Nos. 11-10209, 11-10242

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff/Appellee/Cross-Appellant,

v.

W. SCOTT HARKONEN, M.D.,

Defendant/Appellant/Cross-Appellee.

On Appeal From the United States District Court
For the Northern District of California
No. 3:08-cr-00164-MHP-1

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE IN SUPPORT OF REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, *Amicus Curiae* Pharmaceutical Research and Manufacturers of America states that it is a trade association with no parent corporation and with no publicly-held company owning ten percent or more of its stock. PhRMA's member companies are listed on its website at http://www.phrma.org.

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Pursuant to Federal Rule of Appellate Procedure 29, *Amicus Curiae* Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully submits this brief as amicus curiae in support of reversal of Dr. Harkonen's conviction. All parties have consented to PhRMA's submission of this amicus brief.

STATEMENT OF IDENTITY OF AMICUS CURIAE, ITS INTEREST IN THE CASE, AND THE SOURCE OF ITS AUTHORITY TO FILE[*]

PhRMA is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. During 2010 alone, PhRMA members invested an estimated $49.4 billion in efforts to research and develop new medicines.[1] PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines by its members. PhRMA has frequently filed *amicus* curiae briefs in cases raising matters of significance to its members.

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[*] Pursuant to Federal Rule of Appellate Procedure 29(c)(5), PhRMA states that no party's counsel authored this brief in whole or in part, no party or party's counsel contributed money that was intended to fund preparing or submitting this brief and no person—other than PhRMA, its members, or their counsel—contributed money that was intended to fund preparing or submitting this brief.

[1] *See* PhRMA, *Pharmaceutical Industry Profile 2011*, at 11 fig.3 (2011), *available at* http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf.

In addition, PhRMA was a plaintiff and respondent at the Supreme Court stage in *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), which struck down a state law that infringed on the First Amendment rights of PhRMA's members to market their life-saving and life-enhancing medicines effectively. As discussed below, the teachings of the Supreme Court in *Sorrell* bear on this case in several important ways.

The judgment below is of great concern to PhRMA and its members because pharmaceutical companies constantly communicate with the public about complex scientific and medical issues that are the subject of ongoing and good-faith debate. A robust dialogue on these matters helps to foster the innovation that leads to advancements in medicine and better outcomes for patients. That discourse would be seriously chilled if the judgment below is affirmed.

This *amicus curiae* brief is filed under the authority of Federal Rule of Appellate Procedure 29(a) because all parties have consented to its filing.

PRELIMINARY STATEMENT

This case concerns an unprecedented prosecution of a pharmaceutical executive for expressing in a press release his scientific opinion about the development of a drug to treat disease. An affirmance of the decision below would threaten core First Amendment principles by establishing that scientific debate over how to interpret data can constitute a crime. Criminal liability under a fraud

statute, however, should be limited to misstatements of objectively verifiable fact.

The press release here was not that type of misstatement. It did not misrepresent any facts about how the study was conducted, the number of participants in the study, or the scientific measurements associated with any result. Nor did it claim that Actimmune® was guaranteed to be effective for treating idiopathic pulmonary fibrosis ("IPF"). Rather, the press release drew preliminary inferences from data, acknowledged its limitations, and expressed a scientific opinion on a subject matter over which reasonable scientists could disagree.

The trial court unconstitutionally permitted the jury to find that the press release was false not because no reasonable scientist could have reached the conclusion drawn, but because some scientists, mainly those of the U.S. Food and Drug Administration ("FDA"), disagreed with that conclusion. The trial court compounded the error when, after trial, the court found that the jury's finding of fraud rendered the First Amendment beside the point.

The trial court's approach violated the First Amendment. A person may not be convicted for fraud based upon speech about scientific matters unless the level of scientific consensus is such that no reasonable expert could find the defendant's statement to be true. The trial court's contrary approach risks branding a *minority* view on any controversial scientific subject as a *fraudulent* one, thereby chilling scientific speech on uncertain issues and impeding discovery and innovation in the

pharmaceutical sector. The Government's avowed purpose for this case, to send a message that "will be noted in the executive suites and board rooms of drug companies across the United States," U.S. Sentencing Mem. at 23 (dkt. 287), only confirms this chilling effect.

If the Government enacted specific legislation prescribing what vocabulary could be used to describe study results that tend to indicate a correlation but fall just short of statistical significance, the First Amendment infirmity would be obvious. A First Amendment violation would also be obvious if the government prosecuted one of the defendant's experts for expressing agreement with the defendant's interpretation of the scientific data at issue. These concerns are all the more pronounced here because the Government prosecuted a particular speaker for communicating views that would not be prosecuted if spoken by another.

