at 16) that *Wyeth v. Levine*, 555 U.S. 555 (2009), "put to rest" any concern about "parallel state enforcement regimes." But the very language that Respondent quotes underscores the limits of this Court's holding in *Wyeth*: "[Congress]

determined that widely available state rights of action provided appropriate relief *for injured consumers*." *Id.* at 574 (emphasis added). Although *Wyeth* recognized the "distinct compensatory function" served by personal-injury suits, *id.* at 579, absolutely nothing in that decision suggests that a state may *directly regulate* the content of an FDA-approved label by imposing massive civil penalties on companies that do not use the state's preferred wording.

Respondent further asserts (at 17) that there is no conflict between the $124 million civil penalty and the FDA's approval of the Risperdal label because the penalty order "did not mandate future corrective action" and Janssen may "satisfy the State's civil penalties without changing a word" in its label. In other words, Janssen can continue to use its FDA-approved label as long as it pays South Carolina over a hundred million dollars for the privilege of doing so. That argument strains credulity, and this Court has already rejected it. "[S]tate regulation can be as effectively exerted through an award of damages as through some form of preventive relief," and "[t]he obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992) (plurality op.) (quoting *San Diego Building Trades v. Garmon*, 359 U.S. 236, 247 (1959)).

C. Finally, the imposition of a $124 million civil penalty in the absence of any showing of injury, harm, or reliance violates the Excessive Fines Clause. Pet.28-37. This Court has already held that "minor" or "minimal" harm to the government cannot justify a

$357,000 civil penalty, *United States v. Bajakajian*, 524 U.S. 321, 339 (1998), and it should follow *a fortiori* that a $124 million penalty without *any* showing of harm is unconstitutionally excessive. As the South Carolina Supreme Court conceded, Janssen's conduct "likely had little impact on the community of prescribing physicians" because the risks associated with atypical antipsychotics were "well known." Pet.App.58; *see* Pet.App.145 (civil penalty was not based on "any measure of damages or ill-gotten gain").

Respondent's only answer on this point (at 17-18) is that judgments about the appropriate penalty "belong in the first place to the legislature" and "[t]he civil penalties assessed by the court below are well within the $5,000 per violation allowed by SCUTPA." That response might have had some force if the courts below had imposed a penalty of $5,000 or less. But the total penalty here was $124 million, a sum that was calculated by multiplying a within-statutory-limit penalty times hundreds of thousands of purported "violations," all of which arose out of the same course of conduct. Respondent cites no case, statute, or legislative history suggesting that the South Carolina legislature ever considered, much less approved, such an outcome or any particular conception of a "violation." And because the scope of the "violation" is the difference between a $5,000 penalty and a $124 million penalty, Respondent's appeal to deference to "legislative judgments" is an appeal to nothing at all. It serves only to underscore the need for a clear holding from this Court that the Excessive Fines Clause requires close constitutional scrutiny of the *total* penalty imposed on the defendant as well as the per-violation statutory penalty.

II. This Court Has Jurisdiction Over Each Of The Questions Presented In The Petition.

Respondent does not dispute that Janssen's Excessive Fines Clause challenge to the judgment below is properly presented for this Court's review. That is reason enough to grant certiorari.

Janssen also fully preserved its First Amendment and preemption arguments in accordance with well-established South Carolina law. Janssen raised its First Amendment objections to the trial court's jury instructions in its requested jury charge, at the charging conference, after the jury was charged, and in its post-trial motion for judgment notwithstanding the verdict or a new trial. Janssen also raised its preemption arguments in its motions for directed verdict and judgment notwithstanding the verdict. Not only did Janssen properly present those arguments, but both of the courts below actually addressed them on the merits. Indeed, even Respondent did not argue below that these issues were forfeited. Respondent nonetheless asserts (at 8-11) that this Court lacks jurisdiction over the First Amendment and preemption issues because the South Carolina Supreme Court stated in its opinion that Janssen had not preserved those issues for appellate review. That argument fails for several reasons.

