No. 15-600

IN THE

Supreme Court of the United States

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., F/K/A JANSSEN PHARMACEUTICALS, 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 a Writ of Certiorari to the Supreme Court of South Carolina

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE* [1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies.[2] PhRMA's member companies research, develop, and manufacture medicines that allow patients to live longer, healthier, and more productive lives. In 2014 alone, they invested an estimated $51.2 billion to discover and develop new medicines.[3] PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as an *amicus curiae* in cases before this Court, such as *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156 (2012), and *Astra USA, Inc. v. Santa Clara County*, 131 S. Ct. 1342 (2011).

This case presents constitutional questions of critical importance to PhRMA members: whether state attorneys general, wielding expansive "unfair and

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[1] No counsel for a party authored this brief in whole or in part, and no person or entity, other than PhRMA and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Petitioner's counsel and respondent's counsel each were given timely notice of this brief pursuant to Rule 37.2, and consented to its filing.

[2] A list of PhRMA's current members appears at http://www.phrma.org/about/member-companies. Petitioner Ortho-McNeill-Janssen Pharmaceuticals, Inc.'s corporate parent, Johnson & Johnson, is a member of PhRMA but has not contributed financially to the preparation of this brief.

[3] PhRMA, *2015 Profile: Biopharmaceutical Research Industry* 35 (2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.

deceptive trade practices" statutes, may impose massive civil penalties based on the content of pharmaceutical manufacturers' First Amendment-protected and FDA-regulated speech. PhRMA members share a vital interest in protecting a robust flow of truthful, non-misleading information about FDA-approved drugs. This truthful information enables trained healthcare professionals, exercising independent medical judgment, to decide on appropriate treatment for their patients. PhRMA members likewise need clear, uniform standards that avoid conflict between state-law obligations and federal regulation.

This is not a tort case. There is no allegedly injured plaintiff seeking compensation. This is purely a case where South Carolina seeks to regulate what FDA regulates already. By sanctioning the massive penalties awarded against petitioner Ortho-McNeill-Janssen Pharmaceuticals, Inc. ("Janssen") without any showing of harm to the State or anyone else, the South Carolina Supreme Court's decision intrudes on a regulatory domain reserved exclusively to the federal government. It invites potentially crippling fines untethered to any harm or culpable conduct. And it tramples core principles of free speech that protect PhRMA's members.

The importance of this case to PhRMA and to other participants in the healthcare sector is magnified many times by the proliferation of cookie-cutter cases in state after state. Fueled by contingent-fee arrangements with private plaintiffs' lawyers, state attorneys general across the country increasingly are brandishing indeterminate state statutes to threaten, and to impose, huge penalties against pharmaceutical companies for conduct that the states' lawyers claim is prohibited by FDA's standards, but that FDA,

applying its own standards, allows. The number of such cases is potentially limitless, and the impact of that potential on the nation as a whole and on PhRMA's members in particular, is immediate—in the chill of truthful speech, protected under the First Amendment, and in the interference with FDA's regulation. PhRMA's members have a pressing need for this Court's review to rein in the worst of these abuses.

INTRODUCTION AND SUMMARY OF ARGUMENT

The U.S. Food and Drug Administration comprehensively regulates the approval, marketing, and sale of pharmaceutical products under the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* The Agency has promulgated regulations, issued guidance, and developed other regulatory practices through decades of interactions with pharmaceutical manufacturers.[4]

FDA's regulatory responsibilities include evaluating whether marketing of pharmaceutical products is "false or misleading." *See, e.g.*, 21 U.S.C. § 352(a), (n); id. § 355(d), (e). If FDA believes that a company's marketing is false or misleading, the Agency's options for

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[4] *See, e.g.*, 21 C.F.R. pt. 202 (regulating prescription drug advertising); FDA, Guidance Documents for FDA-Regulated Products, http://www.fda.gov/RegulatoryInformation/Guidances/default.htm; FDA, Regulatory Procedures Manual, http://www.fda.gov/ICECI/compliancemanuals/regulatoryproceduresmanual/default.htm ("FDA Manual") (describing internal procedures used in FDA regulatory and enforcement matters); FDA, Manual of Compliance Policy Guides, http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm (describing FDA standards and procedures applied when determining industry compliance).

addressing the issue range from simple persuasion to threatened regulatory proceedings, to "sequential or concurrent FDA enforcement actions such as recall, seizure, injunction, administrative detention, civil money penalties and/or prosecution to achieve correction." FDA Manual at 4-1-1. FDA's Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications ("DDMAC")—an office of about 40 employees within one of the six FDA Centers responsible for different regulatory areas—was the front line in these efforts. *See* Wayne L. Pines, FDA Adv. & Prom. ¶ 220 (2009).

