IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NO. 13-15197

W. SCOTT HARKONEN,
Plaintiff-Appellant.

v.

UNITED STATES DEPARTMENT OF JUSTICE and
UNITED STATES OFFICE OF MANAGEMENT AND BUDGET
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, NO. 4:12-CV-00629 (WILKENS, J.)

EXCERPTS OF RECORD
VOLUME 2

COLEEN KLASMEIER **KATHLEEN M. MUELLER** **SIDLEY AUSTIN LLP** **1501 K STREET, N.W.** **WASHINGTON, DC 20005** **TEL.: (202) 736-8000** **FAX: (202) 736-8711**	**MARK E. HADDAD** ***COUNSEL OF RECORD*** **SIDLEY AUSTIN LLP** **555 WEST FIFTH STREET, SUITE 4000** **LOS ANGELES, CA 90013** **TEL.: (213) 896-6000** **FAX: (213) 896-6600**

Attorneys for Plaintiff-Appellant Dr. W. Scott Harkonen

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Mark E. Haddad (SBN 205945)
mhaddad@sidley.com
SIDLEY AUSTIN LLP
555 West Fifth Street, Suite 4000
Los Angeles, California 90013
Telephone: (213) 896-6000
Facsimile: (213) 896-6600

Robert B. Martin III. (SBN 235489)
rbmartin@sidley.com
Sheila A.G. Armbrust (SBN 265998)
sarmbrust@sidley.com
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94110
Telephone: (415) 772-1200
Facsimile: (415) 772-7400

Attorneys for W. SCOTT HARKONEN, M.D.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

DMR

W. SCOTT HARKONEN, M.D.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF JUSTICE and UNITED STATES OFFICE OF MANAGEMENT AND BUDGET,

Defendants.

Case No. CV12 0629

COMPLAINT FOR DECLARATORY RELIEF AND PERMANENT INJUNCTION

Plaintiff, W. Scott Harkonen, M.D., by his undersigned counsel, hereby brings this Complaint against Defendants Department of Justice and Office of Management and Budget and alleges as follows:

I. INTRODUCTION

1. This action is filed under the Information Quality Act ("IQA"), P.L. 106-554 §1(a)(3) [Title V, §515], 114 Stat. 2763 (Dec. 21, 2000), codified at 44 U.S.C. § 3516, Statutory and Historical Notes, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 701, *et seq.*, to correct false and misleading statements about Dr. Harkonen in a Department of Justice press release. Pursuant to the IQA, the Office of Management and Budget has issued guidelines (the "OMB Guidelines") that require federal agencies to issue guidelines to "ensure and maximize the quality, objectivity, utility and integrity of information . . . disseminated by the agency.'" 67 Fed. Reg. 8452, 8459 (Feb. 22, 2002). As mandated by the IQA, the OMB Guidelines also require agencies to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency" in violation of the OMB Guidelines. *Id.* at 8452 (quoting Title V, Section 515(b)(2)(B)). The Department of Justice, in turn, promulgated its own guidelines under the IQA (the "DOJ Guidelines"), which are posted on its website, http://www.justice.gov/iqpr/iqpr.html (last visited Feb. 7, 2012).

2. On September 29, 2009, the United States Attorney's Office for the Northern District of California issued a press release (hereinafter, the "DOJ Press Release," attached as Exhibit 1) announcing that a jury, that day, had found Dr. Harkonen guilty of one count of wire fraud. Dr. Harkonen was formerly the Chief Executive Officer of InterMune, Inc. His wire fraud conviction was based on a single press release that InterMune issued in August 2002 (the "InterMune Press Release," attached as Exhibit 2), to announce the preliminary results of a clinical study of Actimmune, a drug marketed by InterMune. The Government repeatedly has conceded that the clinical trial data in the InterMune Press Release was cited accurately. Nonetheless, it prosecuted Dr. Harkonen for wire fraud based on the allegation that the headlines of the InterMune Press Release falsely interpreted those accurate data to demonstrate that Actimmune provided a mortality

benefit in the treatment of idiopathic pulmonary fibrosis ("IPF"), a fatal lung disease. In the government's view, the data at best "suggested," but did not demonstrate, such a benefit.

3. The DOJ Press Release itself misrepresents the facts and evidence from Dr. Harkonen's criminal trial in two respects.

a. First, the DOJ Press Release falsely states that Dr. Harkonen "lied to the public about the results of a clinical trial" by "falsifying test results." The government repeatedly has conceded in the trial and sentencing proceeding that no test results were falsified, that the numbers in the press release were accurately stated, and that Dr. Harkonen was prosecuted solely for the conclusions drawn from those results.

b. Second, the DOJ Press Release states that Dr. Harkonen's actions "served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans." That statement also is untrue. At sentencing, the district court rejected the government's assertion that the InterMune Press Release caused a loss to the Veterans Administration ("VA") (or, indeed, to any person).

4. Following the procedures in the DOJ Guidelines, Dr. Harkonen submitted letter petitions to the Department of Justice requesting retraction of the false and misleading statements contained in the DOJ Press Release. The Department of Justice denied both petitions, initially defending the statements as true, and claiming that in any case DOJ is not accountable under the IQA for false statements in its press releases. Dr. Harkonen submitted timely requests for reconsideration. DOJ denied both requests for reconsideration, each time abandoning its prior arguments that the challenged statements were true, and each time relying solely on its assertion that its press releases are "exempt" from the IQA, and hence DOJ is not obligated to correct false statements it makes about citizens in its press releases. Dr. Harkonen's objections noted the bitter irony of being prosecuted for false statements in a press release about a clinical trial in which his company was involved, by a law enforcement agency that declares itself free to issue press releases with false statements about criminal trials in which that agency was involved.

5. Left with no other administrative recourse, Dr. Harkonen files this lawsuit challenging the Department of Justice's arbitrary and unlawful denial of his requests for correction of the false statements in the DOJ Press Release, which have caused and continue to cause him substantial harm. Because DOJ ultimately based the denial of his request for correction of the false statements in the DOJ Press Release on its view that "press releases" are exempt from the OMB Guidelines and the DOJ Guidelines, Dr. Harkonen also challenges the OMB Guidelines and DOJ Guidelines as arbitrary and capricious, an abuse of discretion, and contrary to the IQA.