A. Respondent relies heavily on the doctrine that this Court will not review a question of federal law that "rests on a state law ground that is independent of the federal question and adequate to support the judgment." *Florida v. Powell*, 559 U.S. 50, 56 (2010). But this Court has repeatedly held that a state-law ground of decision is not "adequate" to foreclose this

Court's review if it "properly may be regarded as essentially arbitrary, or a mere device to prevent a review of the decision upon the Federal question." *Enterprise Irrigation Dist. v. Farmers' Mut. Canal Co.*, 243 U.S. 157, 164 (1917). To ensure that there is no "evasion" of this Court's authority to review federal questions, the Court "insist[s] that the nonfederal ground of decision have 'fair support.'" *Stop the Beach Renourishment v. Florida Dep't of Envtl. Protection*, 560 U.S. 702, 725 (2010); *see Broad River Power Co. v. South Carolina*, 281 U.S. 537, 540 (1930) ("constitutional obligations may not be [] evaded" based on an "unsubstantial" state-law ground of decision).

Relatedly, a state-law procedural ruling is not "adequate" to foreclose this Court's review unless the state rule is "firmly established and regularly followed." *James v. Kentucky*, 466 U.S. 341, 348-49 (1984); *see also Beard v. Kindler*, 558 U.S. 53, 60 (2009). "[S]tate procedural requirements which are not strictly or regularly followed cannot deprive [this Court] of the right to review." *Barr v. City of Columbia*, 378 U.S. 146, 149 (1964). The question "whether a state procedural ruling is adequate is itself a question of federal law." *Beard*, 558 U.S. at 60.

As noted above, the crux of Janssen's First Amendment argument is that the trial court erred by rejecting an instruction that would have allowed the jury to find liability only upon a showing of knowing falsity. *See* Pet.18-22. Janssen plainly preserved that argument before the trial court by submitting a proposed jury instruction with the proper standard, R.2938, and requesting that instruction again at the

charging conference, R.2375-78. Janssen then raised that argument yet again by objecting to the verdict form; objecting to the instructions both before and after the jury was instructed; and raising its First Amendment arguments in its motion for a new trial or judgment notwithstanding the verdict. *See* Pet.App.32-33 (acknowledging that Janssen "requested a First Amendment jury instruction and raised the issue in its motion for JNOV"); R.2492, 2497, 2500, 2504, 9457, 9489-91. And, further underscoring that this issue was properly preserved, the trial court actually *ruled* on Janssen's First Amendment arguments. R.2375-78, 2405-07, 2491-93, 2504.

The South Carolina Supreme Court nonetheless held, *sua sponte*, that this issue was not preserved for appellate review because Janssen did not also raise it in its motion for a directed verdict. Pet.App.32-33. But the South Carolina courts have repeatedly held the exact opposite. *See, e.g.*, *South Carolina v. Daniels*, 737 S.E.2d 473, 476 (S.C. 2012) (challenge to jury instructions was preserved for review where appellant "objected to the offensive language both before and after the trial court delivered [its] instruction"); *J.W. Green Co. v. Turbeville*, 210 S.E.2d 743, 744 (S.C. 1974); *Smith v. City of Greenville*, 92 S.E.2d 639, 642 (S.C. 1956); 15 S.C. Jur. Appeal & Error §81 ("Post-verdict motions are not necessary to preserve an otherwise timely and proper objection to a jury charge.").[1] The South Carolina Supreme Court's

[1] None of the cases cited by the South Carolina Supreme Court in support of its forfeiture theory addressed preservation in the context of a challenge to jury instructions. *See*, *e.g.*, *In re*

purported finding of forfeiture thus disregarded, rather than followed, a "firmly established and regularly followed" procedural rule. *James*, 466 U.S. at 348.