ARGUMENT

I. THE FIRST AMENDMENT PRECLUDES CRIMINALIZING REASONABLY DEBATABLE SCIENTIFIC INTERPRETATIONS OF DATA AS WIRE FRAUD

The wire fraud statute makes it a crime to use the wires to execute a "scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises." 18 U.S.C. § 1343. The elements of wire fraud are (1) proof of a scheme to defraud; (2) use of the wires to

further the fraudulent scheme; and (3) specific intent to defraud. *See, e.g.*, *United States v. Sullivan*, 522 F.3d 967, 974 (9th Cir. 2008).

Under the statute, "[a] statement or representation is 'false or fraudulent' . . . if known to be untrue, or made with reckless indifference as to its truth or falsity, and made or caused to be made with the intent to deceive." *United States v. Federbush*, 625 F.2d 246, 255 (9th Cir. 1980). This Court has held that "[d]eceitful statements of half-truths or the concealment of material facts" will suffice, *United States v. Beecroft*, 608 F.2d 753, 757 (9th Cir. 1979) (citing *Lustiger v. United States*, 386 F.2d 132, 138 (9th Cir. 1967)), although it has also said, more recently, that a "scheme to defraud must . . . include an 'affirmative, material misrepresentation,'" *United States v. Green*, 592 F.3d 1057, 1064 (9th Cir. 2010) (quoting *United States v. Benny*, 786 F.2d 1410, 1418 (9th Cir. 1986)).

Where a wire fraud charge is predicated upon a defendant's speech, courts must ensure that the representations alleged to be "false or fraudulent" are not themselves protected speech under the First Amendment. If the representations are protected, the Government may not re-label the expression as false and render the speech outside the bounds of First Amendment protection. *See, e.g.*, *United States v. Alvarez*, 617 F.3d 1198, 1217 (9th Cir. 2010) (reversing criminal conviction for engaging in protected speech), *cert. granted*, 80 U.S.L.W. 3141 (U.S. Oct. 17, 2011) (No. 11-210); *cf. Snyder v. Phelps*, 131 S. Ct. 1207, 1215 (2011) (reversing

tort liability for engaging in protected speech that a jury found constituted intentional infliction of emotional distress).

A. Scientific Speech is Protected By the First Amendment

Although the First Amendment does not protect a few narrowly limited categories of speech such as fraud and libel, *see Illinois ex rel. Madigan v. Telemarketing Assocs.*, 538 U.S. 600, 612 (2003), "mere labels" like "libel" or "fraud" do not confer "talismanic immunity from constitutional limitations." *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 269 (1964); *see Madigan*, 538 U.S. at 617 ("Simply labeling an action one for 'fraud,' of course, will not carry the day."). Rather, the scope of these non-protected categories "must be measured by standards that satisfy the First Amendment." *N.Y. Times*, 376 U.S. at 269.

Courts have thus long been wary of branding particular views or opinions as fraud. When an assertion constitutes subjective opinion or an interpretation of data rather than empirically verifiable fact, "[t]here is no exact standard of absolute truth by which to prove the assertion false and a fraud." *Am. Sch. of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 104 (1902); *cf. Haynes v. Alfred A. Knopf, Inc.*, 8 F.3d 1222, 1227 (7th Cir. 1993) (in defamation context, "if it is plain that the speaker is expressing a subjective view, an interpretation, a theory, conjecture, or surmise, rather than claiming to be in possession of objectively verifiable facts, the statement is not actionable"). "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 in part and concurring in the judgment); *see Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 339 (1974) ("Under the First Amendment there is no such thing as a false idea."); *Commodity Trend Serv. v. CFTC*, 233 F.3d 981, 993-94 (7th Cir. 2000) (limiting fraud to "statements that could be empirically shown to be false or deceptive" and perceiving "more serious constitutional issues" when government "attempt[s] to punish statements that are more a matter of opinion or belief").

These principles are at their zenith in this case. "Scientific and academic speech reside at the core of the First Amendment." *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 62 (D.D.C. 1998), *vacated as moot*, 202 F.3d 331 (D.C. Cir. 2000); *see also Bd. of Trs. of Leland Stanford Junior Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991) ("the First Amendment protects scientific expression and debate just as it protects political and artistic expression"). Last Term, the Supreme Court confirmed that pharmaceutical manufacturers' communications with doctors about the safety and efficacy of drugs fall within the First Amendment's ambit. Thus, in *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), the Court held that the First Amendment fully protects "the beneficial

speech of pharmaceutical marketing." *Id.* at 2670. "[I]n the fields of medicine and public health," after all, "information can save lives." *Id.* at 2664.

