No. 13-

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**

# PETITION FOR A WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

The Ninth Circuit upheld a wire fraud conviction for the issuance of a press release about a pharmaceutical clinical study. The only statements charged as false expressed a conclusion, *i.e.*, that the data demonstrated that the drug benefitted patients. The government conceded that the data in the press release, which showed that far more patients survived on the drug than on placebo, were accurate. The government challenged as false only the inference that the drug (and not random chance) caused that beneficial outcome.

The questions presented are:

1. Whether a conclusion about the meaning of scientific data, one on which scientists may reasonably disagree, satisfies the element of a "false or fraudulent" statement under the wire fraud statute, 18 U.S.C. § 1343?

2. Whether applying 18 U.S.C. § 1343 to scientific conclusions drawn from accurate data violates the First Amendment's proscription against viewpoint discrimination, or renders the statute, as applied, unconstitutionally vague.

## PARTIES TO THE PROCEEDING

All parties to the proceeding are listed in the caption.

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## PETITION FOR A WRIT OF CERTIORARI

Petitioner W. Scott Harkonen respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit.

## OPINIONS BELOW

The opinion of the court of appeals is unpublished, but is available at 510 F. App'x 633, and is reproduced at Pet. App. 1a-8a. The district court's decision denying the pre-trial motion to dismiss the indictment is unpublished and is reproduced at Pet. App. 55a-81a. That court's decision denying the post-trial motion to dismiss the indictment, for acquittal, or for a new trial is unpublished and is reproduced at Pet. App. 9a-54a.

## JURISDICTION

The judgment of the court of appeals was entered on March 4, 2013. Pet. App. 1a. A timely petition for rehearing en banc was denied on May 7, 2013. Pet. App. 82a. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the First Amendment, Due Process Clause, and 18 U.S.C. § 1343, reproduced at Pet. App. 83a.

## STATEMENT OF THE CASE

This case has drawn national attention because the government has criminalized the expression of a reasonable scientific opinion. Harkonen, a physician, researcher, and former CEO of InterMune, Inc., was

convicted on one count of wire fraud. His conviction stemmed solely from the issuance of a single press release. The press release reported the preliminary results of a randomized, double-blind, placebo-controlled clinical trial, "the 'gold standard'" for clinical trials. Pet. App. 15a. The press release stated that study results demonstrated that a prescription medication, Actimmune, provided a survival benefit to patients with idiopathic pulmonary fibrosis ("IPF"). Pet. App. 84a (original press release reproduced at ER1906-09).

Harkonen's conviction is extraordinary because the "Government has always agreed that there was *no falsification of data here, so that fact is not in dispute*."[1] ER1670 (emphasis added); see ER1710-11. The government concedes that 40% more patients who received Actimmune survived than did patients who received a placebo and that, in a large subgroup of patients with mild-to-moderate IPF, 70% more survived. The results for the study's pre-specified primary endpoint, however, were not "statistically significant" (*i.e.*, the statistical calculation known as a "p-value" exceeded the pre-set target of 0.05). All this, and much more, is in the press release. The government contended, however, that because the study failed to meet its primary endpoint, the study itself was a failure, and the remarkable survival data "at best only '*suggested*'" a survival benefit, but did not *demonstrate* one. ER2497. It is this alleged *"falsification of the conclusions that could be drawn* from the data, that was what the trial was all about." ER1670 (emphasis added).

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[1] Excerpts of Record ("ER") and Supplemental Excerpts of Record ("SER") are from *United States* v. *Harkonen*, Nos. 11-10209 & 11-10242 (9th Cir. filed Oct. 31, 2011, Mar. 30, 2012), ECF Nos. 27, 63.

No federal fraud prosecution should ever be "all about" the conclusions drawn from concededly accurate data, at least where, as here, no law mandates adherence to the government's viewpoint, and no scientific consensus exists on the issue. The fraud laws do not apply to such scientific conclusions, and any prosecution of them violates the First Amendment and the Due Process Clause.

The constitutional violations here are particularly stark. After Harkonen's jury agreed with the prosecutors' "p-value theory" of scientific inference, the Solicitor General filed a brief urging this Court to *reject* that same theory, *i.e.,* that statistical significance determines scientific truth. Instead, the Solicitor General explained, "[s]tatistical significance is a limited and non-exclusive tool for inferring causation," and "a determination that certain data are not statistically significant . . . *does not refute* an inference of causation." Brief for the United States as *Amicus Curiae* at 13-14, *Matrixx Initiatives, Inc.* v. *Siracusano*, 131 S. Ct. 1309 (2010 (emphasis added).

A government witness and former federal medical researcher (SER1326-27) conceded this at Harkonen's trial. He testified that there can be "a lot of vigorous debate" about study data and "the conclusions that one ought to draw from those data," and admitted that the differing conclusions drawn from the data here reflected an "academic debate" for which "there wasn't an obvious right or wrong." ER1085-86.

In this country, "the conclusions that one ought to draw from . . . data" (*id.*) are for scientists to debate, not for the government to prosecute as wire fraud. This Court established that principle over a century ago in *American School of Magnetic Healing* v. *McAnnulty*, 187 U.S. 94 (1902). There, the Court limited the materially identical language of the civil

mail fraud statute to "cases of actual fraud in fact, in regard to which opinion formed no basis." *Id.* at 106. In subsequent criminal and civil cases alleging false or fraudulent scientific conclusions, most recently in *ONY, Inc.* v. *Cornerstone Therapeutics, Inc.*, No. 12-2414-cv, 2013 WL 3198153 (2d Cir. June 26, 2013), the courts of appeal and this Court have followed *McAnnulty*'s principle. By treating *McAnnulty* as a dead letter, the Ninth Circuit's decision sweepingly expands the scope of the federal fraud statutes, creates conflicts with other circuits concerning the constitutional limits on the imposition of liability for scientific interpretation, and validates blatant viewpoint discrimination without adequate notice of what is proscribed. The intended chilling effects of this extraordinary decision warrant review now.

1. The press release announced the preliminary results of a Phase III study, conducted at 58 medical centers world-wide. The study was by far the largest ever conducted for a treatment for IPF, a rare lung disease with a median survival time of only two to three years. The study followed a Phase II study on Actimmune, published in the *New England Journal of Medicine*, which was the first controlled study of any treatment to show "substantial improvements in the condition" of the IPF patients. ER2001.

