No. 13-180

IN THE

Supreme Court of the United States

W. SCOTT HARKONEN,
Petitioner,
v.
UNITED STATES,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA 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. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA's members are dedicated to discovering medicines that help patients lead longer, healthier, and more productive lives. In 2012 alone, PhRMA's members invested an estimated $48.5 billion in efforts to discover and develop new medicines. *See* PhRMA, 2013 Biopharmaceutical Research Industry Profile, at 31 fig.10 (2013), http://phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf.

PhRMA has frequently filed *amicus curiae* briefs with this Court in cases raising matters of significance to its members. In addition, PhRMA was a plaintiff in *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), which overturned a state law that infringed on the First Amendment rights of PhRMA's members to communicate with healthcare professionals about life-saving and life-enhancing medicines. PhRMA has an interest in ensuring that the courts fully protect the First Amendment rights of pharmaceutical manufacturers and their executives.

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[1] No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No one other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief. Letters from the parties consenting to the filing of *amicus curiae* briefs have been filed with the Clerk of the Court.

This case is important to the biopharmaceutical industry. PhRMA's members constantly interpret the meaning of complex scientific data and engage in speech about scientific issues that are often the subject of ongoing and good-faith debate. A robust public dialogue on these issues promotes scientific exchange, improves transparency of company operations, and fosters medical advances that ultimately lead to better outcomes for patients. By upholding the conviction of a scientist who participated in such a dialogue, the decision below contravenes core First Amendment principles by casting a chill of government censorship over scientific speech that is vitally important in the biopharmaceutical arena.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case started when two employees at the Food and Drug Administration disagreed with the conclusions of a press release that discussed the results of a clinical trial. The author of that press release, Dr. Scott Harkonen, is a physician, researcher, and former CEO of InterMune, Inc. He wrote the press release to discharge the company's disclosure obligations under the federal securities laws.

The results of the clinical trial were just like the results of many clinical trials: open to interpretation. Dr. Harkonen thus made a series of statistical and scientific inferences in his press release when discussing the results. Those inferences were based on Dr. Harkonen's scientific interpretation of the clinical trial data, but that did not mean, of course, that every other scientist agreed with him. There are many different ways a scientist might interpret data. Often, no one way is the right way.

Dr. Harkonen's interpretation, however, was not the same as the government's. And although no scientific consensus existed on the meaning of the clinical trial results, the government charged Dr. Harkonen with wire fraud on the basis of his statements in the press release.

The government's decision to prosecute Dr. Harkonen for expressing a scientific opinion is unprecedented and chilling. The "very purpose of the First Amendment is to foreclose public authority from assuming a guardianship of the public mind through regulating . . . speech." *Thomas v. Collins*, 323 U.S. 516, 545 (1945) (Jackson, J., concurring). The government may disagree with a speaker's opinions, but it "may not burden" speech "in order to tilt public debate in a preferred direction." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2671 (2011). Our "forefathers did not trust any government to separate the true from the false for us." *Thomas*, 323 U.S. at 545 (Jackson, J., concurring).

Even more unprecedented and chilling is the Ninth Circuit's decision affirming Dr. Harkonen's conviction by holding that a jury may decide whether speech deserves First Amendment protection. The court expressly "defer[red]" to the jury's finding that Dr. Harkonen's press release was fraudulent and thus outside the ambit of the First Amendment. Pet. App. 4a. The court's deference to the jury's findings of constitutional fact defies the decisions of this Court that assign to judges the exclusive authority to define the outer limits of free speech rights. *See, e.g.*, *Snyder v. Phelps*, 131 S. Ct. 1207 (2011); *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485 (1984); *N.Y. Times Co. v. Sullivan*, 376 U.S. 254 (1964).

If not reversed, the decision below will stand as an obstacle to innovation in the pharmaceutical sector, as researchers and scientists might reasonably fear that expressing a good faith opinion about scientific data could place them in a prosecutor's crosshairs. This fear is real and significant for PhRMA's member institutions, which regularly discuss the meaning of clinical trial results and other scientific data that are open to interpretation. These discussions occur daily at scientific and academic conferences, in medical articles, at continuing education seminars, in communications with the FDA, on websites, in press releases, and even on blogs. All of these communications play a vital role in fostering innovation within the pharmaceutical industry.

