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

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RESTATEMENT OF QUESTIONS PRESENTED

The South Carolina Unfair Trade Practices Act (SCUTPA) prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." S.C. Code Ann. § 39-5-20(a). The South Carolina Supreme Court affirmed the liability judgments against petitioner, concluding there was sufficient evidence to support the jury's finding that petitioner willfully violated SCUTPA during its promotion and marketing of Risperdal in South Carolina. The court also held that petitioner failed to preserve its First Amendment and federal preemption issues. Thus, this Court lacks jurisdiction over those two issues, and the sole question presented over which this Court has jurisdiction is the third issue.

The questions presented are:

(1) Whether the First Amendment prevents a state from imposing civil penalties for unfair trade practices against a pharmaceutical company that makes false, deceptive, and misleading statements when marketing a pharmaceutical drug.

(2) Whether the federal Food, Drug, and Cosmetic Act (FDCA) preempts a state enforcement action where such action results in civil penalties for a pharmaceutical company's willful, unfair, and deceptive representations about, and failure to disclose, the safety risks of its drug while promoting and selling that drug in the state; and

(3) Whether the imposition of a $124 million civil penalty, which is far less than the maximum legislatively prescribed penalty, violates the Excessive Fines Clause.

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JURISDICTION

The South Carolina Supreme Court issued an opinion on February 25, 2015. Pet. App. 70–130. That court granted the petition for rehearing and issued a substituted opinion on July 8, 2015. Pet. App. 1–69. On September 17, 2015, the Chief Justice granted petitioner's request for an extension to file a petition for writ of certiorari until November 5, 2015. Petitioner has invoked jurisdiction under 28 U.S.C. § 1257(a). However, as argued herein, most of petitioner's questions presented rest on independent and adequate state grounds, depriving this Court of jurisdiction.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The First, Eighth, and Fourteenth Amendments to the United States Constitution are reproduced at Pet. App. 151–54. The relevant provisions of SCUTPA, Sections 39-5-20 and 39-5-110 of the South Carolina Code, are reproduced at Pet. App. 155–56.

COUNTERSTATEMENT OF THE CASE

For several years, petitioner Ortho-McNeil-Janssen Pharmaceuticals, Inc. employed misrepresentation and deception to market its blockbuster antipsychotic drug, Risperdal. Spurred by fierce competition, petitioner developed and implemented promotional

strategies to protect Risperdal's market share by attempting to distinguish the drug from its competitors on the basis of safety. But, petitioner profoundly (and illegally) overreached in that effort. Petitioner disregarded patients' safety and welfare by deceiving prescribers about positive study results while hiding negative outcomes (or simply by burying entire studies); by undermining Food & Drug Administration (FDA) safety warnings through unauthorized and purposefully deceptive sales communications with doctors; and by failing to update Risperdal's drug label as soon as petitioner knew of serious safety hazards. That deceptive conduct occurred throughout the country, giving rise to civil and criminal claims against petitioner and its parent company brought by the federal government and several states, including South Carolina. The South Carolina Supreme Court, in reviewing the extensive trial record, concluded "Janssen's deceit was substantial." Pet. App. 58. Accordingly, the court affirmed the unanimous jury finding that petitioner violated SCUTPA by engaging in unfair methods of competition through petitioner's misrepresentations about and willful failure to disclose Risperdal's risks and side effects.

Petitioner complains of the Attorney General's lawsuit and the South Carolina Supreme Court's ruling, characterizing the case as "unfortunately not an outlier." Pet. 2. Even more unfortunate for patient safety, however, is petitioner's implicit position that the pharmaceutical industry ought to be immune from states' consumer protection laws. Petitioner's contention is especially distressing because this Court has already recognized the "widespread agreement that resources for postmarketing drug safety work are especially inadequate" and that such limitations have "hobbled" the FDA's ability to improve and expand

that "essential component of its mission." *Wyeth v. Levine*, 555 U.S. 555, 578 n.11 (2009) (quotation and citation omitted). Additionally, despite billions of dollars in payments for federal and state false claim act and deceptive trade violations, pharmaceutical industry practices of concealing and misrepresenting safety information to induce prescribers to write a greater number of prescriptions continue.

A. Petitioner's Unfair and Deceptive Marketing of Risperdal

In 1994, petitioner began selling Risperdal—an "atypical" or "second generation" antipsychotic drug—throughout the United States, including in South Carolina. Yet even before 1994, petitioner knew that Risperdal was associated with a number of serious health risks, including weight gain and related complications—diabetes mellitus (i.e., "Type II" diabetes) in particular—as well as hyperprolactinemia, a condition of elevated prolactin levels in the body.