The press release was issued on August 28, 2002, by InterMune, a public biotech company that sponsored the study. The headline stated: "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF"; the subtitle stated: "Reduces Mortality by 70% in Patients with Mild to Moderate Disease." Pet. App. 84a. The opening paragraph stated that the "preliminary" data "demonstrate a significant survival benefit in patients with mild to moderate disease randomly

assigned to Actimmune versus control treatment (p=0.004)." *Id.*

Much other information, all accurate, followed the headlines. The opening paragraph stated, and a later sentence repeated, that the results on the study's primary endpoint, an approximately ten percent improvement in survival without progression in disease severity, were not statistically significant.[2] Pet. App. 84a-86a.

The press release also provided the results for survival alone. *Forty percent more* Actimmune patients survived the trial compared to patients given a placebo; the p-value for this result was 0.084. Pet. App. 86a. For a large subgroup (more than three-fourths of those studied) who began the study with mild-to-moderate IPF, the relative survival benefit was 70% and the associated p-value was 0.004. *Id.* These Phase III survival results were consistent with those of the long-term follow-up of the prior Phase II study, in which nearly all the Actimmune patients, but not the control group, survived: the "Kaplan Meier estimate of survival at five years was 77.8% and 16.7% in the Actimmune and control groups, respectively (p=0.009)." *Id.* at 86a-87a.

Dr. Ganesh Raghu, the lead investigator of both the Phase III study and the long-term follow-up on Phase II, was quoted saying that the "'mortality benefit'" was "'very compelling'" and Actimmune "'is the first

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[2] A p-value is a statistical calculation of the likelihood that the observed result (or one more extreme) would have occurred randomly if, in reality, the drug caused no effect. A result with a p-value of 0.05 means that, if the drug truly has no effect, then the probability that the study would have randomly generated the observed result (or one more extreme) is only 5%; the 5% figure is conventional, but arbitrary. ER2560, 2575.

treatment ever to show any meaningful clinical impact in this disease in rigorous clinical trials.'" Pet. App. 85a. Dr. James Pennington, InterMune's Executive Vice President of Clinical and Medical Affairs, said the two studies provide a "'compelling rationale for [the] consideration of Actimmune for the treatment of patients with this disease.'" *Id.* at 87a. Dr. Harkonen said:

> "We are extremely pleased with these results, which indicate Actimmune may extend the lives of patients suffering from this debilitating disease . . . . Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical studies. We believe these results will support use of Actimmune and lead to peak sales in the range of $400-$500 million per year, enabling us to achieve profitability in 2004 as planned."

*Id.* at 85a.

The press release also stated that FDA had not approved any treatment for IPF, and nowhere claimed that FDA would approve Actimmune for IPF. Pet. App. 90a. It announced that InterMune would "discuss these results" on a conference call with analysts and investors that morning at 9:00 a.m. EDT. *Id.* at 85a, 88a. It also stated that "[t]hese data will be presented in more detail" at the annual European Respiratory Society ("ERS") conference in Stockholm on September 15, 2002, and at the annual American College of Chest Physicians conference in San Diego in November 2002. *Id.* at 88a.

The press release reported results on one other secondary endpoint (dyspnea) but not on seven others. It did not state that the "mild-to-moderate

subgroup" was not pre-specified in the study's statistical analysis plan. The survival p-values were not adjusted to account for the study's multiple endpoints (the study's statistical analysis plan, like most, did not require such adjustments). ER2281-94. Such facts and much other information were provided in the next days and month to investors and analysts, to investigators at the medical centers, at public presentations, at the ERS conference, and to FDA reviewers. *E.g.*, ER1917-18, 2345-2402, 2188-2204, 2623-29, 2653-55, 2763-82.

2. On March 18, 2008, the indictment charged Harkonen with wire fraud in violation of 18 U.S.C. § 1343, and misbranding of Actimmune in violation of 21 U.S.C. §§ 331(k), 333(a)(2) & 352(a). The jury acquitted Harkonen of misbranding.[3] With respect to wire fraud, the indictment alleged that Harkonen devised a scheme to "obtain money and property by means of materially false and fraudulent pretenses" to "induce doctors to prescribe, and patients to take, Actimmune for IPF." ER221. The indictment contained no allegation, however, that Harkonen personally and directly profited from the release (*e.g.*, through sales of stock).

Instead, it alleged that the Press Release "contained false and misleading information regarding Actimmune and falsely portrayed the results as establishing that Actimmune helped IPF patients live longer." *Id.* It cited the headline ("InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF") and the subheading ("Reduces Mortality by 70% in Patients with Mild to Moderate Disease") as the "false and misleading" statements. ER221-22.

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[3] The district court had jurisdiction under 18 U.S.C. § 3231.

The indictment also asserted that Harkonen knew the headlines were false because, in a phone call the day before the press release issued, two members of "FDA['s] medical review staff" told Harkonen and others that, in their personal view, the "data were inconclusive" and "would not be enough to get FDA approval for Actimmune to treat IPF, and that further study would be needed to determine whether Actimmune was effective for treating IPF." ER220; see ER509-10. This phone call allegedly put Harkonen on notice that the study "failed to show that Actimmune was effective in treating IPF." ER219.

3. Harkonen moved to dismiss the indictment because the charged statements are scientific opinions protected by the First Amendment. He submitted a biostatistician's declaration that the press release was "true and not misleading." ER2490-94 ¶3. He submitted reports published *one day* after the press release stating that medical experts found the survival data from the study "compelling and supportive of continued utilization of Actimmune" for IPF, and did so notwithstanding their awareness of the failure on the primary endpoint *and* the retrospective nature of the subgroup analysis. *E.g.*, Pet. App. 91a. One report noted that there was "reason to believe" FDA might approve Actimmune for IPF based on "the existing data set" because of "regulatory precedent," namely "FDA approval of Glaxo's Coreg" where mortality was not a pre-specified endpoint and there was "borderline" statistical significance on the primary endpoints.[4]

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[4] Ex. 15, at 4, Topel Decl., No. 3:08-cr-00164 (N.D. Cal. filed Mar. 23, 2009) (Dkt. 89).

The district court denied the motion, holding that a company press release is commercial speech and a jury should decide whether it is fraudulent. Pet. App. 65a-72a. The court rejected Harkonen's argument that "a finding of fraud is barred here because the press release contains statements of scientific opinions and perspectives about the meaning of the clinical data." *Id.* at 69a. The court held that if a jury credited the FDA reviewer's scientific viewpoint, Harkonen's statements would be false. *Id.* at 69a-70a.

