No. 13-180

IN THE

Supreme Court of the United States

W. SCOTT HARKONEN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF *AMICI CURIAE* LAW PROFESSORS IN SUPPORT OF PETITIONER

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

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[*] Counsel of record for the parties received timely notice of *amici*'s intent to file this brief, and consented to its filing. Counsel for *amici* authored this brief in its entirety. No counsel for a party authored this brief in whole or in part, and no counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than counsel for *amici* made a monetary contribution to the preparation or submission of this brief.

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Amici have a common professional interest in issues relating to the First Amendment and scientific speech. They seek to offer this Court their professional academic perspective on these issues as they arise in this case.

SUMMARY OF ARGUMENT

In affirming a criminal conviction for engaging in protected speech, the Ninth Circuit announced and applied erroneous principles of First Amendment law that are of exceptional importance. If allowed to stand uncorrected, the court of appeals' opinion will chill and deter scientific experimentation, exploration, discussion, and debate.

The court of appeals authorized the government to impose criminal penalties against a scientist for reporting scientifically plausible, though not universally accepted, conclusions drawn from experimental data because a particular level of "statistical significance" had not been reached. But just as our Constitution does not "enact Mr. Herbert Spencer's Social Statics" (*Lochner v. New York*, 198 U.S. 45, 75 (1905) (Holmes, J., dissenting)), neither does it set a level of statistical significance below which the government may penalize a learned person for offering an opinion on the conclusions to be drawn from experimental data. The constitutional line between truth and falsity is not to be found in "p-values," as the government insisted in the courts below. In failing to correct this error, the court of appeals abdicated its constitutional duty to independently evaluate whether the speech in question is excluded from the First Amendment's protection.

This case calls out for this Court's review because the government has chosen to impose criminal punishment on a speaker for contributing to an active and ongoing scientific debate. At bottom, this case presents the question whether the government may seek and obtain a criminal conviction for fraud against a medical doctor because he disagreed with U.S. Food and Drug Administration (FDA) convention on a matter of scientific debate. The court of appeals agreed with the government that it is unlawful for a medical doctor to express the conclusion that a drug has a clinical benefit unless a statistical test performed on the experimental data results in what the district court described as a "magic number." If the experimental data do not reach this conventional statistical threshold, the court of appeals concluded, the government has the constitutional authority to prohibit speech. *Amici* submit that this conclusion is every bit as chilling as it sounds. This Court has never authorized the government to use criminal sanctions to favor one side in matters of scientific uncertainty, or to silence plausible scientific views with which it disagrees.

The predictable effort of government to suppress speech that does not comport with the prevailing views of regulators and other officials is precisely the tendency that the First Amendment is designed to protect against. In our country, under our Constitution, the remedy for speech is *more* speech, not suppression. *Whitney v. California*, 274 U.S. 357, 377 (1927) (Brandeis, J., concurring). This is nowhere more true than in the realm of scientific exploration and discovery, where we continue to learn new "truths" and the human condition is often bettered by those free thinkers who dare to challenge the received wisdom. The court of appeals' decision—which

authorizes the jailing of scientists for expressing scientifically plausible views on experimental data—should be reviewed, and reversed, by this Court.

STATEMENT

1. Scott Harkonen, M.D., was the CEO of InterMune, a biotechnology company that holds a biologics license on Actimmune® (Interferon gamma-1b), a drug approved by the FDA for the treatment of two diseases, chronic granulomatous disease and severe, malignant osteopetrosis. Pet. App. 10a.

An independent study published in 1999 in the New England Journal of Medicine suggested that Actimmune might also have a clinical benefit for a third disease, Idiopathic Pulmonary Fibrosis (IPF). IPF is a chronic and incurable lung disease, for which there is no FDA-approved treatment, and which is fatal for most patients within four to five years. Rolf Ziesche et al., *A Preliminary Study of Long-Term Treatment with Interferon Gamma-1b and Low-Dose Prednisolone in Patients with Idiopathic Pulmonary Fibrosis*, 341 New Eng. J. Med. 1264 (1999). After that 1999 study, many doctors began prescribing Actimmune for patients with IPF. Pet. App. 10a.