It is therefore evident that courts should be particularly leery of a government's attempt to criminalize speech concerning the "effectiveness of [a] particular method of treatment of disease." *McAnnulty*, 187 U.S. at 105. "[I]n the science of medicine, as in other sciences, experimentation is the spur of progress." *Reilly v. Pinkus*, 338 U.S. 269, 274 (1949). Because such matters are "to a more or less extent, a fruitful source of difference of opinion, even though the great majority may be of one way of thinking, the efficacy of any special method is certainly not a matter for the decision of the [government] within . . . statutes relative to fraud." *McAnnulty*, 187 U.S. at 105; *see Reilly*, 338 U.S. at 274 (endorsing "the *McAnnulty* decision as a wholesome limitation upon findings of fraud under the mail statutes when charges concern medical practices in fields where knowledge has not yet been crystallized in the crucible of experience"); *Fanning v. Williams*, 173 F.2d 95, 96, 97 (9th Cir. 1949) (resting affirmance of fraud order on the lack of difference of opinion among "trained and intelligent medical minds . . . on the question" and finding that "the testimony given represented the consensus of scientific knowledge"); *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) (rejecting as "almost frivolous" the government's position that health claims by dietary supplement makers are "inherently

misleading" unless consistent with "significant scientific agreement"). Those principles dictate that the First Amendment protects speech about scientific matters over which reasonable scientists may disagree.

In a number of civil contexts -- where liability poses *less* severe consequences for speakers than in a criminal prosecution -- courts have rejected out of hand the notion that a scientifically debatable interpretation of data could be false or fraudulent. These holdings have come in cases with alleged facts quite similar to this one. For example, in *In re Biogen Securities Litigation*, 179 F.R.D. 25 (D. Mass. 1997), securities plaintiffs alleged that a drug company press release was fraudulently misleading for reporting positive aspects of a clinical trial "without also fully discussing the limitations of those findings," namely that the analysis was "retrospective." *Id.* at 37-38. The court dismissed these claims on the pleadings due to the "split of expert opinion regarding the importance of prospectively defined endpoints." *Id.* at 38.

A court in Colorado rejected similar claims that a drug company "misled investors by putting a positive gloss on the results of the clinical trials" without disclosing that the positive aspect "could only be considered as exploratory." *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. CIVA-04CV-1030-RPM, 2005 WL 4161977, at *6 (D. Colo. Oct. 20, 2005). Noting that "[t]he plaintiff does not allege that the defendants reported false data," the court reasoned that "[t]he

interpretation of the data from the [] clinical trials is a matter on which reasonable minds could differ," and therefore not fraudulent or misleading. *Id.* at *11.[2] Nor does the False Claims Act reach "expressions of scientific opinion or judgment about which reasonable minds may differ." *United States ex rel. Haight v. Catholic Healthcare West*, No. CV-01-2253-PHX-FJM, 2007 WL 2330790, at *3 (D. Ariz. Aug. 14, 2007); *see Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) ("[F]alse . . . does not mean scientifically untrue; it means a lie. . . . The [False Claims] Act would not put either Ptolemy or Copernicus on trial."). The Government surely does not have wider scope to punish speech as fraudulent in the *criminal* realm, than in these civil contexts.

Particularly when the government attempts to impose a criminal sanction on speech, it is the courts' duty "to confine the perimeters of [the] unprotected

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

category within acceptably narrow limits in an effort to ensure that protected expression will not be inhibited." *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 505 (1984). And to guard against the chilling of protected "freedoms of expression," speech must be given "the breathing space" necessary to ensure that differences of opinion thrive. *N.Y. Times*, 376 U.S. at 271-72 (internal quotation marks and alteration omitted). In short, when an interpretation of scientific data is alleged to be false or fraudulent, the trial court should not send the case to the jury unless the level of scientific consensus is such that no reasonable expert could find the defendant's statement to be true.

Applying this standard does not, as the government has contended, create a "science" exception to fraud. To be sure, fabrication of data or other outright misstatements of objectively verifiable and material facts, *e.g.*, a researcher misrepresenting the number of patients in a study who experienced a certain outcome, can and should be actionable as fraud. No reasonable scientist would defend those misstatements and they are not a matter for good-faith debate. Matters of interpretation that can be fairly debated by reasonable scientists and are not empirically verifiable, however, stand on a different plane. To avoid chilling scientific discussion, the First Amendment must preclude the Government from punishing the latter category of cases as fraud.