4. At trial, the government pressed its theme that Harkonen knowingly defied "FDA's" scientific views. *E.g.*, ER1616-18. The government opened with the testimony of Dr. Marc Walton, an FDA medical reviewer who told InterMune the study results were inconclusive. The government next presented a biostatistics professor and "special FDA employee," Dr. Thomas Fleming, who chaired the study's Data Safety Monitoring Board, and who sent InterMune a letter strongly criticizing the press release as misleading. Other government witnesses included two former InterMune employees, Drs. Michael Crager and Steven Porter, a biostatistician and medical doctor respectively. Each expressed the view that if results on a study's primary endpoint are not statistically significant, then no conclusions about whether the drug caused an effect may be drawn, and "all other analyses arising out of that study, including analysis of secondary endpoints," are only "'exploratory.'" See Pet. App. 21a.

Citing this testimony, the government argued in closing that the study "failed." ER1601. The study's "only meaningful p-value" is for the primary endpoint, which "was 0.5," and that means "you can't draw any conclusions from this trial." ER1602. It

therefore was "just false," the prosecutor argued, to conclude "that Actimmune . . . has a survival benefit." ER1601.

5. Harkonen's counsel pointed to admissions that the personal views of an FDA reviewer on a phone call are not those of FDA, and that no rule or regulation establishes the prosecution's primary-endpoint/p-value theory of scientific inference. ER429-30, 514. No witness testified that the theory was universally accepted in the scientific community. Several government witnesses conceded that there can be "a lot of vigorous debate" about study data and "the conclusions that one ought to draw from those data." ER1085; see also ER834 (Raghu); ER507-08 (Walton).

Other government witnesses admitted that, in 2002, their view was that the study was "successful" and supported a finding of a "positive survival effect." *E.g.*, ER787, 2403 (Raghu); ER1928 (Crager). Long after Harkonen left InterMune, Porter approved InterMune's Final Clinical Study Report to FDA, which stated that a "stronger survival benefit was demonstrated" in the subgroup of patients with mild-to-moderate IPF. ER2303. At trial, Porter confirmed that this Report accurately concluded that the subgroup analysis "'showed a survival benefit'" (ER 1023-24, 2410, 2416); Porter viewed the likelihood that Actimmune *caused* that benefit as "65 percent" (ER1057-58).

6. Harkonen moved for acquittal under the First and Fifth Amendments and alternatively for a new trial. Citing and quoting *McAnnulty*, Harkonen argued that the evidence established that the challenged conclusions were at least subject to dispute by reasonable minds, and thus outside the wire fraud statute.

a. On July 27, 2010, the district court denied the post-trial motions. Pet. App. 54a.

The court acknowledged that "a number of witnesses who testified, including Crager . . . agreed . . . that the data demonstrated a survival benefit." Pet. App. 33a; see also *id.* at 33a n.3 (describing evidence). Ignoring *McAnnulty* altogether, however, the court stated that "simply because numerous individuals may have repeated a fraudulent characterization of the data from the [study] does not make that characterization less false or fraudulent." *Id.* at 33a.

The Court said it "need not expend much energy" on Harkonen's First Amendment arguments because it is "well settled that the First Amendment does not protect fraud." Pet. App. 40a (quotations omitted). The court explained that testimony supported the government's theory of falsity because it showed that "a p-value of 0.05 is somewhat of a magic number" above which "the results are generally considered unreliable and not statistically significant." *Id.* at 19a.

The court rejected Harkonen's due process challenge as "simply ludicrous" because all are on notice that it could be a crime to "lie[] in a press release about the success of a clinical trial for a drug that might have sales as high as $500 million per year." Pet. App. 42a. The court permitted the jury to infer that Harkonen knew the statements in the press release were false because FDA officials had told him the data were inconclusive (*id.* at 35a) and because he knew the subgroup highlighted in the press release was not pre-specified; the jury also could infer an intent to defraud from Harkonen's "financial motivation" as InterMune's CEO. *Id.* at 36a.

7. At sentencing, the government attributed all subsequent increases in Actimmune prescriptions to the press release, and argued for a 10-year prison term so it "will be noted in executive suites and boardrooms of drug companies across the United States"and because "[g]eneral deterrence is needed in this area." SER4950.

Harkonen presented evidence that pulmonologists prescribed Actimmune based on their evaluation of the study data, not on headlines in one press release. He submitted supporting declarations from a leading pulmonologist and assistant professor at Harvard Medical School who explained that in 2002, he and other pulmonologists independently concluded from the study data and other information that it was appropriate to prescribe Actimmune to patients with mild-to-moderate IPF, and that patients had benefitted from it. ER2622-60. He submitted declarations from two eminent biostatisticians who explained, *inter alia*, why Harkonen's conclusion was consistent with the subsequent article in the *New England Journal of Medicine*, why the scientific viewpoint supporting the prosecution and post-trial opinion "stunned" them, and why criminal punishment would gravely chill communication about scientific research. Pet. App 93a-104a; ER2556-66, 2572-82.

After two sentencing hearings, the district court could not determine "who is a victim in this case, and whether the victims were benefitted in some way." ER1857. The court acknowledged that "some people did apparently derive some benefit" from Actimmune (SER3568) and that "there may be other ways of handling violations of this nature besides through criminal charges." ER1854-55. Harkonen was sentenced to three years probation, with 200

hours of community service and six months of home confinement, which he currently is serving. ER1858.

8. Harkonen appealed the conviction, and the government cross-appealed the sentence. The Ninth Circuit affirmed.

a. The Ninth Circuit gave Harkonen's First Amendment challenge short shrift, because "the First Amendment does not protect fraudulent speech." Pet. App. 2a, 5a-6a. Even though the jury was instructed that it must find "'the defendant made a scheme to defraud by making false or fraudulent statements, with all of you agreeing on at least one false or fraudulent statement that was made'" (*id.* at 53a n.6), the court did not identify any false or fraudulent statement.

Instead, the court deemed the evidence of falsity sufficient because "nearly everybody actually involved in [the Phase III] clinical trial testified that the press release misrepresented [the] results." Pet. App. 3a. Such testimony "also strongly supports the finding that Harkonen had the specific intent to defraud," as did Harkonen's status as CEO. *Id.* at 4a.

b. The court rejected Harkonen's argument that the wire fraud statute does not cover what the government "might think to be false opinions" about science if "intelligent people may and indeed do differ among themselves as to the extent" of the medical benefit. *McAnnulty*, 187 U.S. at 104-06. Although "genuine debates of any sort are, by definition, not fraudulent" (Pet. App. 6a), the court found *McAnnulty* inapplicable because "intent to defraud" under the wire fraud statute criminalizes "*any* 'trick, deceit, chicane or overreaching.'" *Id.* (citing *Carpenter* v. *United States*, 484 U.S. 19, 27 (1987) (emphasis added)).

c. The Ninth Circuit summarily rejected Harkonen's due process challenge because an "ordinary person" would have understood "that if he made misleading statements in a press release with the specific intent to defraud he would be subject to the wire fraud statute." Pet. App. 6a.