InterMune endeavored to study further the effects of Actimmune in IPF patients in a 2000-02 clinical trial. The raw data showed that 40% more patients who received the drug survived than those who received a placebo, while the same figure was 70% when looking only at those with mild or moderate forms of IPF. Upon the trial's conclusion in 2002, Dr. Harkonen wrote and distributed a press release with the title, "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," and a subtitle, "Reduces Mortality by 70% in

Patients with Mild to Moderate [IPF] Disease." C.A. App. 1906-09; *see id.* at 37; Pet. App. 26a-27a.

2. The government charged Dr. Harkonen with wire fraud on the basis of the press release's title and subtitle; the government never disputed that the clinical trial data were reported accurately in the press release's text. The government prosecuted Dr. Harkonen for fraud on a theory that he had committed a "falsification of the conclusions that could be drawn from the data." C.A. App. 1670.

The government's theory that the conclusions were false was based on a particular method of evaluating whether disparities between two sample sets (such as the outcomes of drug recipients versus placebo recipients) might be the result of random chance—*i.e.*, whether the results were "statistically significant." Pet. App. 28a-29a. Statisticians often calculate a "p-value," a number that depends on the size of the sample and the magnitude of differences between the various study groups. A smaller p-value means that it is less likely that differences between the groups can be explained by random chance. It is conventionally, but by no means universally, agreed that test results with a p-value of 0.05 or less can be described as showing a statistically significant result.

The government's liability theory was that a p-value of 0.05 represents the dividing line between truthful and fraudulent statements about clinical test results. Pet. App. 28a. Presented with that theory, a jury found that Dr. Harkonen's conclusions about the test results were "fraudulent." *Ibid.* In response to Dr. Harkonen's post-verdict motion, the district court held that, on the basis of testimony by two government experts, the jury was permitted to

find Dr. Harkonen's conclusions "*objectively untrue*" because they were drawn from p-values of greater than 0.05. *Ibid.* (emphasis added). The district court rejected Dr. Harkonen's First Amendment arguments in a two-paragraph analysis based solely on the jury's finding of fraud. Pet. App. 40a-41a.

3. The court of appeals affirmed in a 10-page unpublished opinion that devoted fewer than three pages to Dr. Harkonen's argument that the conviction violated the First Amendment. Pet. App. 4a-6a. The court of appeals "defer[red]" to the jury's finding of the elements of the offense, and therefore upheld the conviction against Dr. Harkonen's First Amendment challenge. *Id.* at 4a-5a. The court of appeals disagreed that Dr. Harkonen "was engaging in a genuine scientific debate" because "genuine debates of any sort are, by definition, not fraudulent," but here "a jury found . . . [a] specific intent to defraud." *Id.* at 6a.

ARGUMENT

> When the standard governing the decision of a particular case is provided by the Constitution, this Court's role in marking out the limits of the standard through the process of case-by-case adjudication is of special importance. This process has been vitally important in cases involving restrictions on the freedom of speech protected by the First Amendment, *particularly in those cases in which it is contended that the communication in issue is within one of the few classes of "unprotected" speech*.

Bose Corp. v. Consumers Union of U.S., Inc., 466 U.S. 485, 503 (1984) (emphasis added).

1. This Court's review is necessary to correct the court of appeals' error in "defer[ring]" to the jury's verdict. Pet. App. 4a. Where, as here, a criminal defendant raises a First Amendment challenge to his conviction, "appellate court[s] [must] 'make an independent examination of the whole record.'" *Bose*, 466 U.S. at 499 (quoting *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 285 (1964)). That obligation is a "constitutional responsibility that cannot be delegated to the trier of fact," regardless of whether the facts are found "by a jury or by a trial judge." *Id.* at 501 (case tried to court); *see also N.Y. Times*, 376 U.S. at 256 (case tried to jury).