Employees at the FDA surely do not agree with everything scientists say during these formal and informal discussions. Until this case, that disagreement has never been enough to convict someone of wire fraud. Certiorari is needed to prevent the chill that the Ninth Circuit has placed on vitally important scientific discussions.

Certiorari is also warranted because the Ninth Circuit's opinion is irreconcilable with this Court's free-speech jurisprudence. As the Court has explained, the First Amendment secures an "unfettered interchange of ideas," *Roth v. United States*, 354 U.S. 476, 484 (1957), and gives the public "access to discussion, debate, and the dissemination of information," *First Nat'l Bank of Bos. v. Bellotti*, 435 U.S. 765, 783 (1978).

Other circuit courts have faithfully followed these free-speech precedents and refused to impose liability on someone who expresses a scientific opinion. *See, e.g.*, *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 496-97 (2d Cir. 2013) (finding a "statement[]

of pure opinion" to be protected speech because it was "made as part of an ongoing scientific discourse about which there is considerable disagreement"); *cf. Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994) ("Scientific controversies must be settled by the methods of science rather than by the methods of litigation."). The Ninth Circuit's decision conflicts with the decisions of these other circuit courts.

To be sure, this Court has held that the "First Amendment does not shield fraud" because fraudulent speech has "'no essential part of any exposition of ideas.'" *Illinois ex rel. Madigan v. Telemarketing Assocs., Inc.*, 538 U.S. 600, 612 (2003) (quoting *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 340 (1974)). Fabricating data or lying about the results of a clinical trial, for example, are properly actionable offenses. But those things are not at issue here. The government does not contend that Dr. Harkonen made up data or lied about the results of the clinical trial. *See* Pet. App. 2. Rather, its grievance is with Dr. Harkonen's opinion about the meaning of scientific data—a type of speech that *does* have an "essential part" in the exposition of scientific ideas and thus deserves the highest form of First Amendment protection. *See Miller v. California*, 413 U.S. 15, 22-23 (1973).

This Court should grant the petition for certiorari to fix these serious constitutional errors and remove the chilling cloud of criminal punishment that the Ninth Circuit has affixed to scientific speech about matters of good faith public debate.

ARGUMENT

I. THE DECISION BELOW WILL CHILL SCIENTIFIC SPEECH OF VITAL IMPORTANCE TO THE PHARMACEUTICAL INDUSTRY AND PATIENTS

The Ninth Circuit affirmed Dr. Harkonen's criminal conviction because, in the words of the court, "[t]he First Amendment does not protect fraudulent speech," and "we defer to the jury's findings that the Press Release was misleading." Pet. App. 2a, 4a. In other words, the court punted to the jury to resolve the threshold and important legal question of whether a press release that interprets scientific data is protected speech under the First Amendment. In the Ninth Circuit, therefore, expressing a scientific opinion might be a federal crime if twelve laypeople label that opinion "misleading."

Criminalization of scientific speech has significant ramifications for PhRMA's members, which regularly discuss the meaning of clinical trial data. A free and robust scientific dialogue is critical to the development of new treatments for cancer, Alzheimer's, AIDS, and other serious diseases. Chilling that dialogue with the threat of criminal liability could stall innovation and delay discovery—detriments that will ultimately hurt patients.

A. The First Amendment Fully Protects The Robust Scientific Debate That Is Essential For Biopharmaceutical Innovation

The Ninth Circuit's laissez faire constitutional analysis would be troubling in any context. But the court's hands-off approach is especially troubling here

because scientific debate is a matter of great public importance and, as such, "occupies the highest rung of the hierarchy of First Amendment values." *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc*., 472 U.S. 749, 759 (1985) (plurality) (quotation marks omitted). "[I]n the area of freedom of speech . . . courts must always remain sensitive to any infringement on genuinely serious . . . scientific expression." *Miller*, 413 U.S. at 22-23; *cf. Sorrell*, 131 S. Ct. 2653 (holding that the First Amendment protects pharmaceutical companies' communications with doctors about the safety and efficacy of drugs); *Bd. of Trs. of Leland Stanford Junior Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) ("[T]he First Amendment protects scientific expression and debate just as it protects political and artistic expression.").