## REASONS FOR GRANTING THE PETITION

The petition should be granted because a wire fraud prosecution for drawing false conclusions from accurate clinical trial data conflicts with this Court's precedents and decisions of three other circuits, is inherently arbitrary, and is chilling valuable scientific speech and debate on matters of public concern. Harkonen's conviction "stunned" leading members of the scientific community (Pet. App. 97a) who vehemently disagree that p-values are "magic number[s]" (*id.* at 19a) that define when data are "reliable" and bar scientists from inferring causation from clinical trial results where p-values exceed 0.05. *Id.* at 98a-104a; ER2575.

This Court established long ago that the expression of a scientific conclusion about which reasonable minds can differ is not "false and fraudulent" within the meaning of the civil postal mail fraud statute. *McAnnulty*, 187 U.S. at 104-06. The Sixth and Eighth Circuits then faithfully applied *McAnnulty* to the criminal mail fraud statute that is, in all relevant respects, identical to today's wire fraud statute. *Infra* 15-17. The Second Circuit and other courts also have held that a press release expressing a scientific conclusion drawn from accurate data is not actionable under laws prohibiting false or fraudulent statements. *Infra* 17-19.

The Ninth Circuit's decision conflicts with these decisions and raises grave First Amendment and due

process concerns that *McAnnulty*'s limiting construction deliberately avoids. Review is warranted immediately, because pharmaceutical companies routinely do and must issue press releases announcing material clinical trial results. Chilling such speech—forcing it to conform to the opinions of FDA staff—was the avowed intent of this prosecution. Government officials are now empowered to say, in the investigations that pervade the pharmaceutical industry, that those who publicly disagree with the scientific views of government employees do so at their criminal peril. They may send the same message to the many scientists whose research depends on government grants or public funding. The chilling effect of this message is immediate and extraordinary, and fully warrants this Court's review.

## I. THE NINTH CIRCUIT'S DECISION, WHICH EXPANDS THE WIRE FRAUD STATUTE TO COVER DEBATABLE SCIENTIFIC CONCLUSIONS, CONFLICTS WITH *MCANNULTY* AND DECISIONS FROM THREE OTHER CIRCUITS.

This Court held in *American School of Magnetic Healing* v. *McAnnulty* that the civil mail fraud statute does not apply to "mere matters of opinion upon subjects which are not capable of proof as to their falsity." 187 U.S. at 104. There, the Postmaster General banned the delivery of mail and postal money orders for a business that taught that "the mind of the human race is largely responsible for its ills, and is a perceptible factor in the treating, curing, benefiting and remedying thereof." *Id.* at 103 (quotations omitted).

The Court reversed because there was "no exact standard of absolute truth by which to prove the assertion false and a fraud." *Id.* at 104. The Court

recognized that the Postmaster's fraud order "raises some grave questions of constitutional law." *Id.* at 103. The Court found it "unnecessary to decide" those questions, *id.*, however, because it construed the statute not to encompass allegedly false statements that "cannot be the subject of proof as of an ordinary fact." *Id.* at 104. Where scientific knowledge is "still in an empirical stage," and the extent to which a claim is "borne out by actual experience" is a "matter of opinion" over which "intelligent people may and indeed do differ among themselves," then as a matter of law the claim is not "within these statutes relative to fraud." *Id.* at 104-05.

Several decades later, this Court again overturned a civil fraud order, reaffirming *McAnnulty* as a "wholesome limitation" on the government's ability to prosecute scientific opinion. *Reilly* v. *Pinkus*, 338 U.S. 269, 274, 275-76 (1949). Although a defendant cannot avoid a finding of fraud simply by producing a witness "who blindly adhere[s] to a curative technique thoroughly discredited by reliable scientific experiences," the expression of an opinion in a field "where knowledge has not yet been crystallized in the crucible of experience" is *not* "fraud." *Id.* at 274.

1. The Sixth and Eighth Circuits have applied *McAnnulty* to criminal mail fraud prosecutions. See *Stunz* v. *United States*, 27 F.2d 575, 578-79 (8th Cir. 1928) (*McAnnulty* and *Bruce* v. *United States*, *infra*, require reversal of a mail fraud conviction based on allegedly false claims about a medical treatment if "the case only presented a difference of opinion between two sets of experts"); *Bruce* v. *United States*, 202 F. 98, 105 (8th Cir. 1912) (citing *McAnnulty* and reversing mail fraud conviction where medical experts disputed a drug's efficacy where jury was not instructed that "'[n]o conviction of fraudulent purpose

can lawfully be based upon matters merely of opinion'"); *Harrison* v. *United States*, 200 F. 662, 665 (6th Cir. 1912) (*McAnnulty* provides "necessary limitations" on finding a scheme to defraud based on the "expression of honest opinion"). This application of *McAnnulty* is unsurprising because the criminal mail and wire fraud statutes, and the civil mail fraud statute in *McAnnulty*, all share the same relevant language.[5] Had Harkonen been prosecuted in the Sixth or Eighth Circuits, his conviction would have been overturned.

2. The Second Circuit also would have reversed his conviction. Tracking the reasoning of *McAnnulty,* although not citing it, the Second Circuit held that expressing debatable scientific conclusions based on accurate data does not fall within the Lanham Act's prohibition on false advertising. *ONY*, 2013 WL 3198153, at *6.

In *ONY*, two pharmaceutical companies disputed the conclusions that could fairly be drawn from a clinical study comparing their respective drugs. *Id.* at *2. The defendant funded the study "as part of its effort to promote and sell" its drug. *Id.* The defendant's conclusions, as presented at medical conferences, in a medical journal, and in a press release, were that plaintiff's drug was associated with a greater

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[5] *Compare* 18 U.S.C. § 1343 (outlawing "any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises" through use of the wire communication in interstate commerce), *with McAnnulty*, 187 U.S. 100, n.1 (interpreting Section 3929 of the Revised States, which authorized the Postmaster General to deny use of the mails to any person engaged in conducting a "scheme or device for obtaining money through the mails by means of false or fraudulent pretenses, representations, or promises").

likelihood of death than defendant's drug. *Id.* Plaintiff alleged that this conclusion was an "incorrect" statement of "fact." *Id.* Plaintiff alleged that the authors were self-interested, the journal's review process was corrupt, and the authors reached their conclusion only by intentionally omitting data to "mask the fact" that those treated with defendant's drug "had a greater ex ante chance of survival than did the group treated" with plaintiff's drug. *Id.* at *3.