Nonetheless, Risperdal enjoyed huge sales success after its 1994 launch. In 1997, as competitors began to enter the market, petitioner commissioned a clinical trial (Trial 113) designed to establish Risperdal's superiority over a competitor as to metabolic side effects, including weight gain and diabetes. In 1999, the results of Trial 113 confirmed that Risperdal was no better than Risperdal's leading competitor.

As part of its pattern and practice of deception and disregard for the public, petitioner did not disclose or publish the results of Trial 113. Petitioner continued to claim that Risperdal was a superior drug in spite of Trial 113 and other studies revealing that Risperdal posed substantial diabetes risk, weight gain, and

increased prolactin levels. That increased the long-term risk of developing serious health complications such as diabetic coma, various kinds of cancer, osteoarthritis, cardiovascular disease, and stroke.

In May 2000, when the FDA reviewed clinical data pertaining to metabolic side effects, petitioner did not disclose the results of the Trial 113 study but disclosed only favorable study results. The FDA's review was not thwarted by petitioner's efforts, as the FDA's investigation prompted it to request that product labeling for all atypical antipsychotic medications, including Risperdal, include a warning about hyperglycemia and diabetes.

Putting profit share ahead of consumer safety, petitioner determined it would soften the blow of the diabetes warning message through what is known in the industry as a Dear Doctor Letter (DDL). Petitioner began disseminating the DDL on November 10, 2003, but did not include in the letter the text of the new diabetes/hyperglycemia warning. Instead, petitioner resorted to its familiar practice of misrepresentation by stating that Risperdal was often associated with no risk of diabetes or a lower risk of diabetes.

The deceptive letter did, however, prompt a "Warning Letter" from the FDA noting that the DDL was "false or misleading" and that it misrepresented pertinent scientific evidence. Faced with evidence of its dishonesty, petitioner issued a corrective letter admitting that it had "omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims . . . ."

Petitioner's deceit was not limited to its DDL. In a plain effort to protect its market share and avoid financial repercussion, at no time from 1994 until

November 2003 did petitioner put a Warning for diabetes or hyperglycemia on Risperdal's label. Petitioner was directed to add such a Warning by the FDA in September 2003. Petitioner also failed to update Risperdal's label to include a boxed warning regarding the risk of stroke, cardiac arrest, and sudden death in the elderly until February 2005, and at no time from 1994 until August 2008 did petitioner include a Warning of hyperprolactinemia risks on Risperdal's label. Petitioner knew about Risperdal's strong association with all of those serious hazards years before it added any Warnings.

At virtually every stage during the marketing and promotion of Risperdal in South Carolina, petitioner traded financial benefit for public detriment. In this pursuit, petitioner willfully, unfairly, and deceptively represented and failed to disclose the safety risks of its drug in promoting and selling Risperdal in South Carolina.

B. Petitioner's Violations of SCUTPA

South Carolina's "legislature intended . . . [SCUTPA] to control and eliminate the large scale use of unfair and deceptive trade practices within the state of South Carolina." *Noack Enters., Inc. v. Country Corner Interiors, Inc.*, 351 S.E.2d 347, 349 (S.C. Ct. App. 1986) (citations and internal quotation marks omitted). Specifically, SCUTPA equips the South Carolina Attorney General with tools necessary to control and eliminate large-scale, unfair, and deceptive prescription drug marketing and promotional practices in South Carolina.

In light of petitioner's vast and pervasive deception, in April 2007, the Attorney General of South Carolina filed a state law claim against petitioner,

seeking civil penalties under SCUTPA. After an extensive twelve-day trial, the jury returned a verdict on liability in favor of the State. The State's SCUTPA claims and the jury's findings had two distinct factual bases.

First, the jury unanimously found that petitioner had willfully engaged in unfair or deceptive acts in the conduct of trade or commerce in South Carolina in relation to the DDL that petitioner disseminated to Risperdal prescribers and others in the State. Second, the jury unanimously found that Risperdal's product label violated SCUTPA from 1994 until 2007. Specifically, the State proved at trial that petitioner willfully omitted Warnings on Risperdal's label as to diabetes/hyperglycemia and hyperprolactinemia safety risks from 1994 until 2007.