II. JURISDICTION AND INTRA-DISTRICT ASSIGNMENT

6. Dr. Harkonen brings this action to redress the deprivation of rights secured to him under the IQA, the OMB Guidelines and DOJ Guidelines implementing the IQA, and the APA.

7. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1361 and 5 U.S.C. § 701 *et seq.*

8. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) and Local Rule 3-5(b) because plaintiff Dr. Harkonen resides in San Francisco, California, which is in this judicial district, and a substantial portion of the events giving rise to the complaint occurred in this judicial district.

9. Plaintiff W. SCOTT HARKONEN is a medical doctor who was the Chief Executive Officer of InterMune from February 1998 until June 30, 2003, and a member of InterMune's board of directors through September 2003. InterMune is a pharmaceutical company that obtained the right to market and sell Actimmune, a drug developed by Genentech, Inc. Actimmune is a bio-engineered form of interferon-gamma, a protein that acts as a biologic response modifier through stimulation of the human immune system. The Food and Drug Administration approved Actimmune for the treatment of chronic granulomatous disease, an inherited autoimmune disease, and severe malignant osteopetrosis, an inherited disorder in which bone and cartilage become unusually dense and hardened.

10. Defendant UNITED STATES DEPARTMENT OF JUSTICE ("DOJ") is an administrative agency of the federal government with its headquarters in Washington, D.C. According to its website, the DOJ is "the central agency for enforcement of federal laws" in the

United States, and its mission is to "enforce the law and defend the interests of the United States according to the law; to ensure public safety against threats foreign and domestic; to provide federal leadership in preventing and controlling crime; to seek just punishment for those guilty of unlawful behavior; and to ensure fair and impartial administration of justice for all Americans." *See* http://www.justice.gov/about (last visited Feb. 7, 2012).

11. Defendant UNITED STATES OFFICE OF MANAGEMENT AND BUDGET ("OMB") is an administrative agency in the Executive Office of the President with its headquarters in Washington, D.C. *See* http://www.whitehouse.gov/omb/organization_mission (last visited Feb. 7, 2012). Among other statutory responsibilities, the Director of the OMB was required by the IQA to issue guidelines to federal agencies by September 20, 2001 "for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of . . . the Paperwork Reduction Act." Pub. L. No. 106-554, §1(a)(3) (Dec. 21, 2000), 114 Stat. 2763, 2763A-154, codified at 44 U.S.C. §3516, Statutory and Historical Notes.

III. THE IQA AND THE OMB AND DOJ IMPLEMENTING GUIDELINES

12. The IQA provides that the OMB Guidelines "shall" apply to "information disseminated by Federal agencies" and "shall" require that each federal agency issue its own guidelines to ensure the "quality, objectivity, utility, and integrity of information" they disseminate to the American public. 114 Stat. 2763, 2763A-154(b)(1), (b)(2)(A). The OMB Guidelines "shall" also require that each federal agency "establish administrative mechanisms allowing affected persons to *seek and obtain* correction of information maintained and disseminated by the agency that does not comply with the guidelines." *Id.* at 2763A-154(b)(2)(B) (emphasis added).

13. Pursuant to this statutory authority, on June 28, 2001, OMB issued Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. 66 Fed. Reg. 34489 (June 28, 2001) (the "Proposed OMB Guidelines"). OMB explained that it "is crucial that Federal agencies disseminate information that meets" the proposed standards for "quality, utility, objectivity and integrity." *Id.* at 34490. The "fact that the Internet enables persons to communicate information quickly and easily to a wide

audience not only offers great benefits to society, but also increases the potential harm that can result from the dissemination of information that does not meet OMB and agency information quality standards." *Id.*

14. The Proposed OMB Guidelines defined "Objectivity" to include "[w]hether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner." *Id.* at 34492. And the Proposed OMB Guidelines broadly defined "Dissemination" as "the government initiated distribution of information to the public. Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act. . . or Privacy Act. This definition also does not include distribution limited to replies to correspondence and subpoenas or judicial process." *Id.* at 34492-93.

15. The Proposed OMB Guidelines also required agencies to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines." *Id.* at 34492.

16. After receiving public comment, OMB issued final guidelines, although it requested additional public comment on the definition of "objectivity" insofar as it required that, for scientific or statistical information, the results must be "capable of being substantially reproduced." 66 Fed. Reg. 49718 (Sept. 28, 2001).

17. The OMB Guidelines require agencies to "develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated," and define "objectivity" to include "whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner." *Id.* at 49724. In issuing the final guidelines, OMB also clarified that the "affected persons" who may seek and obtain correction of information disseminated in violation of the OMB Guidelines are "people who may benefit or be harmed by the disseminated information. This includes persons who are seeking to address information about themselves as well as persons who use information." *Id.* at 49721.

18. But the OMB Guidelines also contain a more narrow definition of "dissemination" than that which OMB initially proposed. For purposes of this case, the relevant changes occurred in

the last sentence of the definition, which was revised to exclude "press releases," "archival records," and "public filings" from the "agency initiated or sponsored distribution of information to the public" that is subject to the OMB Guidelines. *Id.* at 49725. Although OMB explained the reason for excluding archival records disseminated from agency libraries (because "libraries do not endorse the information that they disseminate") and public filings, such as corporate filings with the Securities and Exchange Commission (because the agencies are not adopting the filings "as representing the agencies' views," but are "simply ensuring that the public can have quicker and easier access to materials that are publicly available"), OMB did not even mention, much less explain, the reason for excluding agency press releases. *Id.* at 49270.

19. After receiving additional comment on the standard for objectivity of scientific and statistical information, OMB issued final guidelines on February 22, 2002 that, for purposes of this case, are substantially the same as the final guidelines issued on September 28, 2001. 67 Fed. Reg. 8452 (Feb. 22, 2002).