One way that DDMAC (and its successor FDA entity) exercises regulatory oversight and conveys its views regarding drug marketing materials is through "warning letters" issued to drug manufacturers. FDA's Regulatory Procedures Manual provides that such warning letters are "informal and advisory." Further, the Manual makes clear that these letters represent only a first step in a dialogue between FDA and pharmaceutical manufacturers regarding their communications with doctors and patients. FDA Manual at 4-1-1. FDA also has made clear that a warning letter is many steps removed from "final agency action" reflecting an Agency finding of misconduct. To be sure, FDA has more forceful weapons it can deploy—subject to additional procedural safeguards—as it moves toward such a definitive finding. Both FDA and the pharmaceutical industry, however, favor accommodation. FDA strongly prefers to achieve voluntary compliance without the disruption, cost, and delay entailed in more draconian steps. The Agency thus carefully calibrates how it uses these enforcement tools, marshaling its limited resources to best advantage in advancing the public health.

In this case, FDA requested in September 2003 that *all* manufacturers of second generation or "atypical" antipsychotic medications modify their product labels to include *exactly the same warning* for a risk of diabetes and hyperglycemia. Janssen marketed one of those drugs, Risperdal, but did not believe that it posed the same level of risk as other drugs in the class. Janssen nonetheless updated Risperdal's label to include the new warning. In addition, after discussing the issue with FDA, Janssen in November 2003 sent a letter to healthcare providers nationwide, enclosing Risperdal's new label and noting the evidence that suggested a different risk profile for the drug as compared to other atypical antipsychotic drugs. Several months later, DDMAC sent Janssen a warning letter alleging that the Company's November 2003 letter to healthcare providers contained "false or misleading" statements in violation of the FDCA. Janssen conferred at length with DDMAC and, while still disputing the allegations in the warning letter, agreed to send a follow-up letter informing healthcare providers of DDMAC's position. DDMAC closed the matter in October 2004 and has taken no action since.

That should have been the end of the matter, but instead it was only the beginning. The South Carolina Attorney General brought an enforcement action asserting that Risperdal's FDA-approved label and Janssen's November 2003 letter were "unfair" or "deceptive" in violation of the State's "unfair and deceptive trade practices" statute. At trial, the State offered no evidence that Janssen's statements actually misled any healthcare provider in South Carolina, that they harmed any patient in the State, or that they caused the State itself any loss. On the State's theory, it did not matter whether Janssen's drug was harmful

or miraculous. The jury instructions, moreover, required no finding that Janssen's speech was actually false, or that Janssen had any intent to deceive. And the instructions made clear that the State did not need to prove reliance by any physician or harm to anyone.

Given the lack of any meaningful limitation on liability, the jury unsurprisingly found that Risperdal's FDA-approved label and Janssen's November 2003 letter to physicians were "unfair" or "deceptive" in violation of South Carolina's statute. The trial court imposed a staggering $327 million civil penalty, with fines ranging from $400 to $4000 for *each* of (a) 228,447 sample boxes of Risperdal distributed in South Carolina with the drug's FDA-approved label, without even a showing that they were distributed to patients, (b) 7,184 copies of Janssen's November 2003 letter sent to healthcare providers in South Carolina, and (c) 36,372 sales calls to South Carolina in the period after November 2003—even though the subject of the November 2003 letter indisputably was not discussed during the vast majority of the calls. Pet. 8-11.

The South Carolina Supreme Court remitted the various per-violation amounts to a total civil penalty of $124 million, and otherwise affirmed. As Janssen's petition amply demonstrates, South Carolina's application of its "unfair and deceptive trade practices" statute punishes protected speech in violation of the First Amendment, runs headlong into FDA's exclusive regulatory authority over labeling and marketing of pharmaceutical products, and imposes an unconstitutionally excessive fine. These grave constitutional errors alone would merit review in a case of this magnitude. But there is more that makes this decision important on a national scale.