"Providing triers of fact with a general description of the type of communication whose content is unworthy of protection has not, in and of itself, served sufficiently to narrow the category, nor served to eliminate the danger that decisions by triers of fact may inhibit the expression of protected ideas." *Bose*, 466 U.S. at 505. To determine whether Dr. Harkonen's statements were "fraudulent" in the constitutional sense of being unprotected by the First Amendment (*see United States v. Alvarez*, 132 S. Ct. 2537, 2544-45 (2012) (plurality opinion)), the court of appeals was obligated to perform an independent review under an objective standard, with no deference to the jury's antecedent determination.

The need for independent review is particularly important in the context of a disagreement with a government agency about technical standards. Any number of government officials may wish to silence members of the public for taking positions contrary to the government's position. This Court's review is necessary to ensure the judiciary remains an independent check on such agencies' desire to enforce the party line by the threat of criminal punishment. Un-

til and unless corrected, the court of appeals' opinion will stand as a stark warning to any scientist considering making a statement with which a government regulator might disagree.

2. The First Amendment's protection of scientific speech is an issue of exceptional importance under any of the many philosophical and jurisprudential foundations of and justifications for free speech. *See, e.g.*, Lawrence A. Alexander, *Freedom of Speech* (2000); Ronald J. Krotoszynski, Jr., *The First Amendment in Cross-Cultural Perspective: A Comparative Legal Analysis of the Freedom of Speech* (2009); Lucas A. Powe, Jr., *The Fourth Estate and the Constitution: Freedom of the Press in America* (1992); Ronald D. Rotunda & John E. Nowak, *Treatise on Constitutional Law: Substance and Procedure* (4th ed. 2007); Timothy Zick, *Speech Out of Doors: Preserving First Amendment Liberties in Public Places* (2009); Dale Carpenter, *The Antipaternalism Principle in the First Amendment*, 37 Creighton L. Rev. 579 (2004); Ronald K.L. Collins & David M. Skover, *The Guardians of Knowledge in the Modern State: Post's Republic and the First Amendment*, 87 Wash. L. Rev. 369 (2012); Heidi Kitrosser, *Containing Unprotected Speech*, 57 Fla. L. Rev. 843 (2005); Steven D. Smith, *Believing Persons, Personal Believings: The Neglected Center of the First Amendment*, U. Ill. L. Rev. (forthcoming), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=350361; William W. Van Alstyne, *First Amendment Limitations on Recovery from the Press—An Extended Comment on "The Anderson Solution"*, 25 Wm. & Mary L. Rev. 793 (1984).

At its core, the First Amendment ensures that "debate on public issues [will] be uninhibited, robust, and wide-open." *N.Y. Times*, 376 U.S. at 270. "Those who won our independence had confidence in the

power of free and fearless reasoning and communication of ideas to discover and spread political and economic truth." *Thornhill v. Alabama*, 310 U.S. 88, 95 (1940). The decision below runs counter to all this.

a. Matters of public concern are at the heart of the First Amendment guarantee, and scientific speech is well within this core protection because it promotes the collective good and fosters individual self-realization. Free speech, which protects the rights of both the speaker and the audience, is essential to educating an informed electorate. *See Bd. of Educ. v. Pico*, 457 U.S. 853, 866-67 (1982) (plurality opinion); Alexander Meiklejohn, *Free Speech and Its Relation to Self-Government* 24-27 (1948); *see also* Erwin Chemerinsky, *Content Neutrality as a Central Problem of Freedom of Speech: Problems in the Supreme Court's Application*, 74 S. Cal. L. Rev. 49, 55-56 (2000) (suppression of speech distorts "the marketplace of ideas").

This Court has specifically recognized that scientific speech regarding medicine and health are matters of public concern at the core of the First Amendment guarantee because such speech promotes individual self-realization. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 756 (1976) (drug price information protected by First Amendment). The right to speak on matters of health and medicine is "more than a convenience," because "[i]t could mean the alleviation of physical pain or the enjoyment of basic necessities." *Id.* at 764.