20. On May 14, 2002, the Department of Justice, pursuant to the IQA and the OMB Guidelines, published notice in the Federal Register that the draft DOJ guidelines were available on the DOJ website and stated that comments should be received by June 10, 2002. *See* 67 Fed. Reg. 34475 (May 14, 2002).

21. On October 4, 2002, the Department of Justice published in the Federal Register notice that the final DOJ Guidelines are available on the DOJ website. 67 Fed. Reg. 62266 (Oct. 4, 2002). The DOJ Guidelines currently can be found at http://www.justice.gov/iqpr/iqpr.html (last visited Feb. 7 2012).

22. The DOJ Guidelines state that a "basic standard of quality will be ensured and established for all information prior to its dissemination." *Id.* The DOJ Guidelines, like the OMB Guidelines, define the standard of "quality" to encompass the "utility, objectivity, and integrity" of the information. *Id.* This case involves the "objectivity" component, which the DOJ Guidelines define to mean that "DOJ components will ensure disseminated information, as a matter of substance and presentation, is accurate, reliable, and unbiased. Objectivity is achieved by using reliable data sources, sound analytical techniques, and documenting methods and data sources." *Id.*

23. Except for certain "categories of information that are specifically exempted from coverage," the DOJ Guidelines "apply to all information disseminated by DOJ . . . , [including] any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. It includes information that an agency disseminates from a web page . . . ." *Id.* One category of information that is specifically exempted from the DOJ Guidelines is "press releases[,] fact sheets, press conferences or similar communications (in any medium) *that* announce, support or give public notice of *information in DOJ*[.]" *Id.* (emphasis added).

24. The DOJ Guidelines acknowledge, however, that DOJ components regularly disseminate information through press releases. Indeed, the U.S. Attorneys' Manual instructs that the "use of a press release . . . is the usual method to release public information to the media by Department of Justice components and investigative agencies." U.S. Attorneys' Manual 1-7.401(A) (2003).

25. As required by the IQA and the OMB Guidelines, the DOJ Guidelines provide procedures for submitting a request for correction of information disseminated in violation of the DOJ and/or OMB Guidelines. Requests must be submitted by letter, e-mail, or fax to the DOJ component or office that disseminated the incorrect information and should state, among other things, "how the information is incorrect," the "effect of the alleged error," and "how the information should be corrected." *See* http://www.justice.gov/iqpr/iqpr.html (last visited Feb. 7 2012). DOJ "will normally respond to requests for correction of information within 60 calendar days of receipt." *Id.*

26. If the request for correction is denied, the requester may file a request for reconsideration with the disseminating DOJ component within 45 calendar days after the DOJ transmits its initial decision. *Id.* "The components should generally provide that the official conducting the second level review is not the same official that responded to the initial request." *Id.* "DOJ will respond to all requests for reconsideration within 45 calendar days of receipt." *Id.*

27. To fulfill the reporting requirements of the OMB Guidelines and the IQA, the DOJ Guidelines assign the Justice Management Division the responsibility of reporting to the Director of

OMB the number and nature of complaints regarding DOJ's compliance with the OMB Guidelines and how those complaints were resolved. *Id.*

28. The DOJ web page discussing Information Quality includes a section reporting on "Information Quality Correspondence." *Id.* As of the filing of this Complaint, that section of the DOJ web page reports that "[t]he Department has received no requests for correction to information disseminated to the public, in accordance with the Information Quality Law." *Id.*

IV. FACTS

A. Request for Correction of Statement that Dr. Harkonen "falsif[ied] test results"

29. Following the procedures set forth in the DOJ Guidelines, Dr. Harkonen on February 11, 2010, sent a letter to DOJ entitled "Request for Correction Under Information Quality Guidelines" ("First Request"), attached as Exhibit 3. The First Request asserted that the following statement in the DOJ Press Release is false and violates the DOJ Guidelines and OMB Guidelines:

> 'Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval,' said FBI Special Agent in Charge Stephanie Douglas.

30. The First Request expressly stated that it was not filed "to dispute the Government's charges" against Dr. Harkonen (which he was disputing in separate post-trial motions filed with the district court), but "to request that the Government correct its *description* of the charges" in the statement in the DOJ Press Release quoted above. Ex. 3 at 1-2. The charges against Dr. Harkonen did *not* include—in the words of the DOJ Press Release—that he lied to the public by "falsifying test results." Indeed, the Government conceded that the clinical trial data cited in the InterMune Press Release were accurately reported and not "transposed or changed in any way." *See id.* at 2 ("For example, during a pretrial conference, [the AUSA] agreed that the test results were not 'transposed or changed in any way.' Ex. G (RT 6/24/09 at 28). And during her closing argument, [the AUSA] stated: 'I don't need to spend any time on the numbers in [the Press Release]. We all know the numbers are correct.' Ex. H (RT 9/23/09 at 3697)."). Instead, the Government challenged those statements in the InterMune Press Release that *interpreted* the concededly accurate clinical trial data

as "demonstrat[ing]" a "survival benefit" or "clinical benefit in IPF." According to the Government, these statements were false because the admittedly accurate data at most suggested, but were not sufficient to "demonstrate," that Actimmune provided a benefit to patients with IPF.

31. Therefore, the First Request said, by asserting that Dr. Harkonen "falsif[ied] test results," the DOJ Press Release "misrepresents what the Government sought to prove in the case and misleads the public as to what the jury actually found, and as to why Dr. Harkonen was convicted." Ex. 3 at 3. This false statement damages Dr. Harkonen's reputation in the medical community, even beyond his conviction. *See id.* For example, under California law, the falsification of test results can be a separate violation of medical ethical rules apart from a criminal conviction. *See* Cal. Bus. & Prof. Code §2236(a) (a criminal conviction can "constitute[] unprofessional conduct"); *id.* §2262 ("creating any false medical record, with fraudulent intent, constitutes unprofessional conduct").

32. The First Request requested that the Government: (1) retract the statement in the DOJ Press Release that Dr. Harkonen "falsif[ied] test results," and publish that retraction in the same manner that the Government distributed the DOJ Press Release; and (2) remove the DOJ Press Release from all official Government websites. Ex. 3 at 3.