The Second Circuit nevertheless held that, given First Amendment constraints, the defendant's expression was not actionable under the Lanham Act. *Id.* at *3. The court observed that "[g]enerally, statements of pure opinion—that is, statements incapable of being proven false—are protected under the First Amendment." *Id.* at *4 (citing *Milkovich* v. *Lorain Journal, Co.*, 497 U.S. 1, 19-20 (1990)).

The court observed that "[s]cientific academic discourse poses several problems for the fact-opinion paradigm of First Amendment jurisprudence." *ONY*, 2013 WL 3198153, at *5. It suggested that "[m]ost conclusions contained in a scientific journal article are, in principle, 'capable of verification or refutation by means of objective proof.'" *Id.* But it recognized, as this Court has in *McAnnulty,* that in a "sufficiently novel area of research," propositions of "empirical 'fact'" may be "highly controversial and subject to rigorous debate by qualified experts." *Id.* Where "a statement is made as part of an ongoing scientific discourse about which there is considerable disagreement," it is "understood by the relevant scientific communities" as "more closely akin" to an "opinion" than a "verifiable 'fact'." *Id.* at *6.

To avoid "intrud[ing] on First Amendment values," and because "courts are ill-equipped to undertake to referee such controversies" in science, *id.* at *4-5, the

Second Circuit held that "statements about contested and contestable scientific hypotheses" should be treated as statements of opinion for "purposes of the First Amendment and the laws relating to fair competition and defamation," *id.* at *6. Accordingly, if "a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement, those statements are not grounds for a claim of false advertising under the Lanham Act." *Id.*

The Second Circuit restricted the application of the Lanham Act just as this Court restricted the application of the civil mail fraud statute. Neither statute may be used to punish the expression of a scientific conclusion about the meaning of accurate data that is the subject of "legitimate ongoing scientific disagreement," *id.*, on which "intelligent people may and indeed do differ among themselves," *McAnnulty*, 187 U.S. at 104.

3. The Ninth Circuit, in contrast, rejected as "unavailing" Harkonen's "*McAnnulty*-based argument," relying upon what it thought was intervening precedent from the circuit and this Court that rendered *McAnnulty* inapplicable. The prior circuit authority, however, was a *misbranding* prosecution under the Federal Food, Drug, and Cosmetic Act—the charge for which Harkonen was acquitted.

The Ninth Circuit also cited this Court's statement in *Carpenter* v. *United States*, 484 U.S. 19, 27 (1987), that "in the criminal mail fraud statutes, the term 'to defraud' has [a] commonplace definition" that "includes any sort of 'dishonest method[] or scheme[],' and any 'trick, deceit, chicane or overreaching.'" Pet. App. 6a (last two alterations in original). That broad

language, the Ninth Circuit thought, allows opinions about what accurate clinical trial data demonstrated to be actionable as a "false or fraudulent statement" under the mail or wire fraud statute. *Id.*

But *Carpenter* holds only that intangible property (there, inside information) can be "property" under the mail fraud statute. 484 U.S. at 28. Given the unrelated nature of its holding, *Carpenter* cannot fairly be read to supersede *McAnnulty* and *Reilly*. Indeed, *Carpenter* itself makes plain that there is no material difference in the statutory language of today's criminal mail and wire fraud statutes (18 U.S.C. §§ 1341 & 1343) and the civil mail fraud statute at issue in *McAnnulty*. Compare *Carpenter*, 484 U.S. at 27 (criminal fraud statutes "reach any scheme to deprive another of money or property *by means of false or fraudulent pretenses, representations, or promises*") (emphasis added), with *McAnnulty*, 187 U.S. at 103 (statute bars "obtain[ing] money and property through the mails *by means of false or fraudulent pretenses, representations or promises*") (emphasis added).

Only this Court can overrule its prior decisions. *Agostini* v. *Felton*, 521 U.S. 203, 237 (1997). This Court also has repeatedly cabined the government's efforts to expand the mail and wire fraud statutes beyond the limits Congress and the Constitution impose. See, *e.g., Skilling* v. *United States*, 130 S. Ct. 2896, 2925-35 (2010); *McNally* v. *United States*, 483 U.S. 350 (1987).

Had InterMune been located in New York, Cleveland, or St. Louis, Harkonen's conviction would have been overturned. The Sixth and Eighth Circuits already have applied *McAnnulty* to criminal mail fraud. And the Second Circuit surely would not accord less protection to scientific speech when

criminally prosecuted by the government than it did in a suit for money damages by a commercial competitor. Only this Court can resolve this conflict, confirm the continued vitality of *McAnnulty* and *Reilly*, and ensure that scientific speech receives the same protection regardless of where the speaker resides.

## II. EXPANDING THE WIRE FRAUD STATUTE TO ENCOMPASS CONCLUSIONS DRAWN FROM ACCURATE DATA VIOLATES THE FIRST AMENDMENT AND THE DUE PROCESS CLAUSE.

The petition also should be granted because the Ninth Circuit's construction of the wire fraud statute squarely presents the "grave questions of constitutional law" that *McAnnulty*'s narrowing construction avoided. *McAnnulty*, 187 U.S. at 103.

1. The first such question implicates the First Amendment. Construing the criminal mail and wire fraud statutes to permit the government to prosecute scientific conclusions with which the government disagrees raises a question of exceptional importance about the role of independent judicial review to prevent the government from prosecuting as "fraud" scientific viewpoints that the First Amendment protects.

Viewpoint discrimination lies at the core of the First Amendment: the government may not proscribe speech "'because of disagreement with the message it conveys.'" *Sorrell* v. *IMS Health Inc.*, 131 S. Ct. 2653, 2664 (2011); *id.* at 2667 ("In the ordinary case it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint-discriminatory") (citing *RAV* v. *St. Paul*, 505 U.S. 377, 382 (1992)). But here the government prosecuted Harkonen

because the press release expressed a conclusion about accurate data—that they demonstrated a survival benefit—with which two individuals at FDA—"FDA medical review staff"—disagreed. ER220, 224.