After dismissing the jury, the trial court separately and thoroughly considered evidence and arguments during a two-day hearing to determine the appropriate penalty for petitioner's SCUTPA violations. The lower court awarded a penalty for each of the Risperdal sample boxes found to have contained a deceptive product label and distributed by petitioner in South Carolina. The trial court also awarded a penalty for each DDL mailed to South Carolina addresses and for each sales call occurring during the relevant time period. Each penalty levied by the lower court was well within the statutory range permitted by SCUTPA.

C. The South Carolina Supreme Court Affirms Petitioner's Liability Under SCUTPA

On February 25, 2015, the South Carolina Supreme Court affirmed the jury's verdict, although it substantially reduced the civil penalty levied against

petitioner. On July 8, 2015, the court withdrew, substituted, and refiled its opinion. In the substituted opinion, the court further reduced the penalty award but again affirmed that petitioner's willful, deceptive conduct violated SCUTPA.

The court specifically held that "[t]he jury verdict, which is supported by evidence, bears out the State's allegations that Janssen engaged in a systematic pattern of deceptive conduct." Pet. App. 21. Contrary to petitioner's representation, while the court held that actual harm resulting from deceptive conduct was not a necessary element of an Attorney General directed claim, there was no finding that "zero harm" resulted from petitioner's deceptive conduct. *See* Pet. App. 58.

The court also held that most of petitioner's issues raised on appeal were not preserved at trial. The substituted opinion remitted civil penalties on the labeling claim to $22,844,700, and remitted civil penalties on the DDL claim to $101,480,000. In total, the South Carolina Supreme Court reduced the lower court's civil penalty award by more than 60 percent.

REASONS FOR DENYING THE PETITION

The Court should deny the petition for a writ of certiorari. The Court lacks jurisdiction over most of the issues raised by petitioner as they were not preserved below and, thus, rest on independent and adequate state grounds. Further, as to any remaining issues, certiorari is unwarranted because the South Carolina Supreme Court's decision does not conflict with any decision of other courts, the petition utterly fails to identify an important unresolved question of federal law that needs to be decided by this Court, and the issues were properly decided below.

I. The Court Lacks Jurisdiction Over Petitioner's First Amendment and Preemption Claims.

The Court should deny the petition for a writ of certiorari because it lacks jurisdiction over the First Amendment and preemption issues raised in the petition for a writ of certiorari.

"It is a long-settled rule that the jurisdiction of this Court to re-examine the final judgment of a state court can arise only if the record as a whole shows either expressly or by clear implication that the federal claim was adequately presented in the state system." *Webb v. Webb*, 451 U.S. 493, 496–97 (1981) (citations omitted); *accord Adams v. Robertson*, 520 U.S. 83, 87-88 (1997). Indeed, "[t]his Court will not review a question of federal law decided by a state court if the decision . . . 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) (quoting *Coleman v. Thompson,* 501 U.S. 722, 729 (1991)).

Under South Carolina law, there is no "plain error" rule for appeals, and it is incumbent on trial counsel to preserve issues for appellate review. *Elam v. S.C. Dep't of Transp.*, 602 S.E.2d 772, 780 (S.C. 2004). South Carolina's issue preservation rules require not only that an issue be raised but also that it be ruled on by the trial court for it to be preserved for appellate review. *Herron v. Century BMW*, 719 S.E.2d 640, 642 (S.C. 2011). "Constitutional arguments are no exception to the preservation rules, and if not raised to the trial court, the issues are deemed waived on appeal." *Id*. (citations omitted). Even when the parties themselves have not argued error preservation, South Carolina appellate courts are not precluded from finding an issue unpreserved. *See, e.g*., *Atlantic Coast*

Builders & Contractors, LLC v. Lewis, 730 S.E.2d 282, 285 (S.C. 2012) ("If our review of the record establishes that an issue is not preserved, then we should not reach it. . . . [W]e should follow our longstanding precedent and resolve the issue on preservation grounds when it clearly is unpreserved.").

Additionally, under South Carolina law, a party may not raise new grounds in a motion for judgment notwithstanding the verdict that were not raised in a motion for directed verdict. *See* S.C. R. Civ. P. 50(a)–(b). South Carolina appellate courts have consistently adhered to this longstanding procedural rule of error preservation. *See, e.g.*, *In re McCracken*, 551 S.E.2d 235, 238 (S.C. 2001); *Collins Cadillac, Inc. v. Bigelow-Sanford, Inc.*, 279 S.E.2d 611, 612 (S.C. 1981); *Guider v. Churpeyes, Inc.*, 635 S.E.2d 562, 566 n.2 (S.C. Ct. App. 2006).