This Court recently reaffirmed the importance of uninhibited speech on health-related topics in *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659 (2011), holding that speech in aid of pharmaceutical market-

ing, which affects individual health choices, is protected by the First Amendment. *See also* Coleen Klasmeier & Martin H. Redish, *Off-Label Prescription Advertising, the FDA and the First Amendment: A Study in the Values of Commercial Speech Protection*, 37 Am. J.L. & Med. 315, 351 (2011) (government should not "influence [individuals'] choices through selective suppression of one side of a debate"). *Sorrell* also put to rest any suggestion that the "commercial" nature of pharmaceutical manufacturers' speech (that is at least plausible and not objectively false) takes it out of the ambit of the First Amendment. 131 S. Ct. at 2665; *see also United States v. Caronia*, 703 F.3d 149, 163-64 (2d Cir. 2012).

b. Scientific knowledge evolves constantly and often radically. Fostering a model of scientific humility that recognizes that scientific "truth" may suffer tectonic shifts, through protection of debate on important scientific issues, is therefore key to scientific advancement.

This Court has explained that "there are no certainties in science." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993). History is littered with the remnants of "scientific truths" later proved utterly false.

Perhaps the most famous example of this phenomenon is the notion that the universe revolves around the Earth, an idea for which Galileo Galilei was forced to renounce his life's work (or suffer torture) because his theory that the earth revolves around the sun challenged Church orthodoxy. Zsolt De Harsanyi, *Galileo and the Inquisition* (1939).

History is full of similar examples of individuals punished for advancing beliefs that the institutions

of their day deemed objectively false, but which are now considered objectively true. For example, Ignác Semmelweis challenged the long-held belief that disease is caused by invisible "miasmas" in the air. Sherwin B. Nuland, *The Doctor's Plague: Germs, Childbed Fever, and the Strange Story of Ignác Semmelweis* 61, 177-79 (2004). Semmelweis was persecuted for his beliefs and eventually died in an institution; he was later proved right when Louis Pasteur confirmed the germ theory. *Id.* Similarly, the medieval idea that rust and other visible evidence of oxidation was caused by a mysterious element called "phlogiston" prevailed for over 100 years before it was disproved by Antoine-Laurent Lavoisier. Richard Morris, *The Last Sorcerers: The Path from Alchemy to the Periodic Table* (2003).

As a noted science historian puts it, "there can be no cast-iron guarantee that the cutting-edge science of today will not represent the discredited alchemy of tomorrow." Patricia Fara, *Science: A Four Thousand Year History* 364 (2009). Indeed, modern science continues to surprise us: Until recently, scientists clung to the belief that ulcers and gastritis must be caused by spicy food or stress because it was believed that no bacteria could survive the intensely acidic environment of the human stomach. Scientists Barry Marshall and Robin Warren won the 2005 Nobel Prize for medicine for their 1982 discovery that bacteria does in fact survive in the stomach and lives to cause ulcers and gastritis. *See* Barry J. Marshall & J. Robin Warren, *Unidentified Curved Bacilli in the Stomach of Patients with Gastritis and Peptic Ulceration*, 323 Lancet 1311 (1984).

Thus, as Justice Frankfurter explained, "[t]he history of civilization is in considerable measure the displacement of error which once held sway as offi-

cial truth by beliefs which in turn have yielded to other truths." *Dennis v. United States*, 341 U.S. 494, 550 (1951) (Frankfurter, J., concurring). To permit the displacement of error, the "search for truth ought not to be fettered, no matter what orthodoxies [a person] may challenge" because "truth [cannot] be pursued in an atmosphere hostile to the endeavor or under dangers which are hazarded only by heroes." *Ibid.*

c. Like a medieval inquisitor, however, the government prosecuted Dr. Harkonen for expressing publicly his plausible conclusion that the Actimmune clinical trial had demonstrated a survival benefit for a certain class of IPF patients. At trial, the government sought to prove that this statement was "false" by eliciting testimony that a drug is not effective at treating a disease unless clinical trial results possess a p-value of less than 0.05. The jury, district court, and court of appeals accepted this arbitrary definition of "truth." Our Constitution, however, contains no requirement of statistical significance.