33. On March 15, 2010, H. Marshall Jarrett, Director of the Executive Office for the United States Attorneys, sent a letter on behalf of DOJ denying the Request ("First Response," attached as Exhibit 4) on two grounds. First, DOJ asserted that the petition "falls outside the scope of" the OMB Guidelines (which, DOJ claimed, do not apply to information disseminated in press releases), and the DOJ Guidelines, which exclude information "disseminated in 'press releases[,] fact sheets, press conferences, or similar communications (in any medium) that announce, support or give public notice of information in DOJ.'" Ex. 4 at 1. Second, DOJ asserted that "[e]ven if the guidelines applied, no retraction is necessary because the statement at issue is correct." While acknowledging that Dr. Harkonen "did not change the data," the First Response said he used the data "to support his false and misleading conclusions. Because data alone is [sic] meaningless without analysis and conclusions, Mr. [sic] Harkonen's false statements regarding the data's meaning were part and parcel of the results. Thus, it was accurate to say that he falsified the results." *Id.* at 2.

34. On April 20, 2010, Dr. Harkonen filed a "Request for Reconsideration under Information Quality Guidelines" ("First Reconsideration," attached as Exhibit 5) according to the procedures set forth in the DOJ Guidelines. In Response to DOJ's claim that the DOJ Guidelines are inapplicable, Dr. Harkonen noted that they "expressly cover material disseminated on DOJ's website, as well as DOJ's press releases." Ex. 5 at 2. The exemption in the DOJ Guidelines of "press releases . . . that announce, support or give public notice of information in DOJ" has no application to the DOJ Press Release at issue here, both because it also is posted and remains on DOJ's website and because it announces the verdict of a criminal trial in a federal court, and thus is not "public notice of information *in DOJ*." *Id.*

35. The First Reconsideration also challenged DOJ's assertion that "the data's meaning were part and parcel of the results," because that ignores the distinction—recognized in both science and law—between scientific *data* and scientific *analysis*. *Id.* at 4. Indeed, the OMB Guidelines require agencies, when dealing with scientific information, to ensure that "the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods." 67 Fed. Reg. 8452, 8459 (Feb. 22, 2002). Dr. Harkonen submitted the First Reconsideration to "'the disseminating component'" designated by the DOJ guidelines, and explained why "the agency, in the exercise of its statutory duty to review the case on rehearing independently, should step in, assess the situation dispassionately and see it for what it is, and correct the record." Ex. 5 at 1, 2.

36. On July 2, 2010, DOJ denied the First Reconsideration, in a letter attached as Exhibit 6. Like the first letter, the second letter also was signed by H. Marshall Jarrett. On reconsideration, DOJ abandoned any effort to defend the truth of the statement that Dr. Harkonen had been convicted for "falsifying test results." *Id.* at 1. Instead, DOJ's sole basis for denying reconsideration was that it "was not required to respond substantively to [Dr. Harkonen's] initial request for a retraction" because the DOJ Guidelines "do not apply to press releases[.]" *Id.* DOJ stated that "a press release that announces a successful prosecution is clearly public information in the Department of Justice," and, therefore, the DOJ Press Release is not covered by the DOJ Guidelines even if it "is posted on

the Internet[.]" *Id.* "Rather, it is the very fact that the information is contained in a press release that exempts it from the guidelines." *Id.*

37. After the denial of reconsideration, the government continued to distinguish between falsifying test results and disseminating a false interpretation of test results, to concede that the trial had only been about the interpretation of accurately stated data, and to concede that Dr. Harkonen had not falsified any test results. Two such concessions are illustrative:

a. On November 15, 2010, at Dr. Harkonen's first sentencing hearing, the AUSA stated: "The *Government has always agreed that there was no falsification of data here* . . . . With respect to whether there was a falsification of the conclusions that could be drawn from the data, that was what the trial was all about.") (Transcript attached as Exhibit 7 at 9:1-7) (emphasis added).

b. On April 13, 2011, at Dr. Harkonen's second sentencing hearing, the court confirmed the point again in a colloquy with the AUSA:

> "Defense counsel: The case is about the conclusions that the manufacturer drew in the press release from what the government has repeatedly conceded was accurately stated data.
>
> Court: Okay, *and there's no dispute*, *is there*, that *the data* that's actually referred to in the press release is *accurately reflected*? Is that correct?
>
> AUSA: *No dispute*. The government says the *conclusions* were inaccurate –
>
> Court: It's the interpretation thereof, et cetera.
>
> AUSA: -- were false.
>
> Court: *It's the interpretation thereof*, et cetera. *Is that correct*? *Okay*."

Transcript attached as Exhibit 8 at 11:23-12:10 (emphasis added).

B. Request for Correction of Statement that Dr. Harkonen's actions "served to divert precious financial resources" from the VA's healthcare mission

38. On June 8, 2011, according to the procedures set forth in the DOJ Guidelines, Dr. Harkonen sent a second letter to DOJ entitled "Request for Correction Under Information Quality Guidelines" ("Second Request"), attached as Exhibit 9. In the Second Request, Dr. Harkonen

asserted that another statement (marked in italics below) in the DOJ Press Release is false and violates the DOJ Guidelines and OMB Guidelines:

> Douglas J. Carver, Special Agent in Charge of the U.S. Department of Veterans Affairs, Office of Inspector General, Western Field Office, stated 'today's verdict, which resulted from a complex and labor-intensive investigation and trial, demonstrates our commitment to work with our law enforcement partners to aggressively pursue all individuals that would jeopardize the integrity and safety of the VA's health care system. *The actions of this defendant served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans.* The VA OIG will continue to aggressively pursue investigations of this type and hold those responsible accountable for their actions.'

39. The statement that Dr. Harkonen's actions "served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans" is untrue. None of the VA documents belatedly produced by the Government in the criminal sentencing proceedings showed that the conclusions in the InterMune Press Release caused any loss or harm to the VA. Ex. 9 at 3. Moreover, the Government was unable to prove, despite multiple opportunities in the criminal proceedings, that the conclusions in the InterMune Press Release caused any loss to *anyone*. *Id.* The Second Request therefore asked that DOJ retract the statement that Dr. Harkonen's actions "served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans" and remove the DOJ Press Release from all official Government websites. Ex. 9 at 4.