The court's analysis of whether Janssen had preserved its preemption argument fares no better. Once again, Janssen raised a preemption defense repeatedly throughout this litigation, including in its motions for directed verdict and judgment notwithstanding the verdict. *See, e.g.*, R.8871, 8880-81, 9031-32, 9047-49. Respondent asserts (at 10-11) that "the Petition presents for the first time an argument that federal law *impliedly*, as opposed to *expressly*, preempts SCUTPA's application to the [November 2003 letter]." But Janssen's briefs below speak for themselves. In its motions for directed verdict and judgment notwithstanding the verdict, Janssen argued that the FDA has primary authority to regulate food and drug labeling under 21 U.S.C. §337(a), and that South Carolina's claims were preempted under *Wyeth* (an implied preemption case), and "barred by federal 'conflict' preemption." R.8606-09, 8612-13, 8871, 8880-81, 9031-32, 9047-49, 9057-59. In those same motions, Janssen also argued that the FDA's response to Janssen's November 2003 letter to healthcare providers preempted further state enforcement efforts related to that letter. R.8607-08, 9031-32, 9051-57. These are the same preemption arguments that Janssen raises in its petition for

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McCracken, 551 S.E.2d 235, 238 (S.C. 2001) (addressing preservation requirement for substantive due process argument).

certiorari. *See* Pet. 22-28 (relying on §337, *Wyeth*, and conflict preemption principles).[2]

B. Even the South Carolina Supreme Court did not act as if its purported finding of forfeiture was "adequate" to support the judgment below. Despite its suggestion that Janssen's First Amendment and preemption arguments were not preserved, the court addressed those issues at length and passed upon the merits of both questions. *See* Pet.App.33-35 (holding that "the First Amendment does not bar imposition of liability on Janssen for violating SCUTPA"); Pet.App.50-55 (SCUTPA claim "is not preempted by the FDCA" and Janssen's implied preemption argument is "without merit").

Indeed, it is highly telling that even Respondent did not argue before the South Carolina Supreme Court that Janssen had forfeited its First Amendment and preemption arguments. *See*, *e.g.*, *Lee v. Kemna*, 534 U.S. 362, 366 (2002) (appellate court's reliance on purported procedural defect was not an "adequate" basis to avoid federal review in part because "[n]either the trial judge nor the prosecutor identified any procedural flaw in the presentation or content of [defendant's] motion for a continuance"). Respondent's counsel tried the case below and had every incentive to raise meritorious forfeiture issues on appeal. The fact that Respondent did not do so strongly suggests that the South Carolina Supreme

[2] Nor did Janssen "concede[]" that it forfeited its preemption arguments. BIO at 10. To the contrary, Janssen emphasized that the South Carolina Supreme Court's finding of forfeiture was "incorrect" because "Janssen's preemption arguments were repeatedly raised throughout this litigation." Pet.28 n.7.

Court's purported forfeiture findings were just a thinly-veiled attempt to insulate its decision from this Court's review.

III. This Case Presents An Ideal Opportunity To Address Important And Recurring Issues That Often Evade Judicial Review.

In urging the Court to deny certiorari, Respondent (at 11-12) focuses heavily on the absence of a square circuit split. But Respondent ignores the fact that cases such as this one rarely proceed to trial, final judgment, and reported decisions. When faced with the potential for a massive damage award based on poorly defined notions of "unfair" or "unethical" conduct, the vast majority of defendants will choose to settle even dubious claims rather than litigate.

Those settlement pressures will surely increase absent review of this case, which provides a roadmap for how a state attorney general (acting through private contingency counsel) can add huge sums to the public fisc even when there is no proof that the defendant's conduct resulted in any actual harm to consumers. This case thus presents an ideal opportunity for the Court to reaffirm and clarify several important doctrinal tools that provide critical protection for defendants in the ever-increasing number of "unfair trade practices" enforcement actions.

CONCLUSION

This Court should grant the petition for certiorari.

Respectfully submitted,

PAUL D. CLEMENT
Counsel of Record
JEFFREY M. HARRIS
SUBASH S. IYER
BANCROFT PLLC
500 New Jersey Avenue, NW
Seventh Floor
Washington, DC 20001
(202) 234-0090
pclement@bancroftpllc.com

WALTER DELLINGER
STEPHEN D. BRODY
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, DC 20006
(202) 383-5300

CHARLES C. LIFLAND
O'MELVENY & MYERS LLP
400 South Hope Street
Los Angeles, CA 90071
(213) 430-6000

GREGG W. MACKUSE
CHANDA A. MILLER
DRINKER BIDDLE & REATH LLP
One Logan Square
Suite 2000
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