A p-value simply measures the probability that variations in outcomes between a control group and a test group can "be explained by the play of chance"; a low p-value means "something other than chance" likely explains the difference. Federal Judicial Center, *Reference Manual on Scientific Evidence* 250 (3d ed. 2011). A "statistically significant" test is one in which the p-value is less than some preselected number. Although "statistical analysts typically use levels of 5% and 1% [*i.e.*, 0.05 or 0.01]," "*such levels are at best useful conventions*." *Id.* at 251-52 (emphasis added). "[S]ignificant differences may be evidence that something besides random error is at work" but "[t]hey are not evidence that this something is legally or practically important." *Id.* at 252. That is because

observations with a low p-value may in fact be the result of random chance, and observations with a high p-value may in fact be significant (nonrandom). A p-value is itself a measure of probability; while it is useful for many purposes, including evaluating the relative strength of experimental data in the laboratory and the admissibility of such evidence in the courtroom, it does not serve to separate objective truth from falsity.

To be sure, some "statements of fact" are capable of being proved objectively false by reference to external evidence, such as whether a person has been awarded the Medal of Honor (*Alvarez*, 132 S. Ct. at 2543) or was elected Prom Queen. Other statements, by contrast, involve subjective views, opinions, or conclusions, such as whether the Prom Queen is beautiful, or whether "[a]s an absolute matter of fact . . . not a single measure" in the President's recent gun control proposals "in any way violates the Constitution" (Jay Carney, White House Press Sec'y, Press Briefing (Mar. 26, 2013)). The test data in this case (that 70% more of those with mild to moderate symptoms who received Actimmune showed improvement than those who received a placebo) are in the former category. The conclusions to be drawn from the data (that the results "demonstrate a survival benefit") are in the latter. Regardless of whether a different constitutional analysis might be applied to statements that can be proved false by reference to objective, external evidence (*cf. Alvarez*, 132 S. Ct. at 2544-45), such statements are not at issue in this case.

Here, the government alleged, and the jury was permitted to find, that Dr. Harkonen's statement that Actimmune had demonstrated a benefit was false because the p-value of the underlying data was

greater than 0.05. Pet. App. 28a. Indeed, the district court characterized 0.05 as "somewhat of a magic number" in biostatistics. *Id.* at 19a. And once the jury found the statement false because of its p-value, according to the district court and the court of appeals, the statement was stripped of all First Amendment protection. *Id.* at 40a-41a; 4a-6a.

Like all conventions, using a p-value of 0.05 as a measure of statistical significance may be useful and efficient in many scenarios, although this Court has cautioned that "a case-by-case approach properly reflects our recognition that statistics come in infinite variety and . . . their usefulness depends on all of the surrounding facts and circumstances." *Watson v. Fort Worth Bank & Trust*, 487 U.S. 977, 996 n.3 (1988) (plurality opinion) (internal quotation marks omitted; alteration in original). For example, an expert's conclusion based on data that did not reach this level of statistical significance could (and in many circumstances should) be excluded from evidence because of the prevailing methodology in the field of study at issue. *See Daubert*, 509 U.S. at 592-93.

At the same time, however, a p-value of 0.05 is *not* a "magic number" that could possibly mark the dividing line between objective truth and falsity under the First Amendment—for all purposes, or in the context of this case.

First, the scientific community at large does not agree that a p-value of 0.05 is the only relevant measurement for drawing conclusions from clinical results. There was a vigorous scientific debate about how to interpret the results of the 2000-02 Actimmune trial, which mirrors a larger scientific debate about the meaning of statistical significance for mak-

ing clinical treatment decisions. There were many scientists on either side of the debate regarding which conclusions could be drawn from the Actimmune trial. The editors of the New England Journal of Medicine concluded, in the published follow-up to the clinical trial, that "a clinically significant survival advantage could not be ruled out." Ganesh Raghu et al., *A Placebo-Controlled Trial of Interferon Gamma-1b in Patients with Idiopathic Pulmonary Fibrosis*, 350 New Eng. J. Med. 125, 125 (2004). Indeed, as one expert explained at sentencing, the article shows that the *only false* statement one could make about the trial data would be that the trial proved that Actimmune had *no* survival benefit. Pet. App. 101a-102a.