A. First Amendment

The South Carolina Supreme Court unanimously concluded that, as with many other issues advanced on appeal, petitioner did not properly preserve its First Amendment argument for appellate review. Pet. App. 32–33. Based on its review of the record, the South Carolina Supreme Court concluded that petitioner "failed to raise any First Amendment issues in its motion for a directed verdict," and the failure to do so did not preserve the claim for appellate review. Pet. App. 33. In an inappropriate and baseless attack on the South Carolina Supreme Court, petitioner plainly acknowledges the holding that it failed to preserve its First Amendment argument. Pet. App. 22 n.5.

The South Carolina Supreme Court's conclusion that petitioner failed to preserve its First Amendment argument was based on a "firmly established and

regularly followed" state procedural rule, independent of its merits determination of the issue. *See Walker v. Martin*, 562 U.S. 307, 316 (2011) (quoting *Beard v. Kindler*, 558 U.S. 53, 60–61 (2009)). Thus, this Court does not have jurisdiction to review petitioner's First Amendment claim because resolution of that issue would not affect the judgment. *See Coleman*, 501 U.S. at 729.

B. Preemption

Petitioner also concedes that it did not preserve for appeal its preemption arguments generally. Pet. App. 28 n.7. For the reasons stated above, this Court should not reach the preemption issue because it was decided on state law grounds adequate to support the judgment. Additionally, and aside from that complete waiver, the Petition presents for the first time an argument that federal law *impliedly*, as opposed to *expressly*, preempts SCUTPA's application to the DDL.

In the court below, petitioner limited its DDL preemption argument to express preemption. *See* Pet. App. 50 ("Janssen argues . . . that the DDL claim is barred by the express preemption provision of the FDCA, 21 U.S.C. § 337(a) (2006).")). In this Court, petitioner does not re-raise its express preemption argument. It instead urges that implied conflict preemption forecloses the State's claims, including the DDL claim. In part, petitioner argues that because it satisfied the FDA with its "corrective" letter, the penalties attributable to the DDL impliedly conflict with FDA decision-making. And, petitioner now seeks shelter from *Wyeth v. Levine* in Justice Breyer's concurrence by speculating that state-law civil penalties applied to the DDL might raise drug prices beyond

what sick people could afford, thereby (arguably) raising an implied conflict between SCUTPA and FDA regulation. Pet. App. 27–28.

But petitioner never raised those contentions in the trial court *or* the South Carolina Supreme Court, and this Court should not consider them for the first time. This is "a court of final review and not first view." *Adarand Constructors, Inc. v. Mineta*, 534 U.S. 103, 110 (2001) (quotation and citation omitted); *id*. at 109 ("We ordinarily do not decide in the first instance issues not decided below." (internal quotation marks and citation omitted)). Like its other preemption arguments, the contention that FDA regulation impliedly prevents South Carolina from penalizing petitioner for its false and deceptive DDL is waived.

II. Petitioner Has Failed To Present Any Compelling Reason For Granting Certiorari.

The petition for a writ of certiorari does not raise any question that warrants review by this Court. "A petition for a writ of certiorari will be granted only for compelling reasons." U.S. Sup. Ct. R. 10. Here, there are no compelling reasons to grant certiorari.

The South Carolina Supreme Court's decision does not "conflict[] with [a] relevant decision[] of this Court" or "of another state court of last resort or of a United States court of appeals" — and the petition does not contend otherwise. U.S. Sup. Ct. R. 10(b), (c). Instead, the South Carolina Supreme Court correctly applied South Carolina law governing unfair and deceitful marketing to affirm the jury's factual findings and reduce the trial court's award. The court reached its decision after thoroughly reviewing the tens of

thousands of pages in the record of this case spanning eight years.