40. On August 4, 2011, DOJ denied the Second Request in a letter from H. Marshall Jarrett, the Director of the Executive Office for the United States Attorneys ("Second Response"), attached as Exhibit 10. DOJ gave two reasons for denying the Second Request. First, DOJ asserted that the DOJ Press Release is not covered by the OMB Guidelines or the DOJ Guidelines because it discusses the outcome of DOJ's law enforcement efforts and thus "constitute[s] 'information in DOJ'." Ex. 10 at 2. Second, DOJ asserted "[e]ven if the guidelines applied, no retraction is necessary" because the challenged statement "accurately described the government's position" in the sentencing proceedings and could "reasonably be interpreted to mean that Dr. Harkonen's wrongdoing necessitated an investigation . . . by the Veterans Administration [that was] comprehensive[.]" *Id.*

41. On August 22, 2011, according to the procedures set forth in the DOJ Guidelines, Dr. Harkonen filed a "Request for Reconsideration under Information Quality Guidelines" ("Second Reconsideration"), attached as Exhibit 11. Dr. Harkonen specifically asked, per DOJ guidelines, for review by "an official other than Mr. Jarrett," and asked DOJ to reconsider its position that press releases are exempt from the DOJ Guidelines and thus DOJ is free to make false statements in any of its press releases. Ex. 11 at 1. The Second Reconsideration explained that the exemption for "press releases . . . that announce, support, or give public notice of information in DOJ" is not applicable because the DOJ Press Release at issue here (1) is posted on DOJ website and the DOJ Guidelines expressly apply to information "disseminate[d] from a web page . . ."; and (2) reported on the results of a criminal trial in an Article III court and on the impact of the defendant's conduct on the financial resources that allegedly would otherwise have been allocated to veterans by the Department of Veterans' Affairs, none of which is "information in DOJ." *Id.* at 3. Likewise, the exemption in the OMB Guidelines for "distribution limited to . . . press releases" (67 Fed. Reg. 8452, 8459 (Feb. 22, 2002)) is not applicable because (1) they are not controlling after the DOJ issued its own guidelines; and (2) the "distribution" of the DOJ Press Release was not "limited to" a press release, because it was also posted on the DOJ web pages. *Id.* at 4-5. Finally, on the merits, the Second Reconsideration disputed DOJ's claim that the statement that Dr. Harkonen "diverted" VA funds could reasonably be read to mean that his conduct required the VA to expend investigatory resources. *Id.* at 6. Instead the "natural and direct meaning" of the DOJ Press Release is the false accusation that Dr. Harkonen's conduct caused the diversion of funds allocated for the provision of health care to veterans. *Id.*

42. On October 7, 2011, DOJ denied the Second Reconsideration in a second letter signed, as was the initial rejection letter, by H. Marshall Jarrett, attached as Exhibit 12. As it did in response to Dr. Harkonen's First Reconsideration, DOJ again dropped its defense that the challenged statement in the DOJ Press Release was true. Ex. 12 at 1. Instead, DOJ defended its refusal to correct the challenged statement solely on the grounds that it "was not required to respond substantively" to Dr. Harkonen's request for retraction because the DOJ Guidelines "do not apply to press releases[.]" *Id.*

43. More than two years after the DOJ Press Release first was published on the website of the U.S. Attorney's Office for the Northern District of California, it remains one of the top Internet search results for "Scott Harkonen," and it remains, uncorrected, on the DOJ website. Dr. Harkonen continues to suffer from the effects of this false information, which carries the imprimatur of the nation's chief law enforcement agency that led the Government's efforts to obtain the conviction discussed in the DOJ Press Release. Falsifying test results is qualitatively different, and far more serious, conduct than the conduct for which Dr. Harkonen was convicted. Many scientists and others understand that scientists may differ over the conclusions to be drawn from data; none, including Dr. Harkonen, condones the falsification of data.

44. It would be intolerable in a free society governed by law, even absent the IQA, for the DOJ to have unlimited discretion to issue and post press releases that give the public false information about the facts it established in a criminal trial. In the aftermath of the IQA, where Congress specifically has directed agencies to provide individuals affected by government misinformation the ability to seek and obtain a remedy, DOJ no longer has such unfettered discretion, and so its misconduct here may not escape judicial condemnation and redress.

45. Dr. Harkonen has filed two separate requests for correction, and two separate requests for reconsideration, all in accordance with the IQA and agency guidelines, and all supported by clear legal argument and numerous exhibits. In the face of these efforts to seek and obtain a remedy from the agency, DOJ's categorical statement that press releases are "exempt" from the IQA, as well as DOJ's refusal to correct the DOJ Press Release, to publish and disseminate a retraction, to remove the DOJ Press Release from the DOJ website, or even to deem Dr. Harkonen as having made a cognizable IQA request for correction subject to reporting to OMB, is final agency action that establishes that Dr. Harkonen has no further administrative remedy to pursue.

COUNT I (against the Department of Justice)

46. The allegations contained in paragraphs 1-45 are incorporated herein by reference.

47. Dr. Harkonen has no adequate remedy at law.

48. DOJ's denial of Dr. Harkonen's first and second Requests for Correction Under Information Quality Guidelines is arbitrary and capricious, an abuse of discretion, and contrary to

law. 5 U.S.C.§ 706(2)(A) & (C); 114 Stat. 2763 (Dec. 21, 2000), codified at 44 U.S.C. § 3516, Statutory and Historical Notes.

COUNT II (against the Department of Justice)

49. The allegations contained in paragraphs 1-48 are incorporated herein by reference.

50. Dr. Harkonen has no adequate remedy at law.

51. The exclusion of press releases from the Department of Justice Information Quality Guidelines is arbitrary and capricious, an abuse of discretion, and contrary to law. 5 U.S.C.§ 706(2)(A) & (C); 114 Stat. 2763 (Dec. 21, 2000), codified at 44 U.S.C. § 3516, Statutory and Historical Notes.