Other medical researchers have emphasized that reliance on statistical significance alone may cause "clinically important differences" to be incorrectly "denoted as non-significant and ignored." Jonathan A.C. Sterne & George Davey Smith, *Sifting the Evidence—What's Wrong with Significance Tests?*, 322 Brit. Med. J. 226, 227 (2001). A study that demonstrates that many patients treated with Actimmune live longer may be meaningful to doctors and patients—especially given that IPF is a fatal and otherwise untreatable illness—regardless of the fact that the study results do not meet the 0.05 level. *See id.*

Second, government agencies do not demand statistical significance for all inquiries related to drug development. Indeed, the FDA itself has acknowledged that there has been an active debate about "what constitutes sufficient evidence of effectiveness" for drawing conclusions from clinical drug tests. Food and Drug Administration, *Guidance for Industry Providing Clinical Evidence of Effectiveness for*

Human Drug and Biological Products 1 (1998), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory/Information/Guidances/UCM078749.pdf. The FDA has indicated that its drug-approval criteria (including the "conventional levels of statistical significance" of "p-value = 0.05") merely represent the agency's "current thinking" and are not dispositive one way or the other for any specific new drug application. *Id.* at 1 n.1, 5 & n.5. It thus appears that the FDA—the expert agency charged with regulating drugs—does not agree with the Department of Justice's absolutist approach to statistical significance in this case.

Similarly, the U.S. Patent and Trademark Office explicitly does *not* require applicants to prove a drug's beneficial effects "as a matter of statistical certainty" to be patentable. *See* Manual of Patent Examining Procedure § 2107.03 (8th ed. Rev. 9, Oct. 2012); *see also Ex parte Quadranti*, 25 U.S.P.Q.2d 1071, 1072-73 (B.P.A.I. 1992). It thus appears that the PTO—another expert agency with considerable experience with statistical and other scientific aspects of pharmaceutical innovation—does not agree with the Justice Department's views of statistical significance in this case.

Third, in the context of the securities laws, the Court recently held that the absence of statistical significance does not disprove a causal link between treatment with a drug and an observed effect: "A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link." *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1319-20 (2011) ("medical professionals and researchers do not limit the data they consider to the results of randomized clinical

trials or to statistically significant evidence") (internal quotation marks omitted).

This Court's holding in *Matrixx* was supported by the Solicitor General's *amicus* brief, which explained that "a determination that certain data are not statistically significant . . . does not refute an inference of causation"; for example, "[a] study in which the cure rate for cancer patients who took a drug was twice the cure rate for those who took a placebo could generate meaningful interest even if the results were not statistically significant." Brief for the United States as *Amicus Curiae* Supporting Respondents, *Matrixx*, 131 S. Ct. 1309 (No. 09-1156), 2010 WL 4624148, at *14-15 & n.2 (citing Sterne & Smith, *supra*). It thus appears that the Solicitor General—the highest litigating official of the Department of Justice—does not agree with the concept of statistical significance advanced by his subordinates who prosecuted this case.

As these diverging views demonstrate, there is no basis even in extant government practice, much less in science or law, to use a p-value of 0.05 to draw the line between "truth" and "falsity"—between constitutionally protected and unprotected speech. A plausible conclusion drawn from experimental data, even if not statistically significant at the 0.05 level, is nonetheless a statement protected by the First Amendment. It might or might not have much scientific (or evidentiary) value; but that is for the marketplace of ideas, not government regulators, to determine. It would set a dangerous precedent indeed to allow the jailing of scientists for expressing plausible views on test data based solely on the absence of an arbitrary level of statistical significance.

CONCLUSION

The petition for writ of certiorari should be granted, and the judgment of the court of appeals should be reversed.

Respectfully submitted.

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