The "theory of freedom of expression" enshrined in the Constitution "developed in conjunction with, and as an integral part of, the growth of the scientific method." Thomas I. Emerson, *Colonial Intentions and Current Realities of the First Amendment*, 125 U. Pa. L. Rev. 737, 741 (1977). The proponents of the First Amendment "put their faith in progress through free and rational inquiry. Hence the process they envisaged operates upon the same principles as those that guided the men of science: the refusal to accept existing authority; the constant search for new knowledge; [and] the insistence upon exposing their facts and opinions to opposition and criticism." *Id*.

The First Amendment fosters the very truth-seeking functions that lie at the heart of scientific inquiry. That inquiry involves the testing and challenging of existing ideas, which leads to the discovery of new ideas to test and challenge, which leads to advances in scientific knowledge. Protecting this robust debate in

pursuit of truth is the core of free speech: "The First Amendment presupposes that the freedom to speak one's mind is not only an aspect of individual liberty—and thus a good unto itself—but also is essential to the common quest for truth and the vitality of society as a whole." *Bose Corp.*, 466 U.S. at 503-04.

The First Amendment serves a critical function "in the fields of medicine and public health, where information can save lives." *Sorrell*, 131 S. Ct. at 2664. Free speech rights allow scientists to pursue new ideas without fear of facing criminal sanctions if their ideas cause controversy, dissent, or disagreement. The First Amendment *encourages* speech that unsettles conventional thought: "[A] function of free speech under our system of government is to invite dispute." *Terminiello v. City of Chicago*, 337 U.S. 1, 4 (1949). Speech does not lose constitutional protection simply because it causes "sharp differences" of opinion. *N.Y. Times*, 376 U.S. at 271 (quoting *Cantwell v. Connecticut*, 310 U.S. 296, 310 (1940)).

These constitutional protections hold firm when a scientist's "dispute" or "sharp difference[]" of opinion is with the government. The First Amendment promotes a robust "public discussion" in which everyone—including the government—can compete to have their ideas accepted by the marketplace. *Id.* at 270 (quoting *Whitney v. California*, 274 U.S. 357, 375-76 (1927) (Brandeis, J., concurring)). The government is not the referee of this competition; it is a coequal contestant. *See United States v. Alvarez*, 132 S. Ct. 2537, 2543 (2012) ("[T]he First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content." (quoting *Ashcroft v. Am. Civil Liberties Union*, 535 U.S. 564, 573 (2002))); *see also Cohen v. California*, 403

U.S. 15, 25 (1971) (explaining that the government cannot "cleanse public debate" by criminalizing speech with which it disagrees).

If the government disagreed with Dr. Harkonen's interpretation of the clinical trial results, it should have responded with counterspeech by issuing its own press release, not by bringing criminal charges. "Those who won our independence . . . . eschewed silence coerced by law—the argument of force in its worst form." *N.Y. Times*, 376 U.S. at 270 (quoting *Whitney*, 274 U.S. at 375-76 (Brandeis, J., concurring)). "However pernicious an opinion may seem, we depend for its correction not on the conscience of judges and juries but on the competition of other ideas." *Gertz*, 418 U.S. at 339-40; *cf. Alvarez*, 132 S. Ct. at 2549 (invalidating as unconstitutional a statute that made it a crime to falsely claim receipt of military medals because, in part, the "Government has not shown, and cannot show, why counterspeech would not suffice to achieve its interest"); *Whitney*, 274 U.S. at 377 (Brandeis, J., concurring) ("[T]o expose . . . falsehood and fallacies, . . . the remedy to be applied is more speech, not enforced silence.").