The freedom to disagree with other scientists, and especially with government staff, is fundamental to the First Amendment. The Second Circuit so held in *ONY*. The Ninth Circuit, however, fell back on the First Amendment's categorical exclusion of fraud as unprotected speech, and affirmed Harkonen's conviction without independently reviewing whether the challenged conclusions were, indeed, false or misleading. Pet. App. 2a, 5a-6a. First Amendment protections cannot rest solely on labels; they require fair scrutiny of the defendant's statement in the context of legitimate scientific disagreement.

The Ninth Circuit's decision thus raises an important question that this Court has resolved for other categories of unprotected speech, but not yet for fraud, about an appellate court's "constitutional duty to conduct an independent examination of the record as a whole" and to decide "whether a given course of conduct falls on the near or far side of the line of constitutional protection." *Hurley* v. *Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos., Inc.*, 515 U.S. 557, 567 (1995).

There is, of course, no First Amendment right to commit fraud. *E.g.*, *United States* v. *Stevens*, 130 S. Ct. 1577, 1586 (2010). But "[s]imply labeling an action one for 'fraud,' of course, will not carry the day." *Ill. ex rel. Madigan* v. *Telemarketing Assocs. Inc.*, 538 U.S. 600, 617 (2003). A prosecution denominated as one for "fraud," when based on protected speech that a legislature cannot ban directly, requires a "swift dismissal" because a prosecutor "surely cannot gain case-by-case ground this Court

has declared off limits to legislators." *Id.* As Justice Scalia stated, it "is axiomatic that, although fraudulent misrepresentation of facts can be regulated," the "dissemination of ideas cannot be regulated to prevent it from being unfair or unreasonable." *Riley* v. *Nat'l Fed'n of the Blind*, 487 U.S. 781, 803 (1988) (Scalia, J., concurring).

This Court should now grant review to establish that courts have a constitutional duty independently to enforce that very line. When the government prosecutes, as false and misleading, speech the defendant maintains expresses a constitutionally protected viewpoint, the question of the protected nature of the speech cannot be left solely to the jury any more than in other cases, such as defamation, that involve a category of speech unprotected by the First Amendment.

Experience has shown that "[p]roviding 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 . . . to eliminate the danger that decisions by triers of fact may inhibit the expression of protected ideas." *Bose Corp.* v. *Consumers Union of United States, Inc.*, 466 U.S. 485, 505 (1984). Therefore, this Court has requireed independent judicial review in cases involving speech that allegedly falls into many unprotected categories, including not only "fighting words," but also obscenity, child pornography, incitement to imminent lawless action, and libel. See *id.* at 504-10. Independent judicial review ensures that "the speech in question actually falls within the unprotected category" and "confine[s] the perimeters of any unprotected category within acceptably narrow limits" so "protected expression will not be inhibited." *Id.* at 505.

This Court recently exercised its duty to conduct an "'independent examination of the whole record'" and reversed a jury verdict because independent review established that the jury had punished speech on issues "'of public concern.'" *Snyder* v. *Phelps*, 131 S. Ct. 1207, 1216 (2011). The Court also independently reviewed the record and then reversed a state court's finding that an attorney's statement on his letterhead was "actually or inherently misleading" and thus outside the First Amendment's protection of commercial speech. *Peel* v. *Attorney Registration & Disciplinary Comm'n*, 496 U.S. 91, 108-10 (1990) (plurality opinion) (reversing sanction because there was no "empirical evidence" that the statement's "inherent character" was deceptive); *id.* at 111 (Marshall, J., concurring in the judgment). Just as independent review was necessary in *Snyder* and *Peel* to ensure that the factfinders did not punish protected speech, so it is necessary here, where prosecutors have attacked the expression of a protected scientific opinion that government officials condemned.

2. Independent review of the press release and record here would lead to reversal of Harkonen's conviction, just as independent review led to reversal of the bar censure in *Peel*, the defamation finding in *Bose*, and the jury verdict in *Snyder*.

The "magic number" p-value theory of when studies support inferences of causation is indefensible, which presumably is why the Ninth Circuit dodged the district court's analysis of the challenged statements. The Ninth Circuit's alternate tact—observing that "nearly all" government witnesses stated that the press release "misrepresented" the study results—is equally indefensible because those who so testified did so based on a single viewpoint about the proper

interpretation of data: that a clinical study lacking statistically significant p-values on pre-specified endpoints cannot "demonstrate" anything. ER304-05 & 502-03 (Walton); ER547-52 (Fleming); ER1037-39 & 1049 (Porter); ER1168 (Crager); ER1601-02 (closing argument). Yet the government made no attempt to establish the universality of its p-value restriction on truthful scientific inference. No such showing could be made.

Two weeks after the United States filed a brief in the district court asking for "a substantial sentence of 120 months in prison" (SER4951), the Solicitor General filed a brief in this Court that refutes the scientific "rules" prosecutors presented to Harkonen's jury. The Solicitor General's brief was premised on an extended section captioned "*Statistical significance is a limited and non-exclusive tool for inferring causation.*" *Matrixx* Brief at 13. Whereas prosecutors told Harkonen's jury that if the results on a study's primary endpoint are not statistically significant, then "*you cannot conclude* that the [drug] has a survival benefit" (ER1601-02), the Solicitor General told this Court the exact opposite: "a determination that certain data are not statistically significant . . . *does not refute* an inference of causation." *Matrixx* Brief at 14 (emphases added). The Solicitor General further explained that its core message—that "certain data are not statistically significant . . . does not refute an inference of causation"—applies equally "to studies suggesting that a particular drug is efficacious." *Id.* at 14, 15 n.2; see generally *id.* at 13-16, 19-20, 22 n.5.

This Court agreed with the Solicitor General, holding that a "lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link" between a drug and

an effect. *Matrixx Initiatives, Inc.* v. *Siracusano*, 131 S. Ct. 1309, 1319 (2011). It stated that courts "frequently permit expert testimony on causation based on evidence other than statistical significance," and medical professionals and researchers do not limit the data they consider to "'statistically significant evidence.'" *Id.* at 1319-20 (citing Brief for Medical Researchers as *Amicus Curiae* 31).

The First Amendment does not permit the government to prosecute a scientific viewpoint in one courtroom while championing that same viewpoint in another. By failing to conduct any independent analysis of whether the charged statements were false or misleading, the Ninth Circuit freed itself to ignore evidence that supports Harkonen's viewpoint and illustrates the legitimate scientific disagreement about the study results.