COUNT III (against the Office of Management and Budget)

52. The allegations contained in paragraphs 1-51 are incorporated herein by reference.

53. Dr. Harkonen has no adequate remedy at law.

54. The exclusion of press releases from the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies is arbitrary and capricious, an abuse of discretion, and contrary to law. 5 U.S.C.§ 706(2)(A) & (C); 114 Stat. 2763 (Dec. 21, 2000), codified at 44 U.S.C. § 3516, Statutory and Historical Notes.

RELIEF SOUGHT

WHEREFORE, Dr. Harkonen seeks the following relief:

55. A declaration that DOJ's denial of Dr. Harkonen's first and second Requests for Correction Under Information Quality Guidelines is arbitrary and capricious, an abuse of discretion, and contrary to the IQA;

56. A declaration that the DOJ Guidelines are arbitrary and capricious, an abuse of discretion, and contrary to the IQA to the extent that they exclude information disseminated in a press release;

57. A declaration that the OMB Guidelines are arbitrary and capricious, an abuse of discretion, and contrary to the IQA to the extent that they exclude information disseminated in a press release;

58. A permanent injunction:

a. Requiring DOJ to retract the statement in the DOJ Press Release that Dr. Harkonen was convicted for "falsifying test results," and to publish that retraction in the same manner that the Government distributed the DOJ Press Release;

b. Requiring DOJ to retract the statement in the DOJ Press Release that Dr. Harkonen "served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans," and to publish that retraction in the same manner that the Government distributed the DOJ Press Release;

c. Requiring DOJ to remove the DOJ Press Release from all official Government websites;

d. costs and attorneys fees incurred in this action; and

e. such other and further relief as may be just and proper.

Dated: February 8, 2012

Respectfully submitted,

SIDLEY AUSTIN LLP

By: /Mark E. Haddad/RBM

Mark E. Haddad

Attorneys for Plaintiff
W. SCOTT HARKONEN, M.D.

EXHIBIT 1

United States Department of Justice

United States Attorney Joseph P. Russoniello
Northern District of California
11th Floor, Federal Building
450 Golden Gate Avenue, Box 36055
San Francisco, California 94102
(415) 436-7200
FAX: (415) 436-7234

FOR IMMEDIATE RELEASE
SEPTEMBER 29, 2009
WWW.USDOJ.GOV/USAO/CAN

CONTACT: Jack Gillund
(415) 436-6599
Jack.Gillund@usdoj.gov

W. SCOTT HARKONEN, FORMER BIOTECH CEO, CONVICTED OF WIRE FRAUD

SAN FRANCISCO – W. Scott Harkonen, M.D., and the former CEO of InterMune, Inc., was convicted of wire fraud for the creation and dissemination of false and misleading information about the efficacy of InterMune's drug Actimmune (Interferon gamma-1b) as a treatment for idiopathic pulmonary fibrosis ("IPF"), the United States Attorney's Office for the Northern District of California and the Civil Division of the United States Department of Justice announced.

The jury, in its third day of deliberations, found the defendant guilty of wire fraud related to a press release issued on Aug. 28, 2002. The defendant was acquitted of a misbranding charge brought under the Federal Food, Drug, and Cosmetic Act. The guilty verdict followed a seven-week jury trial before U.S. District Court Judge Marilyn Hall Patel.

Evidence at trial showed that Harkonen, a medical doctor, was the Chief Executive Officer of InterMune from February 1998 through June 30, 2003, and a member of InterMune's Board of Directors. Under defendant Harkonen's direction, InterMune marketed and sold Actimmune to treat the fatal disease IPF sprdespite the fact that Actimmune was not approved by the Food and Drug Administration ("FDA") as a safe and effective treatment. The cost of Actimmune for one IPF patient for one year was approximately $50,000 and the vast majority of InterMune's sales of Actimmune were for the unapproved, off-label use of treating IPF.

Evidence at trial further showed that the defendant caused InterMune to issue a press release publicly announcing the results of a clinical trial of Actimmune for the treatment of IPF on Aug. 28, 2002. Although the clinical trial in fact failed, Harkonen caused the issuance and distribution of a false and misleading press release to portray that the results of the trial established that Actimmune helped IPF patients live longer. Specifically, the press release's headline falsely stated that, "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," with the subheading "Reduces Mortality by 70% in Patients With Mild to Moderate Disease."

In October 2006, InterMune agreed to enter into a deferred prosecution agreement and to pay nearly $37 million to resolve criminal charges and civil liability in connection with the illegal promotion and marketing of its drug Actimmune. InterMune also entered into a five-year Corporate Integrity Agreement with the Office of Inspector General for the Department of Health and Human Services.

"This conviction of W. Scott Harkonen demonstrates the Department of Justice's commitment to hold accountable those corporate executives who provide false or fraudulent information about pharmaceutical trials," said Ann Ravel, Deputy Assistant Attorney General for the Civil Division. "When corporate executives provide false or fraudulent information about pharmaceutical trials, they jeopardize the public health and welfare. The Department of Justice is committed to ensuring that doctors and patients receive

truthful information about medical products."

“Today’s verdict demonstrates that pharmaceutical executives will not be able to hide behind a corporate shield when they promote drugs using false or fraudulent information,” said Thomas P. Doyle, Special Agen in Charge of FDA’s Office of Criminal Investigations, Metro Washington Field Office. "Pharmaceutical companies do not run themselves, and those who engage in criminal conduct will be held personally accountable."

"Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval," said FBI Special Agent in Charge Stephanie Douglas.

Douglas J. Carver, Special Agent in Charge of the U.S. Department of Veterans Affairs, Office of Inspector General, Western Field Office, stated “today’s verdict, which resulted from a complex and labor-intensive investigation and trial, demonstrates our commitment to work with our law enforcement partners to aggressively pursue all individuals that would jeopardize the integrity and safety of the VA’s health care system. The actions of this defendant served to divert precious financial resources from the VA’s critical mission of providing healthcare to this nation’s military veterans. The VA OIG will continue to aggressively pursue investigations of this type and hold those responsible accountable for their actions.”