Absent this Court's review, the South Carolina Supreme Court's decision will encourage 50 roving state regulators to upend important aspects of the federal scheme for enforcing the FDCA. Litigation was proliferating before the decision; now it could redouble. FDA has issued thousands of warning letters in the past and continues to issue them, not only for drugs, but also medical devices and biologics, and not only for promotion and labeling, but also for manufacturing procedures and compliance with other regulatory requirements. Warning letters of the type at issue here are an integral element of the Agency's approach to ensuring voluntary compliance with the FDCA and avoiding costly, unnecessary administrative enforcement proceedings and litigation. In the main, whether they agree with FDA's position or not, recipients of such letters accommodate the Agency's concerns by taking corrective action, as occurred here. From FDA's perspective, this achieves the appropriate balance of enforcement priorities, and typically ends the matter. But under the decision below, warning letters would have unintended and unauthorized legal consequences—they could serve as the basis for States to displace FDA's enforcement decisions with their own regulatory or fiscal priorities, by seeking massive civil penalties under state law. Indeed, States are increasingly doing exactly this. As a result, regulated entities will have the incentive to dispute warning letters and litigate, rather than implement, FDA's advice. That upsets the "delicate balance" the Agency strikes in its enforcement efforts. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

The decision below intrudes in particular on FDA's regulatory authority over pharmaceutical product labeling. It simply is not feasible to have 50 separate States regulating the labeling of FDA-approved

medicines. And while Congress may have "determined that widely available state rights of action provided appropriate relief for *injured consumers*," *Wyeth v. Levine*, 555 U.S. 555, 574 (2009) (emphasis added); *accord* Opp. 16 (quoting same), this case and others like it serve no compensatory purpose. Under South Carolina's statute, the State did not need to prove harm, and did not prove it as to itself, individual patients, or anyone else. The civil penalties awarded by the South Carolina courts thus are exactly that: penalties, and nothing more. State enforcement actions seeking such penalties, unmoored from injury to patients—or, for that matter, anyone—is a far cry from the compensatory state-law tort claim *Levine* allows.

This Court should grant review to address the serious constitutional defects in this proceeding and to rein in the worst abuses in these recurring cases.

ARGUMENT

I. STATE PENALTY ACTIONS LIKE THIS ONE DISRUPT FDA'S REGULATORY REGIME

A. The Decision Below Transforms Nearly Every FDA Pre-Enforcement Letter Into a Potential Massive State Penalty Action

FDA's DDMAC sent a warning letter asserting that Janssen's November 2003 letter to physicians about Risperdal was "false or misleading" under the FDCA. The letter was one of more than a hundred issued by that particular office between 2002 and 2005, nearly every one of them repeating this language from the FDCA. Though that preliminary and formulaic

assertion had no legal significance under federal law, and in fact was part of a regulatory process designed to *avoid* escalation, it had the opposite effect in South Carolina. The State Attorney General took FDA's warning letter as an invitation to state enforcement, leading to a *nine-figure* civil penalty. This Court's review is needed to preserve FDA's ability to seek and achieve compliance without formal enforcement action.

An FDA warning letter is just what its name suggests: a warning that the recipient should modify its conduct, or face a potential FDA enforcement action. Signed by an FDA official multiple levels below the Commissioner, warning letters like the one sent to Janssen do not reflect formal findings by FDA. To the contrary, FDA regulations dictate that such statements by Agency employees do "not necessarily represent the formal position of FDA, and do[] not bind or otherwise obligate or commit the agency to the views expressed." 21 C.F.R. § 10.85(k). FDA's Regulatory Procedures Manual reinforces that the letters are "informal and advisory." FDA Manual at 4-1-1. A warning letter "does not commit FDA to taking enforcement action." *Id.* Similarly, FDA describes the purpose of a warning letter as being to prompt voluntary action to *avoid*—not precipitate—administrative proceedings, formal findings, or serious penalties: "Warning Letters are issued to achieve voluntary compliance and to establish prior notice." *Id.* FDA also issues "untitled letters," which serve similar purposes and are used in situations "that do not meet the threshold of regulatory significance for a Warning Letter." *Id.* at 4-2-1.

When FDA wants to elevate a statement by its employees to the status of a "finding," the Agency has

specific procedures to do so. For example, FDA has created a process for issuing an advisory opinion, which "represents the formal position of FDA on a matter . . . [and] obligates the agency to follow it until it is amended or revoked." 21 C.F.R. § 10.85(e). Advisory opinions include preambles to regulations, compliance policy guides, and written opinions on behalf of the Commissioner. But the list does not include warning or untitled letters. *Id.* § 10.85(d).