B. The District Court Erred by Allowing the Jury to Convict Dr. Harkonen Without Regard to Whether His Statements Were Debatable by Reasonable Scientists

The press release at issue related to a matter of public health, the potential benefits of a drug to patients. Moreover, the press release was alleged to be false not for misstating any objectively verifiable fact, but for mischaracterizing the strength of certain subjective inferences that could be drawn from the data and for lacking purportedly necessary context. This case accordingly should not have been submitted to the jury without the trial court determining whether the press release expressed an interpretation of clinical trial results with which no reasonable scientist could agree.

But the district court applied the diametrically opposite standard: the court found that "the matter must be decided by a jury" *unless* "reasonable minds could not differ as to whether Harkonen committed fraud." D. Ct. 6/4/09 Order Denying Motion to Dismiss the Indictment (dkt. no. 124) at 12-13. Thus, the district court subjected the defendant to criminal exposure for engaging in speech with which reasonable minds could agree, leaving protected only such speech as represents a uniform consensus of scientific opinion. That standard precludes speakers from engaging in scientific debate.

Indeed, Dr. Harkonen's scientific experts expressed opinions in the trial court that supported the views of Dr. Harkonen but that sharply differed with the

Government's views. Yet no one would seriously contend that Dr. Harkonen's experts committed perjury. The same First Amendment principles protect Dr. Harkonen's expression in the press release.

The district court imported its standard from a civil securities case that did not involve any open scientific questions or the interpretation of data. *See Fecht v. Price Co.*, 70 F.3d 1078 (9th Cir. 1995). In its post-trial decision, the court likewise relied erroneously on cases involving different contexts and objectively verifiable facts. *See United States v. Lyons*, 472 F.3d 1055, 1066 (9th Cir. 2007) (whether charitable donations would be used for charitable purposes); *United States v. Woods*, 335 F.3d 993, 996-97 (9th Cir. 2003) (value of "prizes" in telemarketing scam); *Lustiger v. United States*, 386 F.2d 132 (9th Cir. 1967) (existence of roads, utilities, and water access in newly developed subdivision). As applied here, however, the district court's standard permitted the jury to find that the proponent of one scientific view made false statements because the jury believed that a contrary view was more persuasive.

In sending the case to the jury, the district court also rested on the misplaced notion that the FDA is the exclusive arbiter of truth, such that the statement became false simply because FDA did not agree with it. *See* D. Ct. 6/4/09 Order Denying Motion to Dismiss the Indictment (dkt. no. 124) at 10 (denying motion to dismiss because "the FDA affirmatively disagreed" with and "refused to accept"

Dr. Harkonen's interpretation), 11 (holding indictment valid because "the FDA's medical reviewers disagreed with [Dr. Harkonen's] interpretation" and "the medical staff at the FDA advised Harkonen that the trial data were not sufficient"). An interpretation of data should not create criminal liability for wire fraud simply because the FDA takes a different view of the merits. There is no "First Amendment Free Zone," *United States v. Stevens*, 130 S. Ct. 1577, 1585 (2010), for scientific views the Government thinks are wrong. That is particularly true where the Government has a view that is entitled to no deference, but is merely different perspective on a matter of scientific debate.

Because Dr. Harkonen was convicted under the wire fraud statute, this case does not question the Government's regulatory power to control statements made by pharmaceutical manufacturers in a drug's labeling. Quite to the contrary, the indictment charged Dr. Harkonen with one count of felony misbranding under 21 U.S.C. § 352, Indictment ¶¶ 27-28 (dkt. no. 1), but the jury acquitted Dr. Harkonen of that count.

After trial, the district court once again abdicated its critical obligation to "conduct[] an independent review of the record both to be sure that the speech in question actually falls within the unprotected category." *Bose Corp.*, 466 U.S. at 505. Devoting a scant two paragraphs to the First Amendment in its lengthy order denying a new trial, the district court reduced the issue to a tautology: "[t]he jury

concluded that Harkonen committed wire fraud"; and "[a]s a result, the First Amendment provides Harkonen with no defense from his conviction." D. Ct. 7/27/10 Order Denying Motions for New Trial (dkt. no. 268) at 23.

But "[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 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 Corp.*, 466 U.S. at 505; *cf. Snyder*, 131 S. Ct. at 1219 (First Amendment protection "cannot be overcome by a jury finding that the [speech] was outrageous"). The fact that the jury found fraud here no more disposes of the First Amendment issues than did the jury's finding of libel in *New York Times v. Sullivan*. *See* 376 U.S. at 268 (noting that the general proposition that "the Constitution does not protect libelous publications" does "not foreclose our inquiry here"). The trial court erred in treating the jury's guilty verdict as obviating any First Amendment issues. The First Amendment demands searching analysis, not *ipse dixit* circularity.