Safeguarding these broad constitutional protections for scientific speech is especially important for research on the newest frontiers of innovation, such as clinical trials of pharmaceutical products. The data that are created during these trials are rarely black and white; they are open to various interpretations that, in turn, lead to fresh and differing perspectives for further research. Chilling speech at this stage of the scientific process could freeze out insights about the meaning of newly created data, which could delay or prevent the discovery of new medicines. Fortunately, the First Amendment protects the entire

frontier of scientific discovery, not just those segments that the government approves.

The decision below seriously imperils this discovery process. Scientists now must think twice before entering the marketplace of ideas with a novel theory, unconventional opinion, or interpretation of data that the government might dispute.

This chilling effect is especially far-reaching because the Ninth Circuit's decision potentially extends to all scientific speech, not just speech contained in press releases. If the decision stands, a scientific opinion expressed in any number of contexts could lose its constitutional protection if the government can convince a jury that the opinion is "misleading." Pet. App. 4a. Researchers who debate the meaning of clinical trial data in an article, on a blog, or at a medical conference might be hauled into federal court and charged with a crime. To avoid facing potential charges, scientists will either be forced to agree with the government's scientific opinions or stay silent—the exact dilemma "that the First Amendment was drawn to prohibit." *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 335 (2010); *cf. Heinrich v. Sweet*, 308 F.3d 48, 68 (1st Cir. 2002) ("There would surely be a chilling effect on research in the medical field and deterrence of important progress in medical treatments if doctors and scientists could not frankly assess the successes and failures of their studies . . . so that others can build on their work and learn from it.").

Applying the protections of the First Amendment to novel or controversial speech does not create a "science" exception to fraud, as the government contended below. Fabricating data or telling other lies about objective facts is properly actionable as fraud.

No reasonable scientist would defend such misstatements. They are not matters for good-faith debate; nor are they at issue here. There is no allegation that Dr. Harkonen fabricated data or misrepresented the actual study results. *See* Pet. App. 2. Rather, the government contends that his interpretation of the actual data was not correct. *See id*.

Matters of scientific interpretation that are fairly debatable stand on a fundamentally different First Amendment plane. *See Riley v. Nat'l Fed'n of the Blind of N.C., Inc*., 487 U.S. 781, 803 (1988) (Scalia, J., concurring in part and concurring in the judgment) ("[A]lthough fraudulent misrepresentation of *facts* can be regulated, the dissemination of ideas cannot be regulated to prevent it from being unfair or unreasonable." (emphasis added) (citations omitted)). To avoid chilling scientific discussion, the First Amendment forbids the government from criminalizing interpretations of data that a reasonable scientist could defend.

B. Scientists Must Communicate With The Public About The Meaning Of Clinical Trial Results That Are Open To Varying Interpretations

The chilling effect of the Ninth Circuit's decision is particularly troubling, and warrants this Court's review, because securities laws frequently require disclosure of clinical trial results. *See Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1318-19 (2011). Speakers now must balance these disclosure requirements against the risk of criminal punishment if the government disagrees with their scientific opinions in a disclosure. That result is untenable.

Public companies and their executives may not "omit to state a material fact" that might impact the trading decision of a reasonable investor. 17 C.F.R. § 240.10b-5(b) (implementing 15 U.S.C. § 78j(b)). The "fundamental purpose" of these reporting requirements is to create "a philosophy of full disclosure." *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 477 (1977); *cf.* N.Y. Stock Exchange Listed Company Manual § 202.05 (2013) ("A listed company is expected to release quickly to the public any news or information which might reasonably be expected to materially affect the market for its securities.").

The results of a clinical trial routinely are material to a pharmaceutical company's business because of their potential to impact financial prospects. *See N.J. Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 48 (1st Cir. 2008) (noting that the "financial fortunes" of some pharmaceutical companies "may turn on the outcome of . . . experimental drug trials"). Thus, failing to report *negative* clinical trial results might lead to charges that the company and its executives defrauded investors by keeping stock prices artificially high. *See, e.g.*, *In re PLC Sys., Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 120 (D. Mass. 1999) (concluding that a company's "failure to disclose" the "absence of a *positive* result" in a clinical trial was actionable under Rule 10b-5). By contrast, executives who do not promptly report positive clinical trial results could face insider trading liability if they purchase company stock at what might be deemed to be an artificially low price in light of the lack of disclosure of positive news. *See, e.g.*, Complaint at 1, SEC v. Fan, No. C11-0096MJP, 2011 WL 182902 (W.D. Wash. Jan. 10, 2011) (alleging that the manager of a biopharmaceutical company had committed insider trading by leaking to a family member

confidential information about positive clinical trial results).