Lacking any credible basis for asserting a compelling reason for certiorari, and making no direct constitutional challenge to SCUTPA, petitioner spends the gravamen of its brief attacking the philosophy behind state enforcement actions for unfair trade practices. However, SCUTPA is a critical mechanism by which the Attorney General can protect the public by regulating unfair or deceptive acts or practices affecting commerce, which are illegal under South Carolina law. *See Singleton v. Stokes Motors, Inc.*, 595 S.E.2d 461, 466 (S.C. 2004) (citing S.C. Code Ann. § 39-5-20(a) (2002)); *see also Levine*, 555 U.S. at 624 (recognizing "the historic primacy of state regulation of matters of health and safety"). The South Carolina Supreme Court made the necessity of SCUTPA, and state unfair trade practice claims generally, clear in its well-reasoned opinion:

> Because of its deceptive conduct in the marketing of Risperdal, Janssen has been the subject of litigation throughout the country. Indeed, the deceptive marketing that gave rise to this action also formed the basis of federal civil and criminal claims against Janssen and its parent company for, among other things, making "false statements about the safety and efficacy of Risperdal." . . . When viewed objectively based on the jury verdict, Janssen over the course of many years consciously engaged in lies and deception in the marketing of Risperdal.

Pet. App. 64. Moreover, petitioner's thinly veiled attacks on the South Carolina Supreme Court's integrity and the legislative wisdom of SCUTPA

underlie its failure to provide any credible reasons why certiorari is warranted in this case.

This case involves nothing more than a state supreme court applying long-established state-law principles, within the ambit of its historic primacy and constitutional authority, to quell petitioner's disregard for the health and welfare of the citizens of South Carolina.

III. Petitioner's Substantive Arguments Fail On the Merits.

Even if this Court were to look beyond petitioner's jurisdictional deficiencies and its failure to provide any compelling reasons for granting certiorari, petitioner's arguments lack substance and merit.

A. First Amendment

Petitioner erroneously contends the South Carolina Supreme Court improperly held that "Janssen may not avail itself of the protections of the First Amendment." Pet. 18. However, petitioner mischaracterizes the South Carolina Supreme Court's resolution of its First Amendment argument.

Even if petitioner's First Amendment arguments were not jurisdictionally barred, the South Carolina Supreme Court alternatively held that, because there was evidence to support the jury's finding that petitioner's conduct in the conduct of its trade or commerce was unfair and deceptive, "Janssen may not avail itself of the protections of the First Amendment to shield itself from its deceptive conduct and false representations." Pet. App. 34–35.

The South Carolina Supreme Court's conclusion that the First Amendment did not immunize petitioner from liability under SCUTPA did not conflict with this Court's First Amendment jurisprudence, nor did it decide an unsettled question of federal law. SCUTPA only targets "acts or practices in the conduct of any trade or commerce," S.C. Code Ann. § 39-5-20(a), and, while commercial speech does receive First Amendment protection, it is well-settled that "[t]he government may ban forms of communication more likely to deceive the public than inform it, or commercial speech related to illegal activity." *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563–64 (1980) (internal citations omitted). Also, petitioner incorrectly suggests that the South Carolina Supreme Court held that petitioner was not entitled to any First Amendment protections whatsoever. The court simply concluded that, because 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, there was no First Amendment bar to finding that petitioner violated SCUTPA.

B. Preemption

The FDCA does not preempt state laws prohibiting unfair and deceptive representations in drug labeling, including letters to doctors like petitioner's November 2003 DDL. Petitioner cannot bear the heavy burden to show that Congress intended to displace the State's sovereign authority to regulate for the safety and welfare of its citizens. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Further, *Levine* arguably left open a solitary avenue for a drug company to prove implied conflict preemption of state law: the manufacturer must show

"clear evidence" that the FDA considered and rejected the specific, stronger warnings that the State urged here. *See Levine,* U.S. at 571. But petitioner makes no mention of such "clear evidence," much less attempts to satisfy that burden.

Petitioner instead attempts to distinguish *Levine* on the basis of "compensation for actual injuries" through a state-law tort action versus state-law consumer protection actions. Pet. 23. But, petitioner makes no effort to show that Congress intended to differentiate private tort remedies from statutory consumer remedies brought by the states, citing nothing in the FDCA's text or history indicating that a patient's suit for injuries suffered due to inadequate labeling information (*Levine*) is more consistent with the FDCA's purposes than a state's effort to redress the dissemination of willfully false and misleading information on behalf of its citizens. In fact, *Levine* recognized that the purposes of the FDCA and state-law consumer protections are aligned: "[S]tate-law remedies *further consumer protection* by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." 555 U.S. at 574 (emphasis added). And, if anything, claims brought by state officials are *less* vulnerable to preemption than individual common-law tort claims. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) ("[O]ne would think that tort law . . . is less deserving of preservation. . . . [I]t is implausible that [federal law] was meant to grant greater power . . . to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." (internal quotation marks omitted)).