C. The Government Did Not Establish That the Press Release in This Case Was Outside the Range of Reasonable Scientific Opinion

The evidence in this case fell short of showing that no reasonable scientist would have drawn the same conclusions from the data as Dr. Harkonen. The Government did not argue that the alleged falsity of the press release was a matter of general scientific consensus or that no reasonable scientist could hold the views

Dr. Harkonen advanced; indeed, the Government did not even put on any expert testimony at all.

In denying Dr. Harkonen's motion for acquittal or a new trial, the district court relied heavily on testimony by government witnesses that "a p-value of 0.05 is somewhat of a magic number." D. Ct. 7/27/10 Order Denying Motions for New Trial (dkt. no. 268) at 8. But the Government told the U.S. Supreme Court in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), that hypothetical study results showing that a drug had adverse effects with a p-value of 0.06, though not "considered statistically significant at the 0.05 level," would "clearly bear on the drug's safety" because they "indicate a 94% likelihood that the observed association would *not* have occurred randomly." Brief for the U.S. as Amicus Curiae Supporting Respondents, 2010 WL 4624148, at *14 (emphasis in original).

"The same principle," the Government further explained, "applies to studies suggesting that a particular drug is efficacious." *Id.* at 15 n.2. To adapt the Government's own formulation in *Matrixx*, then, the p-value of .084 for the Phase III trial results showing increased survival benefit in the overall patient population "indicate a 91.6% likelihood that the observed association would *not* have occurred randomly" and thus "clearly bear" on Actimmune's efficacy for IPF. When the p-values and thus the statistical limitations and caveats are fully disclosed, as they

were here, the difference between a 91.6% or 94% likelihood and a 95% likelihood is not a valid basis for a criminal fraud prosecution.

The Supreme Court's ultimate holding in *Matrixx* is also in serious tension with the judgment below. Adopting the position the United States urged in its amicus brief, the Court held that non-statistically-significant information about adverse events may be "material" and thus required to be disclosed under the securities laws. 131 S. Ct. at 1321. As the Court explained, "medical professionals and regulators act on the basis of evidence of causation that is not statistically significant" and "statistical significance (or the lack thereof) . . . is not dispositive of every case." *Id.* If companies may be *required* to disclose non-statistically-significant information about adverse events, it makes no sense to *deter* them, through a threat of criminal liability, from describing non-statistically significant *positive* information about efficacy.[3]

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[3] In some circumstances, companies may even be *required* to disclose very preliminary or non-statistically significant positive information about efficacy as material non-public information. In this case, InterMune believed the trial data could be material to valuation of the company's shares and that it was required to disclose that information to the public once it was known by certain individuals. *See* Tr. 8/25/09 at 1100, Tr. 9/15/09 at 2611; *see generally* SEC Regulation FD, 17 C.F.R. § 243.100(a) (generally prohibiting selective disclosure). In a pending case in Massachusetts, regulators contend that limited "retrospective" information supporting the efficacy of a drug for a kidney disease was "material," exposing an investor to insider trading liability for purchasing company stock while in possession of that non-public information. *See* Duff Wilson, *Columbia Professor*

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The Government may respond that it does not seek to bar companies altogether from disclosing non-statistically significant or retrospective information, only from characterizing inferences from that information as stronger than the Government deems appropriate. If it was acceptable to disclose the underlying information, however, the Government's disagreement with characterization amounts to quibbling over semantics. In a pretrial brief, the Government focused on the press release's statement that the data "*Demonstrat[ed]* Survival Benefit of Actimmune in IPF," insisting that "*suggested*" would instead have been the more accurate verb. U.S. Opp. to Def.'s Mot. in Limine filed 4/20/09 (dkt. no. 104) at 16 (emphasis in original). Where, as here, the underlying facts and limitations (e.g., p-values greater than 0.05; results derived from subgroup analysis) are disclosed, criminal liability for fraud should not turn on the shades of difference between words such as "suggested" and "demonstrated." Both words are understood by readers in the context of the underlying substantive information. The First Amendment does not permit the government to imprison a person for broadcasting his opinion about correlations simply because the government would prefer the data reach a certain level of statistical significance before that opinion is

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is Linked to Insider Trading Case, N.Y. Times (Sept. 17, 2011). To the extent that disclosure of such information is *required*, the tension with the judgment below is even more glaring.

spoken. A contrary result would be arbitrary and would foreclose any breathing space under the First Amendment.