The maximum statutory penalty for 18 U.S.C. § 1343 (wire fraud) is 20 years in prison, $250,000 fine, three years supervised release, and $100 mandatory special assessment. However, any sentence following conviction would be imposed by the Court after consideration of the U.S. Sentencing Guidelines and the federal statute governing the imposition of a sentence, 18 U.S.C. § 3553.

This case is being prosecuted by Assistant U.S. Attorney Ioana Petrou of the Northern District of California and Trial Attorney Allan Gordus of the Office of Consumer Litigation in the Civil Division in Washington, D.C., with the assistance of Associate Chief Counsel Anne Walsh of the FDA Office of Chief Counsel, Paralegal Specialists Matthew McCrobie and Matthew Robinson, and Legal Technician Jennifer Hiwa. The prosecution is the result of a multi-year investigation by the Federal Bureau of Investigation; the Food and Drug Administration's Office of Criminal Investigations; the U.S. Department of Veterans Affairs, Office of Inspector General; and the Office of Personnel Management, Office of the Inspector General.

Further Information:

Case #: 08-164 MHP

A copy of this press release may be found on the U.S. Attorney’s Office’s website at www.usdoj.gov/usao/can.

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This site does not contain all press releases or court filings and is not an official record of

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proceedings. Please contact the Clerk of Courts for the United States District Court for official copies of documents and public information.

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EXHIBIT 2

Investor contact: Myesha Edwards, InterMune, Inc., 415-466-2242, medwards@intermune.com
Media contact: Jim Weiss, InterMune, Inc., 415-362-5018, weisscomm@earthlink.net

INTERMUNE ANNOUNCES PHASE III DATA DEMONSTRATING SURVIVAL BENEFIT OF ACTIMMUNE IN IPF

- Reduces Mortality by 70% in Patients with Mild to Moderate Disease -

BRISBANE, Calif., August 28, 2002 – InterMune, Inc. (Nasdaq: ITMN) announced today that preliminary data from its Phase III clinical trial of Actimmune® (Interferon gamma-1b) injection for the treatment of idiopathic pulmonary fibrosis (IPF), a debilitating and usually fatal disease for which there are no effective treatment options, demonstrate a significant survival benefit in patients with mild to moderate disease randomly assigned to Actimmune versus control treatment ($p = 0.004$). These data confirm the survival benefit seen in the Phase II trial presented earlier this year at the 98th Annual Conference of the American Thoracic Society. There was also approximately a 10% relative reduction in the rate of progression-free survival associated with Actimmune versus placebo, the trial's primary endpoint, but this was not a statistically significant difference.

The company will hold a conference call at 9:00 a.m. EDT today to discuss these results (details below).

"We are extremely pleased with these results, which indicate Actimmune may extend the lives of patients suffering from this debilitating disease," said W. Scott Harkonen, M.D., President and CEO of InterMune. "Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials. 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."

"The mortality benefit is very compelling and represents a major breakthrough in this difficult disease," said Ganesh Raghu, M.D., Professor of Medicine, University of Washington in Seattle, and the Phase III study's lead principal investigator. "Interferon gamma-1b is the first treatment ever to show any meaningful clinical impact in this disease in rigorous clinical trials, and these results would indicate that Actimmune should be used early in the course of this disease in order to realize the most favorable long-term survival benefit."

Study Details and Results

A total of 330 patients were randomized into this double-blind, placebo-controlled trial conducted at 58 centers around the United States and Europe. Patients received either placebo or 200 micrograms of Actimmune injected subcutaneously three times per week. All patients remained in the trial until the last patient received 48 weeks of therapy. Median treatment duration was 60 weeks. The primary endpoint was progression free survival time defined as either one of the following: (i) a decrease in forced vital capacity (FVC) of >10 percent, (ii) an increase in A-a gradient of 5 mmHg, or (iii) death. While this endpoint did not reach statistical significance, there was a trend in favor of Actimmune-treated patients, representing an approximately 10% relative reduction in the rate of progression-free survival versus placebo.

Importantly, Actimmune also demonstrated a strong positive trend in increased survival in the overall patient population, and a statistically significant survival benefit in patients with mild to moderate IPF. In the overall population, there were 16/162 deaths in the Actimmune-treated group (9.9%) compared to 28/168 deaths in the placebo group (16.7%), representing a 40% decrease in mortality in favor of Actimmune vs. placebo ($p = 0.084$). Further, of the 254 patients with mild to moderate disease (FVC >= 55 percent), there were 6/126 deaths in the Actimmune-treated group (4.8%) and 21/128 deaths in the placebo group (16.4%), representing a 70% decrease in mortality in favor of Actimmune versus placebo ($p = 0.004$).

There were also trends later in the course of the study in favor of Actimmune in terms of improved breathing (i.e., dyspnea) and reduced need for supplemental oxygen. Actimmune treatment was also very well tolerated with the most common side effects reported being flu-like symptoms.

These data appear to confirm long-term follow-up data, reported earlier this year at the ATS meeting, which involved 18 patients from a randomized, controlled, open-label trial of Actimmune, in which 16 patients received one or more doses of Actimmune following study completion. The Kaplan Meier estimate of survival at five years was 77.8% and 16.7% in the Actimmune and control groups, respectively ($p = 0.009$).

Tracking Longer Term Outcomes

InterMune plans to transition all remaining Phase III trial patients in the active and placebo groups into an open-label clinical trial in which all patients receive Actimmune to track longer-term outcomes with Actimmune for a minimum of one year.

"We felt we had an ethical obligation to get this important news out about the survival benefit of Actimmune so physicians can evaluate it when making treatment decisions for their patients," said James E. Pennington, M.D., InterMune's Executive Vice President of Clinical and Medical Affairs. "We now have two well-controlled trials in IPF patients supporting a survival benefit, providing what we believe is compelling rationale for consideration of Actimmune for the treatment of patients with this disease."

About Actimmune

Interferon gamma-1b is a naturally occurring protein that stimulates the immune system. InterMune markets Actimmune for the treatment of life-threatening congenital diseases chronic granulomatous disease and severe, malignant osteopetrosis. InterMune is also conducting a Phase III study of Actimmune in ovarian cancer and a Phase II study of Actimmune for the treatment of severe liver fibrosis, or cirrhosis, caused by hepatitis C virus (HCV).