In *Matrixx*, this Court held that reports of possible adverse reactions to a drug might be material—and thus subject to disclosure—even if the evidence of a causal relationship between the drug and the adverse reaction is not statistically significant. 131 S. Ct. at 1321. Scientific experts might infer a causal link by relying on non-statistically significant evidence such as "biologic plausibility" and "consistency of findings" across other data sources. *Id*. at 1320. And if scientists might make decisions based on that sort of evidence, then investors might rely on it as well. *Id*. at 1321. The government itself argued in *Matrixx* that pharmaceutical companies have a duty to disclose reports of adverse reactions to a drug even if the causal link is not statistically significant. *See* Brief for the United States as Amicus Curiae Supporting Respondents, *Matrixx*, 2010 WL 4624148, at *14-15 & n.2 (Nov. 12, 2010).

These disclosure obligations make the implications of the Ninth Circuit's decision all the more sweeping and problematic. On the one hand, executives cannot avoid criminal liability by remaining silent; they must speak about the material results of clinical trials. On the other hand, speaking freely about those results exposes executives to criminal punishment if the government disagrees with their scientific opinions. Until now, such disagreements have never been sufficient to support a claim of fraud. *See, e.g.*, *DeMarco v. Depotech Corp*., 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) ("[A] legitimate difference in opinion as to the

proper statistical analysis . . . hardly state[s] a securities fraud claim.").[2]

C. The Ninth Circuit's Decision Departs From Decisions Of Other Courts Fully Protecting Reasonable Scientific Speech

The Ninth Circuit's decision to criminalize scientific expression stands alone. Other courts in similar contexts have refused to impose liability on a speaker for expressing a reasonable opinion about the meaning of scientific data. The Ninth Circuit's departure from this basic principle underscores the urgent need for this Court's review.

The Second Circuit recently addressed the constitutional protections afforded to scientific speech in the context of a false advertising claim. A plaintiff alleged that statements in a scientific article were false and misleading because they did not correctly interpret the results of a clinical trial. *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 494 (2d Cir. 2013). Reasoning that "statements of pure opinion . . . are

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[2] *Accord Padnes v. Scios Nova Inc.*, No. C 95-1693 MHP, 1996 WL 539711, at *5-6 (N.D. Cal. Sept. 18, 1996) (dismissing a securities fraud claim because a press release was not false or misleading where "[r]easonable minds could differ with respect to the value of the . . . study in determining the therapeutic effects of [the drug]," even if tests were ultimately unsuccessful and contained "protocol defects"); *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) (dismissing securities fraud claims relating to a drug company press release construing clinical trial data because "[m]edical researchers may well differ over the adequacy of given testing procedures and in the interpretation of test results" and "[a]lthough the [FDA] may have disagreed, there is nothing to suggest that Defendants could not reasonably have entertained the opinion").

protected under the First Amendment," the court held that the allegedly inaccurate scientific statements were fully protected speech. *Id*. at 496. Civil liability, at least in the Second Circuit, cannot rest on a statement "made as part of an ongoing scientific discourse about which there is considerable disagreement." *Id*. at 497. "Needless to say, courts are ill-equipped to undertake to referee such controversies." *Id*.