The separate elements of scienter and materiality do not moot the need for independent review of falsity. Every witness who testified on the issue *agreed* that Harkonen and Pennington consistently expressed their views that the data demonstrated a survival benefit and disagreed with those who suggested otherwise. *E.g.*, ER886, 949-50, 1061, 1118-21, 1434-36, 1514-16, 1569; Pet. App. 87a. The only practicing physician to testify at trial wrote in 2002 to his Department Chair, after receiving the study results and hearing Fleming's criticisms, that the study was "successful" and prescribed Actimmune to 60 of his IPF patients. ER787, 834.

Although independent review of scienter or materiality also would lead to reversal, and may indeed be warranted, independent review of falsity clearly is pivotal. If the charged statements are not false or misleading, then they are constitutionally protected. Publishing statements that cannot consti-

tutionally be deemed false or misleading, regardless of intent, cannot *deceive* people into parting with their money or property, which is the "legally cognizable harm associated with a false statement" that renders fraud unprotected by the First Amendment. *United States* v. *Alvarez*, 132 S. Ct. 2537, 2545 (2012) (plurality opinion); see also *id.* at 2553-54 (Breyer, J., concurring in judgment). Independent review of falsity is therefore essential to protect scientific speech.

Some of science's greatest leaps forward defied conventional thinking and were roundly and publicly condemned. Leaving juries to decide whether a scientific conclusion drawn from accurate facts is false or misleading, without the check of independent judicial review, is a recipe for viewpoint discrimination and chilling extraordinarily important speech. This Court should grant the petition to clarify that the First Amendment mandates independent judicial review of falsity where, as here, the government prosecutes speech about the meaning of scientific research results, to ensure that a fraud prosecution does not transgress "acceptably narrow limits" and impermissibly regulate protected scientific opinion.

3. The second "grave question[] of constitutional law" that *McAnnulty* avoided (187 U.S. at 103) implicates the Due Process Clause. Construing the wire fraud statute to encompass "conclusions drawn from" data violates due process because the public lacks fair notice of the standards that determine the truth or falsity of a scientific conclusion drawn from accurate facts. Were the standards invoked by prosecutors here universally applied, the jails would be flooded with scientists, including government employees.

It is a "fundamental principle in our legal system" that "laws which regulate persons or entities must give fair notice of the conduct that is forbidden or required." *FCC* v. *Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012). When "speech is involved, rigorous adherence" to this notice requirement "is necessary to ensure that ambiguity does not chill protected speech." *Id.* at 2317, 2320 (holding FCC violated due process by retroactively applying its revised "indecency" policy).

The Seventh Circuit overturned a wire fraud conviction on due process grounds where the defendant's conduct violated no rule or commonly accepted standard, and the government's case turned on the implication, from "the oral testimony of an agency [FDA] employee" that the conduct was improper. *United States* v. *Farinella*, 558 F.3d 695, 699 (7th Cir. 2009). As the court explained, the "'idea of secret laws is repugnant. People cannot comply with laws the existence of which is concealed.'" *Id.* Had Harkonen's conviction arisen in the Seventh Circuit, it would have been reversed on due process grounds.

The Ninth Circuit ignored both *Fox* and *Farinella*, though both cases were argued prominently. It summarily dismissed Harkonen's due process defense because an ordinary person would understand that it is a crime to make "misleading statements in a press release with the specific intent to defraud." Pet. App. 6a. That is a fair point *only* if the person has notice of the standards by which the law distinguishes a fair scientific inference from a misleading one. The Ninth Circuit never explains how a reasonable person would know that the criminal law bars inferring causation from accurate clinical study data in the absence of statistically significant p-values on pre-

specified endpoints. No reasonable explanation exists.

The due process violation here is even more extreme than in *Fox*, because no federal agency has ever issued a rule restricting scientists from drawing causal inferences from accurate data, let alone a "scientific conclusions" policy that Harkonen's statements would violate. The government's witnesses admitted there were no such rules. ER429-30, 514.

To the contrary, government scientists routinely publish press releases and reach conclusions that conflict with the prosecution's "rules" presented in this case. See *infra* at 33-34 & nn.8-9. Scientists regularly publish articles that do not comply with them. See, *e.g.*, See Rui Wang et al., *Statistics in Medicine—Reporting of Subgroup Analyses in Clinical Trials*, 357 New Eng. J. Med. 2189, 2192 (2007) (in 68% of articles reporting subgroup analyses it was unclear whether any subgroups were "prespecified or post hoc") (available at ER2745-50); ER2578-79 ("literature is replete with published examples of unadjusted p-values for secondary endpoints or subgroup analyses"). FDA itself has approved drugs based on data from clinical studies lacking statistically significant p-values on the primary endpoint (*see, e.g., supra* at 8; Pet. App. 99a-101a)—the very aspect of the Actimmune study data that the prosecutor said made it "just false" to conclude that the results demonstrated a "survival benefit." ER1601.

Case-law also gives no notice that a reasonable, even if government-disputed, interpretation of accurate clinical study data constitutes wire fraud. *McAnnulty* and *Reilly* protected the expression of scientific opinions about which reasonable minds could differ. *Supra*, at 15-16. The D.C. Circuit

mocked as "almost frivolous" FDA's argument that a disagreement between government and company scientists over the meaning of data could render a statement "inherently misleading" and justify a ban on the company's expression of its view. *Pearson* v. *Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999). Lower courts routinely dismiss civil claims that a scientifically debatable interpretation of data is false or fraudulent. *E.g.*, *United States ex. rel. Haight* v. *Catholic Healthcare W.*, No. cv-01-2253, 2007 WL 2330790, at *2 (D. Ariz. Aug. 14, 2007) (holding, in a False Claims Act case involving an NIH grant application, that "[e]xpressions of opinion, scientific judgment, or statements as to conclusions about which reasonable minds may differ cannot be false") (quotations omitted), *appeal dismissed*, 602 F.3d 949 (9th Cir. 2010); *Noble Asst Mgmt.* v. *Allos Therapeutics, Inc.*, No. CIVA-04CV-1030-RPM, 2005 WL 4161977, at *11 (D. Colo. Oct. 20, 2005) (dismissing securities fraud action where "interpretation of the data from the . . . clinical trials is a matter on which reasonable minds could differ"; that FDA's Oncology Drug Committee "ultimately did not recommend approval does not mean that the defendants' statements about the results" of the study were "false"); *DeMarco* v. *DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) ("legitimate difference in opinion as to the proper statistical analysis" does not state "a securities fraud claim").