II. THE COMMERCIAL SPEECH DOCTRINE DOES NOT APPLY TO THE PRESS RELEASE AND, EVEN IF IT DID, THE CONVICTION VIOLATES THE FIRST AMENDMENT

If full First Amendment scrutiny is applied, there is no question that Dr. Harkonen's conviction cannot stand because the district court permitted the jury to find speech fraudulent without first ensuring that it was unprotected, *i.e.*, that no reasonable expert could reach the same conclusion as Dr. Harkonen. The Government attempts to avoid strict scrutiny by classifying the press release at issue in this case as so-called "commercial speech" that presumably gives the Government greater leeway to classify scientific opinion as fraudulent. The press release was not, however, mere commercial speech. Far from being a run-of-the-mill advertisement, it expressed a scientific viewpoint on a matter of public concern, the treatment of disease. The exact same statements, made by any speaker other than a pharmaceutical executive, would have been indisputably non-commercial. Even if the press release is viewed as purely commercial speech, the conviction in this case cannot withstand even the less rigorous scrutiny that applies to regulations or punishment of commercial speech.

A. The Press Release Is Not Mere Commercial Speech

The Government is wrong that the press release in this case should be

analyzed as commercial speech. Because "[s]ome of our most valued forms of fully protected speech are uttered for a profit," *Bd. of Trs. of SUNY v. Fox*, 492 U.S. 469, 482 (1989), a mere commercial *motivation* for issuing the press release does not downgrade the level of First Amendment protection afforded to it. Rather, "what defines commercial speech" -- to the extent that it can be defined -- is that it specifically "*proposes* a commercial transaction." *Id.* (emphasis in original); *see also Mattel, Inc. v. MCA Records, Inc.*, 296 F.3d 894, 906-07 (9th Cir. 2002) ("If speech is not 'purely commercial' -- that is, if it does more than propose a commercial transaction -- then it is entitled to full First Amendment protection.").

Moreover, full scrutiny applies where speech that might be considered commercial in the abstract "is inextricably intertwined with otherwise fully protected speech." *Riley v. N.C. Fed'n of the Blind*, 487 U.S. 781, 787 (1988); *see Nike, Inc. v. Kasky*, 539 U.S. 654, 663 (2003) (Stevens, J., concurring) ("novel First Amendment questions" presented by "blending of commercial speech, noncommercial speech and debate on an issue of public importance"); *id.* at 677-78 (Breyer, J., dissenting) (statements "outside a traditional advertising format" and "concern[ing] a matter that is of significant public interest" entitled to full First Amendment protection even if they also have commercial characteristics); *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2667 (2011) (noting but not resolving whether

"a special commercial speech inquiry or a stricter form of judicial scrutiny" should be applied to restrictions on pharmaceutical marketers' communications with doctors). This Court too has held that "*even in the context of commercial speech*, knowingly false speech about a matter of public concern is potentially entitled to heightened First Amendment scrutiny." *United States v. Alvarez*, 617 F.3d 1198, 1206 n.6 (9th Cir. 2010), *cert. granted*, 80 U.S.L.W. 3141 (U.S. Oct. 17, 2011) (No. 11-210).[4]

To the extent a press release announcing an interpretation of data to the scientific community could be deemed to "propose a commercial transaction" at all, that is far from the only function it serves. Such a press release "is unlike speech -- say, the words 'dolphin-safe tuna' -- that commonly appears in more traditional advertising or labeling contexts." *Nike*, 539 U.S. at 678 (Breyer, J., dissenting). Indeed, it bears little in common with the messages the Supreme

[4] The commercial speech doctrine persists for now despite severe doubts expressed by this Court, Justices of the Supreme Court, and learned commentators about the wisdom of relegating commercial speech to a separate and inferior status. *See, e.g.*, *Nordyke v. Santa Clara Cty.*, 110 F.3d 707, 712 (9th Cir. 1997); *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 82-83 (1983) (Stevens, J., concurring in the judgment) ("Because significant speech so often comprises both commercial and noncommercial elements, it may be more fruitful to focus on the nature of the challenged regulation rather than the proper label for the communication."; Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech*, 76 Va. L. Rev. 627, 628-29 (1990) ("the commercial/noncommercial distinction makes no sense" and "has led to troubling results").