The Seventh Circuit has also concluded that reasonable scientific opinions are not actionable if they are the subject of good faith debate. *See, e.g.*, *Luckey v. Baxter Healthcare Corp*., 183 F.3d 730, 732 (7th Cir. 1999) (holding that a difference of opinion about whether a particular blood test is "effective" cannot support a claim of fraud brought under the False Claims Act); *Haynes v. Alfred A. Knopf, Inc*., 8 F.3d 1222, 1227 (7th Cir. 1993) (holding that "a subjective view, an interpretation, a theory, conjecture, or surmise" is "not actionable" as defamation). "Scientific controversies," the court has explained, "must be settled by the methods of science rather than by the methods of litigation." *Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994); *see also Sanderson v. Culligan Int'l Co*., 415 F.3d 620, 624 (7th Cir. 2005) (reasoning that "disputes about the efficacy of competing products" are "question[s] about science, not law, and scientific disputes must be resolved by scientific means").[3]

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[3] *Accord United States ex rel. Haight v. Catholic Healthcare W*., No. CV-01-2253-PHX-FJM, 2007 WL 2330790, at *3 (D. Ariz. Aug. 14, 2007) (holding that the False Claims Act does not reach "expressions of scientific opinion or judgment about which reasonable minds may differ"); *Noble Asset Mgmt. v. Allos Therapeutics, Inc*., No. CIVA-04CV-1030-RPM, 2005 WL

The Ninth Circuit's decision conflicts with these cases and the underlying principle that speech about matters of good faith scientific debate is not actionable. If a private party had sued Dr. Harkonen for fraud in the Second Circuit or the Seventh Circuit, the claim would have been dismissed. Not so in the Ninth Circuit, where a scientist who expresses an opinion might not only be subject to *civil* liability but also to *criminal* punishment. This Court should grant certiorari to unify the law on this issue, and make clear that all reasonable scientific speech falls within the First Amendment's protective umbrella.

II. THE COURT SHOULD GRANT CERTIORARI TO REAFFIRM THAT THE NONDELEGABLE DUTY OF INDEPENDENT JUDICIAL REVIEW APPLIES IN ALL CASES INVOLVING FREE SPEECH RIGHTS

The Ninth Circuit's decision to defer to the jury's finding that the press release was unprotected speech is troubling for still another reason: it creates a novel and improper exception to this Court's well settled

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4161977, at *6, *11 (D. Colo. Oct. 20, 2005) (dismissing claims that a drug company had "misled investors by putting a positive gloss on the results of . . . clinical trials" without also disclosing that the positive aspect "could only be considered as exploratory" because "[t]he interpretation of the data from the . . . clinical trials is a matter on which reasonable minds could differ"); *In re Biogen Sec. Litig*., 179 F.R.D. 25, 38 (D. Mass. 1997) (citing a "split of expert opinion" as a basis for dismissing claims against a drug company for allegedly making misleading statements in a press release about the results of a clinical trial); *cf. Arthur v. Offit*, No. 01:09-CV-1398, 2010 WL 883745, at *6 (E.D. Va. Mar. 10, 2010) ("Courts have a justifiable reticence about venturing into the thicket of scientific debate.").

rule that judges reviewing a verdict resting on the content of speech must "make an independent examination of the whole record" to "see whether [the speech is] of a character which the principles of the First Amendment . . . protect." *N.Y. Times*, 376 U.S. at 285 (alteration and quotation marks omitted). This judicial obligation ensures that the verdict below "does not constitute a forbidden intrusion on the field of free expression." *Bose Corp.*, 466 U.S. at 499.

A court's "constitutional responsibility" of independent appellate review "*cannot be delegated to the trier of fact*." *Id.* at 501 (emphasis added). Judges—not jurors—are the "expositors of the Constitution." *Id.* at 511. In cases testing the limits of free speech, "the stakes—in terms of impact on future cases and future conduct—are too great to entrust them finally to the judgment of the trier of fact." *Id.* at 501 n.17; *accord Pell v. Procunier*, 417 U.S. 817, 827 (1974) ("Courts cannot, of course, abdicate their constitutional responsibility to delineate and protect fundamental liberties."). Simply "[p]roviding triers of fact with a general description of the type of communication whose content is unworthy of protection [does] not . . . serve[] to eliminate the danger that decisions by triers of fact may inhibit the expression of protected ideas." *Bose Corp.*, 466 U.S. at 505; *see also id.* at 511 ("First Amendment protection is not merely a question for the trier of fact.").