FDA can use other mechanisms as well to formally determine a violation of law. But with regard to marketing, FDA's practical options in this case were to persuade Janssen to address the Agency's concerns or to undertake the enforcement actions threatened in the warning letter. In such an enforcement action, the Justice Department, on behalf of FDA, could have filed an action in court seeking an injunction, seizure of the products, or criminal penalties. *See, e.g.*, 21 U.S.C. §§ 332-334. Those proceedings have one thing in common: they require FDA to prove its allegations, a burden the Agency does not bear before sending a warning or untitled letter. Indeed, FDA generally issues pre-enforcement letters without affording the regulated company any prior opportunity to be heard.

From 1995 to 2007, FDA issued 8692 warning letters; a quarter of them related to pharmaceuticals.[5] Focusing just on the period since 2010, and just on the marketing and advertising of FDA-approved drugs, the Agency issued more than 150 warning and untitled letters to pharmaceutical manufacturers.

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[5] M. Salas et al., *Analysis of US Food and Drug Administration Warning Letters: False Promotional Claims Relating to Prescription and Over-the-Counter Medications*, Pharm Med. 2008;22:119-25 (Mar. 2008), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3864040/pdf/nihms499576.pdf.

These letters were sent to dozens of companies and concern more than 100 different FDA-approved medicines. The letters address statements made by companies in product labeling, printed promotional materials, websites, social media posts, emails, television and radio advertisements, television interviews, press releases, sales calls and visits, and virtually all other means of communication. And the letters touch upon almost every major disease or therapeutic area, including cancer, depression, anxiety, asthma, hypertension, chronic pain, Hodgkin's lymphoma, chronic obstructive pulmonary disease, hyperlipidemia migraines, HIV, hemophilia, and vaccinations.

Notably, while nearly every one of these warning and untitled letters asserted that the recipient's statements about its medicine were "false or misleading," almost none led to formal FDA enforcement action. Recipients of the letters, rather, voluntarily addressed FDA's concerns to the Agency's satisfaction, and the matters were closed.

But under the sort of nebulous state statute applied in this case, States could use almost any FDA warning or untitled letter as the basis for a potentially massive enforcement action. And they could do so without the need to identify any knowing falsehood, actual deception, or harm to anyone.

This misuse of "unfair and deceptive trade practices" and other state statutes as a penalty enhancement for warning letters is not only unfair, but also destructive to the "delicate balance" of FDA's enforcement efforts, and in particular, to the Agency's voluntary compliance program. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). If FDA pre-enforcement letters may nonetheless trigger state enforcement actions, regulated companies will

have incentives to contest warning letters and put FDA to its proof rather than negotiate a mutually acceptable resolution. And if accommodating FDA's concerns and accepting its suggestions is seen by state officials as an admission of wrongdoing, companies will be far less likely to accommodate FDA's position. Litigation will displace dialogue, and FDA will have lost an important, low-cost means of achieving compliance with the FDCA. This interference with the federal regulatory scheme directly conflicts with the FDCA, at a minimum, exerting the sort of "extraneous pull on the scheme established by Congress" that establishes federal preemption. *Id.* at 353.

These concerns are not merely hypothetical. Every State has an "unfair and deceptive trade practices" statute. *See* Carolyn L. Carter, Consumer Protection in the States: A 50-State Report on Unfair and Deceptive Acts and Practices Statutes, Nat'l Consumer Law Center (Feb. 2009), *available at* https://www.nclc.org/images/pdf/udap/report_50_states.pdf. Many of these state statutes are just as broadly worded as South Carolina's. In addition, at least 30 States have "false claims" statutes, which often are put to similar effect. By way of example, the attorneys general of Louisiana and Arkansas each brought state "false claims" enforcement actions against Janssen based on the same November 2003 letter to physicians at issue here. Before state appellate courts reversed, trial courts in Louisiana and Arkansas imposed fines of $258 million and $1.2 *billion*, respectively. Multiply these sorts of figures by 50 States, and the results powerfully underscore the enormous stakes here.

Janssen's Risperdal is hardly the only target of recent state penalty actions challenging FDA-regulated pharmaceutical marketing and product labeling.