The final report to FDA on this study was over 950 pages, excluding appendices. ER2295-2303. The press release necessarily contained only a fraction of the data and analysis. No standards exist to determine which facts to include or exclude in announcing the preliminary results. For every omitted fact that allegedly rendered the press release

misleading (*e.g.*, that the cut-off for the mild-to-moderate subgroup was not pre-specified), there is at least another omitted fact that *supported* the reasonableness of the conclusion (*e.g.*, that the other subgroups of mild-to-moderate IPF patients also showed a high relative survival benefit with a p-value less than 0.05).

In the absence of standards as to what data must be included and what conclusions may be drawn, a reasonable scientist cannot know what omissions or conclusions could lead to a federal fraud conviction, a demand for incarceration, and collateral civil sanctions (also brought here by federal and state agencies) that seek to end a distinguished professional career. A jury's agreement with an FDA official's views can no more support Harkonen's conviction than it could Farinella's. The Court should grant the petition to reconcile that conflict and clarify that the due process principles of *Fox* apply equally to prosecutions of opinion under the mail and wire fraud statutes.

## III. ALLOWING THE CONVICTION TO STAND WILL IMMEDIATELY, IRREPARABLY, AND INDEFINITELY CHILL SCIENTIFIC SPEECH ON MATTERS OF VITAL PUBLIC CONCERN.

The public interest in the free flow of information has particular relevance "in the fields of medicine and public health, where information can save lives." *Sorrell*, 131 S. Ct. at 2664. Press releases expressing opinions about the import of the latest clinical studies are integral to this communication.

Many such releases are issued every week. For pharmaceutical companies alone, we found 97 such press releases issued between January 2012 and

June 2013, often to comply with federal securities law. For example, SEC rules require public disclosure of information material to shareholders, and Regulation FD requires prompt public disclosure of material confidential information after disclosure to certain non-insiders. 17 C.F.R. § 243.100. A "press release distributed through a widely circulated news or wire service" is generally an "acceptable method[]" for satisfying these obligations. Selective Disclosure and Insider Trading, Securities Act Release, No. 7881, Fed. Sec. L. Rep. (CCH) ¶ 86,319 (Aug. 15, 2000). InterMune issued this press release to ensure prompt and uniform public disclosure within 24 hours after disclosure to the Steering Committee, which included leading outside physician-investigators. ER973-77, 1143-44, 1453, 2344. But pharmaceutical companies are not the only speakers.

Academic medical centers, nonprofit organizations, and government agencies such as the National Institutes of Health ("NIH") also regularly issue press releases trumpeting the results of clinical trials. During that same 2012-13 time period, for example, we found 25 such press releases from the American Cancer Society, eleven from the Susan G. Komen for the Cure Foundation, and 25 from the NIH. As for academic medical centers, a study in the *Annals of Internal Medicine* found that, in just one year, 20 such centers alone issued a combined total of almost 1000 press releases discussing their research.[6]

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[6] S. Woloshin et al, *Press Releases by Academic Medical Centers: Not So Academic?*, 150 Annals of Internal Med. 613, 616 & tbl.1 (2009) ("Press releases issued by 20 academic medical centers frequently promoted preliminary research . . . without providing basic details or cautions needed to judge the meaning, relevance, or validity of the science.").

Two criticisms have been and always can be levied against such press releases. One is that they omitted important information; that is unavoidable, because no release can contain the same details as could a full report to FDA, a journal article, or a conference presentation, and scientists will disagree on what is most important. The other is that the conclusions overstate the importance of the results; such disagreement again is inevitable, because drawing conclusions from data involves exercising judgment.

Inevitable disagreement over inferences from data is why FDA frequently convenes advisory committees, and why committee votes often are divided.[7] Even the press releases of academic medical centers are criticized for omissions and overstatement. Woloshin, *supra*, at 616. NIH itself "overstates" its results, at least according to the prosecutor's standards here. During Harkonen's trial, for example, NIH issued a press release that was roundly criticized for announcing that an expensive trial "demonstrates" that a combination of vaccines provided a benefit against HIV infection, while omitting data showing that, for those patients who actually followed the prescribed regimen, there was no statistically significant benefit; NIH officials responded that they had included the most important data and would discuss the rest at upcoming conferences.[8]

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[7] *See* U.S. Food & Drug Admin., *Advisory Committees: Critical to the FDA's Product Review Process*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143538.htm (updated Aug. 12, 2011) (FDA convenes advisory committees to "comment on whether adequate data support approval, clearance, or licensing of a medical product for marketing" to address complex questions and hear "diverse perspectives"); ER2580-81.

[8] ER2680-82, 2710-11, 2715-26.

In May 2013, NIH issued a press release about a study that did not meet its primary endpoint; per Harkonen's prosecutors, this was a "failed" study, but NIH nonetheless claimed a "finding" that anti-oxidants provided two subgroups an important benefit.[9] The press release does not disclose that NIH retrospectively defined one of those subgroups.

Pharmaceutical companies sponsor important research. Their scientists should enjoy the same freedoms that government and academic scientists have to express conclusions about the meaning of data. See *Sorrell*, 131 S. Ct. at 2665 (invalidating law that "imposes a burden based on the content of speech and the identity of the speaker"). They certainly should be free to rely on criteria the Solicitor General identified in *Matrixx* for inferring causation.

By allowing fraud prosecutions to target scientific conclusions, the Ninth Circuit let the government cross a line into criminalizing scientific opinion that no court before let it cross. It authorized the government to send its message that speech contrary to the scientific views of government employees is subject to criminal prosecution. This decision chills speech on matters of profound public concern. Whether the government may convict scientists of fraud for the inferences they draw from accurate data is a question of exceptional importance to which this

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[9] *See* Press Release, Nat'l Insts. Of Health, *NIH Study Provides Clarity On Supplements For Protection Against Blinding Eye Disease* (May 5, 2013), http://www.nei.nih.gov/news/pressreleases/050513.asp; *Lutein+Zeaxanthin and Omega-3 Fatty Acids for Age-Related Macular Degeneration, The Age-Related Eye Disease Study 2 (AREDS2) Randomized Clinical Trial*, 309 J. Am. Med. Ass'n 2005 (2013), http://jama.jamanetwork.com/article.aspx?articleid=1684847.

Court should promptly provide a uniform national answer.

## CONCLUSION

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

Respectfully submitted,

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