For similar reasons, the judicial duty of independent review also requires a "*reexamination of facts* tried by a jury" when those facts inform the constitutional inquiry. *Id.* at 508 n.27 (emphasis added). "[T]he reaches of the First Amendment are ultimately defined by the facts it is held to embrace." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515

U.S. 557, 567 (1995). Thus, when a constitutional question is "intermingled" with the facts, courts must "analyze the facts" in deciding whether a federal right has been violated. *Fiske v. Kansas*, 274 U.S. 380, 385-86 (1927).

Consistent with those principles, this Court has rejected the contention that facts underlying a constitutional question—so-called "constitutional facts"—are "insulated from review." *Bose Corp*., 466 U.S. at 506-07. "That the question is one of fact does not relieve [the Court] of the duty to determine whether in truth a federal right has been denied. . . . Otherwise, review by this Court would fail of its purpose in safeguarding constitutional rights." *Norris v. Alabama*, 294 U.S. 587, 589-90 (1935).

The Ninth Circuit ignored these constitutional commands by deferring to the jury's finding that Dr. Harkonen's press release was fraudulent and therefore unworthy of First Amendment protection. Where, as here, constitutional liberties are at stake, "the Court has been reluctant to give the trier of fact's conclusions presumptive force and, in so doing, strip a federal appellate court of its primary function as an expositor of law." *Miller v. Fenton*, 474 U.S. 104, 114 (1985). The Ninth Circuit was not reluctant; it freely—and expressly—imbued the jury's findings with presumptive force. *See* Pet. App. 4a ("[W]e defer to the jury's findings.").

If all courts were to do what the Ninth Circuit did and defer to a jury's findings of constitutional fact, two conflicting verdicts about the scope of free speech rights could both survive judicial review. Different juries might disagree about whether a particular expression is misleading, and both verdicts might be "supported by sufficient evidence" to survive the Ninth

Circuit's deferential standard of review. Pet. App. 4a. The same speech would receive different levels of constitutional protection depending on the fortuity of jury composition. That sort of balkanized constitutional landscape and "free-floating test for First Amendment coverage" is both "startling and dangerous." *United States v. Stevens*, 130 S. Ct. 1577, 1585 (2010). Free speech rights do not depend on which twelve laypeople sit in a jury box. *Cf. Miller*, 413 U.S. at 30 ("Under a National Constitution, fundamental First Amendment limitations . . . do not vary from community to community.").

To be sure, the Court has recognized a small number of narrow categories of unprotected speech, including fraud, *see Illinois ex rel. Madigan v. Telemarketing Assocs.*, 538 U.S. 600, 612 (2003), but the "mere label[]" of "fraud" does not confer "talismanic immunity from constitutional limitations," *N.Y. Times*, 376 U.S. at 269; *see also id.* at 268 ("[T]hat the Constitution does not protect libelous publications . . . . do[es] not foreclose our inquiry here."); *Madigan*, 538 U.S. at 617 ("Simply labeling an action one for 'fraud,' of course, will not carry the day."). The speech beneath that label must always "be measured by standards that satisfy the First Amendment," and those standards must be set—and applied—by judges, not juries. *N.Y. Times*, 376 U.S. at 269.

This case therefore does not begin and end with the jury's finding that Dr. Harkonen's speech was fraudulent, as the Ninth Circuit held. Instead, the trial court should have determined the appropriate legal standard to ensure that Dr. Harkonen's free speech rights were fully protected, and only then allowed the jury to determine whether the press release satisfied that legal standard.

The Ninth Circuit thus made a gross constitutional error in limiting its review on the basis that the jury found the press release to be fraudulent. A jury's finding that speech was "libelous" in *New York Times* did not stop the Court from independently reviewing the record; a jury's finding that speech was "outrageous" in *Snyder* did not stop the Court from holding that the speech was protected; and the trial court's finding that the defendant in *Bose Corp*. had spoken with defamatory "actual malice" did not stop the Court from independently reviewing the record and vacating the judgment below.

Because here the Ninth Circuit did not follow these precedents and independently analyze the record, this Court should grant certiorari and reiterate that the judicial duty of independent review applies to *all* cases involving free speech rights.

CONCLUSION

The Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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