Since 2007, dozens of States—from Hawaii to New York—have brought or participated in similar enforcement actions against numerous pharmaceutical manufacturers.[6] These actions involve FDA-approved medicines prescribed to treat conditions ranging from anemia to arthritis, and from blood thinners to pain reducers, from anti-inflammatories to anti-depressants. And, facing virtually limitless fines in state courts, most companies settle out of necessity, despite the serious constitutional infirmities attending these actions.

B. The Decision Below Invites Unwarranted State Intrusion Into FDA's Regulation of Pharmaceutical Product Labeling

Beyond Janssen's letter to physicians, the South Carolina courts imposed a $22.8 million penalty based on the absence of diabetes and hyperglycemia warnings in Risperdal's FDA-approved label until the 2003 revision. The state courts found Risperdal's pre-revision label "unfair" or "deceptive," even though the content of the label at all times was the product of extensive and ongoing communications between Janssen and FDA. This, too, improperly intrudes on FDA's exclusive regulatory authority.

Product labeling is the primary risk communication tool for FDA-regulated medicines, and it must convey a wealth of information necessary for safe and effective use, including information on ingredients,

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[6] *See generally* National State Attorneys General Program, Consumer Protection Report, *available at* http://web.law.columbia.edu/attorneys-general/policy-areas/consumer-protection/resources-and-publications/consumer-protection-newsletter.

dosages, usage, contraindications, adverse reactions, warnings, precautions, interactions, use in specific populations, and abuse and dependence. And labeling must provide all this information in a way that users can effectively understand. If labeling is too long, it loses effectiveness. If it contains too many warnings, users may miss the ones most relevant to them.

In the prescription-drug context, healthcare professionals need to be able to identify patient-specific concerns and risks from complex, detailed warnings. FDA's current labeling rule was developed to address concerns that the ever-growing length and complexity of prescription-drug labeling made it less effective in communicating to healthcare providers. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3922-23 (Jan. 24, 2006). The rule seeks to streamline information to enable healthcare providers to advise their patients effectively about proper use and potential risks.

FDA supervision of product labeling begins with the new drug approval process. In addition to establishing that new medicines are safe and effective, applicants must submit proposed labeling, which FDA must approve before a medicine is marketed. *See* 21 U.S.C. § 355(b); 21 C.F.R. § 314.105. FDA regulations prescribe labeling requirements, dictating required categories and precise information each category should include. 21 C.F.R. §§ 201.56-57, 201.66, 201.80. When it comes to pharmaceutical product labeling, consistency and uniformity in regulation are particularly critical. *See* S. Rep. No. 105-43, at 63 (1997).

Once a medicine obtains FDA approval and enters the market, FDA tracks adverse event reports and other research regarding the medicine to ensure it

remains safe and effective for its labeled uses. *See* 21 C.F.R. § 314.80. Manufacturers must notify FDA of, and generally must obtain the Agency's approval for, all labeling changes before they are implemented. *See id.* § 314.70(b)(2)(v). FDA suggests and rejects labeling changes based in part on its monitoring of adverse event reports. And throughout the process, FDA engages in dialogue with companies about product labeling.

FDA conducts this federal regulation of labeling because all medicines have unavoidable side effects. Developing medically appropriate labeling to ensure the safe and effective use of medicines requires a careful balance of multiple considerations. FDA is uniquely positioned to do this balancing and to decide what labeling best serves patients.

In accordance with these procedures, FDA approved Risperdal and its labeling in 1993, and then monitored the safety and effectiveness of the drug, as well as its labeling, as Janssen marketed it. In 2003, when FDA directed that the label for Risperdal and *all* other drugs in its class include a warning about diabetes and hyperglycemia, Janssen added the warning, even though the Company disagreed that the warning was necessary for Risperdal.

South Carolina drastically penalized Janssen based solely on the State's disagreement with the content of Risperdal's FDA-approved label. This is a classic case for applying federal preemption.