Court has called commercial speech.[5] The GIPF-001 clinical trials and press release prompted a vigorous debate in the scientific and medical communities on a matter of public health: how the disease of IPF could best be treated. *See, e.g.*, Ganesh Raghu, M.D., et al., *A Placebo-Controlled Trial of Interferon Gamma-1b in Patients with Idiopathic Pulmonary Fibrosis*, 350 New Eng. J. Med. 125 (2004) (article describing study and results, published along with separate critique taking opposite view); Ex. 36 to Topel Decl. (dkt. no. 89) (op-ed letters to the *New England Journal of Medicine* joining the debate). Any aspects of the press release that could be said to propose a specific commercial transaction were secondary to and inseparable from its more fundamental communicative purpose.

Interpretations of data about the potential efficacy of a drug for treating disease could just as easily be found in a medical or scientific journal, or in a debate among colleagues in an academic setting, who would never be prosecuted for saying the same things Dr. Harkonen said. Thus, if the interpretations are to be treated as inferior "commercial speech," that is not because of their intrinsic content, but solely because of the identity of the speaker. "Laws designed or

[5] *See, e.g.*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (point-of-sale and outdoor advertising of cigarettes and tobacco products); *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173 (1999) (radio and television advertisements for casino gambling); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (newspaper ads for cut-rate liquor prices).

intended to suppress or restrict the expression of specific speakers contradict basic First Amendment principles." *United States v. Playboy Entm't Grp.*, 529 U.S. 803, 812 (2000); *see Citizens United v. Fed. Elec. Comm'n*, 130 S. Ct. 876, 898 (2010) (First Amendment forbids "distinguish[ing] among different speakers, allowing speech by some but not others"). Because the Government's prosecution of Dr. Harkonen thus "disfavors specific speakers, namely pharmaceutical [executives]," *Sorrell*, 131 S. Ct. at 2663, it is subject to the most exacting First Amendment scrutiny.

B. The Judgment Below Is Inconsistent With the First Amendment Even if the Press Release is Viewed as Commercial Speech

Even if the imposition of criminal liability here is viewed as affecting solely commercial speech and not disfavoring a particular speaker, it still is subject to and fails scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). Under *Central Hudson*, unless commercial speech relates to unlawful activity or is inherently misleading, the Government has the burden of showing that its restriction of that speech directly advances a substantial government interest and is not more extensive than necessary to serve that interest. *See, e.g.*, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002); *Sorrell*, 131 S. Ct. at 2667-68 (requiring a "fit" between means and ends to "ensure not only that the [Government's] interests are proportional to the resulting burdens placed on speech but also that the law does not seek to suppress a

disfavored message").[6]

1. The Government contends that the speech in this case is outside *Central Hudson* and entirely unprotected by the First Amendment because it is "misleading." However, only "inherently misleading" speech falls outside *Central Hudson*'s protection. In contrast, restrictions on commercial speech that is only *potentially* misleading are fully subject to *Central Hudson* scrutiny. *See Peel v. Att'y Registration & Disciplinary Comm'n*, 496 U.S. 91, 100 (1990) (plurality opinion); *In re R.M.J.*, 455 U.S. 191, 203 (1982); *Ass'n of Nat'l Advertisers, Inc. v. Lungren*, 44 F.3d 726, 731-32 (9th Cir. 1994). Simply put, "[i]n order to end the *Central Hudson* analysis on the first prong, the speech must be 'inherently misleading' . . . ." *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 66 (D.D.C. 1998), *vacated as moot*, 202 F.3d 331 (D.C. Cir. 2000).

An expression of interpretation about a scientific matter that is fairly debatable among reasonable scientists cannot be "inherently misleading." The D.C. Circuit has called "almost frivolous" the government's position that health claims by dietary supplement makers are "inherently misleading" unless consistent with "significant scientific agreement." *Pearson v. Shalala*, 164 F.3d 650, 655

[6] There has been no contention here that the press release was unprotected by the First Amendment on the ground that it related to illegal activity. It was never illegal for physicians to prescribe Actimmune for the treatment of IPF.

(D.C. Cir. 1999).

The Supreme Court has distinguished between potentially misleading and inherently misleading speech by asking whether the information could "be presented in a way that is not deceptive," for example by including additional explanation or disclaimers. *R.M.J.*, 455 U.S. at 203. That question practically answers itself in this case because the Government's primary theory of fraud was lack of "adjustment for context" and "omissions of critical information." D. Ct. 7/27/10 Order Denying Motions for New Trial (dkt. no. 268) at 15. The Court granted, at the Government's request, a special instruction permitting the jury to convict Dr. Harkonen on the basis of "half-truths, or statements which omit material facts." Instruction No. 16 (reprinted as Ex. A to U.S. Opp. to Defs.' Post-Trial Motions, filed 1/15/10 (dkt. no. 256)). A statement cannot be "inherently misleading" if additional context would render it not so.