With regard to the remainder of petitioner's conflict preemption arguments, petitioner presents no previously undecided issues. *Levine* put to rest the concern about "parallel state enforcement regimes." Pet. 24. The Court in *Levine* decided that Congress must have *intended* a parallel federal-state enforcement scheme. 555 U.S. at 574 ("[Congress] determined that widely available states rights of action provided appropriate relief for injured consumers."); *id.* at 581 (recognizing the "longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies"). Petitioner further protests that the State's lawsuit "empowered lay juries" to determine the sufficiency of a particular label. Pet. 24. But *Levine* rejected that argument as well, noting that even the FDCA "contemplates that federal *juries* will resolve most misbranding claims," signifying "the FDA's belief that a drug is misbranded is not conclusive." *Id.* at 570 (emphasis added) (citations omitted). Petitioner also condemns the imposition of civil penalties when it had (allegedly) done "nothing more than use the label that was expressly authorized by the FDA" Pet. 25. But, of course, *Levine* dispelled the notion that FDA approval shields manufacturers from state-law liability. *Id.* at 568, 574. Lastly, petitioner laments that while any state involvement in drug labeling is intrusive enough, it considers the award of state civil penalties "utterly intolerable." Pet. 26. But, the FDCA does not preempt complementary state laws that promote the same objectives as federal law. *Id.* at 579; *cf. Riegel*, 552 U.S. at 330 (noting that the Medical Device Amendments' express preemption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.").

Finally, the Court should recognize that the judgment in this case did *not* restrict or mandate the use of any particular Risperdal label and did not touch upon the Risperdal label in use now or at the time of trial. Thus, petitioner's alleged concerns over "force[d] changes to wording" of drug labels and state-mandated "warnings that even the FDA" would have refused ***never arose in this case***. Pet. 25–26. And, under the circumstances of this case, such issues never would arise. Petitioner may satisfy the State's civil penalties without changing a word in Risperdal's labeling. In keeping with SCUTPA's purpose, the penalties award rightly "discourage[d] . . . unfair or deceptive acts in the conduct of any trade or commerce," but it did not mandate future corrective action. *Taylor v. Medenica*, 503 S.E.2d 458, 460 (S.C. 1998); *cf. Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 445 (2005) ("[A]n event, such as a jury verdict, that merely motivates an optional decision is not a requirement."). It is not surprising, then, that petitioner never explains why or how it would be impossible to comply with both South Carolina unfair trade practices law and federal drug regulation, though such a showing is mandated. *Levine*, 555 U.S. at 573, 589.

C. Excessive Fines

Finally, Petitioner fails to show the fines in the case were constitutionally excessive. This Court will only find a violation of the Excessive Fines Clause if the penalties are "*grossly* disproportional to the gravity of a defendant's offense." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998) (emphasis added). Such an inquiry recognizes that "judgments about the appropriate punishment for an offense belong in the first place to the legislature." *Id*. at 336 (citations omitted).

These legislative determinations regarding the assessment of civil penalties "represent the collective opinion of the American people as to what is and is not excessive." *United States v. 817 N.E. 29th Drive*, 175 F.3d 1304, 1309 (11th Cir. 1999).

The civil penalties assessed by the court below are well within the $5,000 per violation allowed by SCUTPA and are well supported by the facts. Indeed, the opinion below is replete with findings of fact demonstrating petitioner's egregious conduct. *See, e.g.*, Pet. App. 58 ("In order to maintain its market share, Janssen's furtive efforts to mislead prescribing physicians about the risks and side effects associated with Risperdal were reprehensible and in callous disregard for the health and welfare of the public."); *see also* Pet. App. 78–83. As the South Carolina Supreme Court aptly concluded, "the penalty in this case, now substantially reduced, bears a rational relationship to the gravity of Janssen's conduct in perpetuating a marketing scheme in South Carolina designed to be unfair and deceptive under our law." Pet. App. 62.

Constrained by those findings of fact, petitioner attempts to use its Eighth Amendment challenge as a vehicle to attack the state court's determination of the *number* of SCUTPA violations. *See, e.g.,* Pet. 33 ("But while the selection of the number of violations was essentially arbitrary, it drove the South Carolina Supreme Court's Excessive Fines analysis and rendered it meaningless."). Of course, the quantity of violations is fundamentally a fact issue and one based on state-law rules of statutory interpretation. As such, it is not appropriate for this Court's review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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