The State nonetheless argues that preemption does not apply because Janssen failed to present "clear evidence" that FDA rejected the specific warnings that allegedly should have been included. Opp. 14-15 (quoting *Levine*, 555 U.S. at 571). But while *Levine*

may have permitted "*injured consumers*" to challenge certain labeling deficiencies under state law, this Court has never permitted States to regulate the labeling of pharmaceuticals by imposing pure penalties based on the content of labeling. *Id.* at 16 (quoting *Levine*, 555 U.S. at 574). *Levine* involved state tort law, which the Court found was a field that States had "traditionally occupied," 555 U.S. at 1194 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). Moreover, the Court relied on FDA's "traditional recognition of state law remedies." *Id.* at 1203. Unlike in *Levine*, this case does not involve tort law, and it does not involve state-law "remedies." There was no allegedly injured plaintiff seeking a remedy here. Nor was there any indication that the State suffered the slightest monetary loss. Put simply, no one was harmed by the supposed inadequacy of the challenged labeling. The State was acting in a quintessentially regulatory capacity, using the bluntest of regulatory instruments to press its own judgment as to the content Risperdal's label should have included from 1994 until late 2003. That makes this case a far cry from *Levine*.

This case thus presents an issue of national importance, one that has arisen and will continue to arise in state after state, that will threaten to impose crushing liability on pharmaceutical companies, that will displace FDA regulation, and that will chill the legitimate communication of truthful information about prescription drugs. The case cries out for this Court's intervention.

II. THE DECISION BELOW COULD CHILL PROTECTED SPEECH THAT BENEFITS HEALTHCARE PROVIDERS AND PATIENTS

Certiorari is especially warranted because the proliferation of state enforcement actions based on the content of pharmaceutical labeling and marketing penalizes scientific speech by pharmaceutical companies, a form of speech that merits heightened First Amendment scrutiny. The South Carolina Supreme Court's decision exemplifies the problem. In essence, South Carolina chose one side in a scientific debate about the risk of Risperdal as compared to other atypical antipsychotic drugs, and punished Janssen for being on the other side. In doing so, the state court's decision disregards longstanding First Amendment safeguards and threatens the vitality of scientific debate.

Many scientific issues are not clear cut, and good faith exchange is the engine of scientific progress. The drafters of the Constitution understood this truth, reflected in the words of one political philosopher they studied: "It is to contradiction, and consequently to the liberty of the press, that physics owes its improvements. Had this liberty never subsisted, how many errors, consecrated by time, would be cited as incontestible axioms." Eugene Volokh, *In Defense of the Marketplace of Ideas/Search for Truth as a Theory of Free Speech Protection*, 97 Va. L. Rev. 595, 597 (2011) (quoting the philosopher Helvetius). Under the First Amendment, government must allow breathing room for scientific debate. The First Amendment accordingly would not permit the government to "put either Ptolemy or Copernicus on trial." *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992).

As this Court recently reiterated, these protections fully encompass "the beneficial speech of pharmaceutical marketing." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2670 (2011). After all, the Court observed, "in the fields of medicine and public health . . . information can save lives." *Id.* at 2664. A robust scientific exchange on medical issues often yields that lifesaving information as established medicines and therapies are frequently adapted to new purposes. *See id.* at 2671-72.

Further, to exercise sound medical judgment about treatment options for patients, healthcare providers need to be fully informed about benefits and risks of available medications. It is therefore critical to patient outcomes that healthcare providers have access to timely, accurate, and comprehensive information about such benefits and risks. Because manufacturers collect—indeed are expected to collect—the most comprehensive and up-to-date clinical information for the medicines they develop, permitting a free flow of truthful and non-misleading information from manufacturers would substantially increase the level of information available to healthcare providers in deciding how best to treat their patients. Conversely, staunching that flow could impede such decision-making.

While the government of course can regulate deliberately false statements that cause injury, such as fraud or libel, *Illinois ex rel. Madigan v. Telemarketing Assocs.*, 538 U.S. 600, 612 (2003), merely claiming that speech is fraudulent—much less such nebulous constructs as "unfair or deceptive"—does not confer "talismanic immunity from constitutional limitations." *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 269 (1964). To avoid disrupting the marketplace of

scientific ideas, the government, before seeking to penalize a speaker, must show not only that the speech was knowingly or recklessly false, but also that it was outside the bounds of reasonable, good-faith scientific debate. Stated differently, "false . . . does not mean scientifically untrue; it means a lie." *Wang*, 975 F.2d at 1421. That FDA criticizes particular statements by issuing a warning letter does not come close to establishing that the statements are false, much less beyond the bounds of reasonable scientific debate.

By disregarding these core First Amendment principles and relying on an FDA warning letter to impose drastic penalties on Janssen for its November 2003 letter to physicians—which discussed and cited clinical studies about risk—the decision in this case creates a chilling effect for future manufacturer communications about risk. This chilling effect is contrary not only to the First Amendment, but to the interests of patients.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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