To categorize speech as inherently misleading and therefore subject to an outright ban, the Supreme Court has also demanded actual evidence of deception. If there is no evidence that anyone was actually deceived, mere "concern about the possibility of deception in hypothetical cases" is not sufficient to justify treating speech as "inherently misleading." *Ibanez v. Fla. Dep't of Business & Prof. Reg'n, Bd. of Accountancy*, 512 U.S. 136, 145 (1994); *Peel*, 496 U.S. at 100-01, 106 (plurality). Here, there is no evidence that anyone was actually deceived by the

press release. *See* D. Ct. 4/18/11 Order Denying Motions for New Trial (dkt. no. 369) at 10 (acknowledging the Government did not establish any physician "made treatment decisions in reliance on the press release itself"). That lack of evidence reinforces that the press release was not outside *Central Hudson* for being "inherently misleading."

This Court has likewise considered "the ability of the intended audience to evaluate the claims made." *Lungren*, 44 F.3d at 731. That factor too points toward finding the press release not inherently misleading. The message was read by trained scientific and medical professionals well versed in biostatistical and epidemiological issues. *See Edenfield v. Fane*, 507 U.S. 761, 775 (1993) (government has diminished interest in regulating communications with "sophisticated and experienced" audience that is "less susceptible to manipulation"); *United States v. Caronia*, 576 F. Supp. 2d 385, 397 (E.D.N.Y. 2008) (holding pharmaceutical representative's statements were not "inherently misleading" because of "the sophistication of the audience" consisting of "physicians who are . . . able to independently evaluate the validity of [the] claims") (internal quotation marks omitted), *later judgment appealed*, No. 09-5006-cr (2d Cir.).

2. Assuming *arguendo* that the Government can show it directly and materially advances some substantial government interest, it fails *Central*

Hudson's final prong because prosecution of this type of scientific speech under the wire fraud statute is a far too blunt instrument that suppresses far too much expression. The Government had much less draconian means than criminal punishment at its disposal for addressing perceived problems created by a drug manufacturer's scientific speech. Most notably, it could have engaged in its own counter-speech, which is often the constitutionally preferred alternative to a restriction on the speech of others. *See Sorrell*, 131 S. Ct. at 2671; *Linmark Assocs. v. Twp. of Willingboro*, 431 U.S. 85, 97 (1977).

When courts have upheld speech restrictions under *Central Hudson* despite the availability of counter-speech as an alternative, it is usually because either the government is already engaging in counter-speech, or the counter-speech would be ineffective to combat the perceived problem. *See, e.g.*, *Eller Media Co. v. City of Oakland*, No. C 98-2237 WHA, 2000 WL 33376585, at *9 (N.D. Cal. Dec. 7, 2000). The Government can make neither argument here. It has used counter-speech in closely analogous situations. For example, in a near-contemporaneous instance where FDA believed a press release about a drug was false and misleading, FDA issued its own responsive "talk paper." *See* FDA Talk Paper T-03-18, *FDA Warns Public About Misrepresentations in Marketing Claims About Drug to Treat Cancer* (Mar. 14, 2003). To the extent the press release created an imbalance of information, there can be little dispute that a timely responding press

release from FDA would have been more effective at correcting any such imbalance than a punitive indictment years later.

Apart from counter-speech, the district court itself remarked at sentencing that "there may be other ways of handling violations of this nature besides through criminal charges." Tr. 4/13/11 at 155-56. "[T]he power of the state to prosecute and punish an individual for his or her conduct" is "one of the most awesome powers delegated to government in a free society." *Application of Herald Co.*, 734 F.2d 93, 105 (2d Cir. 1984). Where, as here, the Government could have but did not invoke civil remedies to address alleged misstatements, it is axiomatic that the use of criminal enforcement power is "more extensive than necessary to serve [the Government's] interest." *Central Hudson*, 447 U.S. at 566.

In sum, whether or not the press release at issue in this case is viewed as commercial speech, the First Amendment prohibited Dr. Harkonen's conviction for wire fraud absent a finding that no reasonable scientist could espouse the statements he made.

CONCLUSION

For the foregoing reasons, PhRMA respectfully submits that this Court should reverse Dr. Harkonen's conviction and remand with directions to enter a judgment acquitting Dr. Harkonen.

Respectfully submitted,

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November 4, 2011

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) (and amicus brief length limitation of Fed. R. App. P. 29(d)) because the brief contains 6,737 words according to the word count function of Microsoft Word 2007, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) and 32(a)(6), respectively, because this brief has been prepared in a proportionately spaced typeface using Microsoft Word 2007 in Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that on November 4, 2011, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

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