About Idiopathic Pulmonary Fibrosis

Idiopathic pulmonary fibrosis (IPF) is the most common form of idiopathic interstitial pneumonia. Once symptoms appear, there is a relentless deterioration of pulmonary function and death three to five years after diagnosis. The most common treatment is steroids; however, previously published studies suggest that fewer than 20 percent of patients with IPF respond to steroids. In patients having failed treatment with steroids, cytotoxic drugs such as azathioprine or cyclophosphamide are sometimes added to the steroid treatment. However, a large number of studies have shown little or no benefit from treatments involving steroids and other cytotoxic drugs. There are currently no drugs approved by the FDA for the treatment of IPF.

Conference Call Details

To access the live teleconference, dial 888-799-0528 (U.S.) or 706-634-0154 (international). A replay of the webcast and teleconference will be available approximately three hours after the call for two

business days. To access the replay, please call 1-800-642-1687 (U.S.) or 706-645-9291 (international), and enter the conference ID# 5479918. To access the webcast, please log on to the company's website at www.intermune.com at least 15 minutes prior to the start of the call to ensure adequate time for any software downloads that may be required.

These data will be presented in more detail at the European Respiratory Society meeting in Stockholm at a symposium on Sept. 15, 2002, and later this year at the American College of Chest Physicians meeting in November in San Diego, Calif.

About InterMune

InterMune is a commercially driven biopharmaceutical company focused on the marketing, development and applied research of life-saving therapies for pulmonary disease, infectious disease and cancer. For additional information about InterMune, please visit www.intermune.com.

Except for the historical information contained herein, this press release contains certain forward-looking statements that involve risks and uncertainties, including without limitation the statements indicating that the company believes that these results will: (i) support use of Actimmune for the treatment of IPF, (ii) lead to $400-$500 million in peak Actimmune sales, (iii) enable the company to achieve profitability in 2004, and (iv) provide compelling rationale for consideration of Actimmune for the treatment of patients with IPF. All forward-looking statements and other information included in this press release are based on information available to InterMune as of the date hereof, and InterMune assumes no obligation to update any such forward-looking statements or information. InterMune's actual results could differ materially from those described in InterMune's forward- looking statements. Factors that could cause or contribute to such differences include, but are not limited to those discussed under the heading "Risk Factors" and the risks and factors discussed in InterMune's 10-K report filed with the SEC on March 21, 2002, and other periodic reports (i.e., 10-Q and 8- K) filed with the SEC. The risks and other factors that follow, concerning the forward-looking statements in this press release, should be considered only in connection with the fully discussed risks and other factors discussed in detail in the 10-K report and InterMune's other periodic reports filed with the SEC. The forward-looking statements that the company believes that these results will: (i) support use of Actimmune for the treatment of IPF, (ii) lead to $400-$500 million in peak Actimmune sales, (iii) enable the company to achieve profitability in 2004, and (iv) provide compelling rationale for consideration of Actimmune for the treatment of patients with IPF, are subject to the uncertainties and risks of a continuing increase in sales of Actimmune for IPF, an indication for which Actimmune has not been approved by the FDA; reimbursement risks associated with third-party payors; and regulation by the FDA with respect to InterMune's communications with physicians concerning Actimmune for the treatment of IPF.

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EXHIBIT 3

SIDLEY AUSTIN LLP
SIDLEY

SIDLEY AUSTIN LLP
555 WEST FIFTH STREET
LOS ANGELES, CA 90013
(213) 896 6000
(213) 896 6600 FAX

BEIJING
BRUSSELS
CHICAGO
DALLAS
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GENEVA
HONG KONG
LONDON
LOS ANGELES

NEW YORK
PALO ALTO
SAN FRANCISCO
SHANGHAI
SINGAPORE
SYDNEY
TOKYO
WASHINGTON, D.C.

mhaddad@sidley.com
(213) 896 6604

FOUNDED 1866

February 11, 2010

By Federal Express

The Honorable Joseph P. Russoniello
United States Attorney, Northern District of California
United States Attorney's Office
450 Golden Gate Avenue, 11th Floor
San Francisco, California 94102

Re: *United States v. Harkonen*, No. CR 08-0164 MHP (N.D. Cal.)
Request for Correction under Information Quality Guidelines

Dear Mr. Russoniello:

We represent W. Scott Harkonen, the defendant in the above-referenced matter. On his behalf, we submit this letter as a Request for Correction under the Information Quality Guidelines ("Guidelines"), promulgated by the U.S. Department of Justice pursuant to the Information Quality Act, Pub. L. No. 106-554, Appendix C § 515(a), 114 Stat. 2763A-154 (2000) (codified at 44 U.S.C. § 3516 note). *See* www.justice.gov/iqpr/dojinformationqualityguidelines.htm (setting forth Guidelines).

On September 29, 2009, the U.S. Attorney's Office of the Northern District of California issued a press release titled "W. Scott Harkonen, Former Biotech CEO, Convicted of Wire Fraud." Ex. A, *available at* www.justice.gov/usao/can/press/2009/2009_09_29_harkonen.convicted.press.html. The DOJ press release contains the following statement: "'Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval,' said FBI Special Agent in Charge Stephanie Douglas." *Id.*

We are filing this Request not to dispute the Government's charges against him—we have done that in separate post-trial motions filed with the District Court—but rather to request

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that the Government correct its *description* of those charges in the statement quoted above. The charges against him did *not* include—in the words of the DOJ press release—that he "falsif[ied] test results." By stating otherwise, the DOJ press release announcing his conviction is itself false. The statement thus violates the Guidelines, which provide in part: "DOJ components will ensure disseminated information, as a matter of substance and presentation, is accurate . . . ."

During Dr. Harkonen's trial, the Government challenged statements from an August 28, 2002 press release ("Press Release") that announced the preliminary results of a Phase III clinical trial of the prescription drug Actimmune (interferon gamma-1b) for treating idiopathic pulmonary fibrosis ("IPF"). *See* Ex. B (2002 press release); Ex. C (RT 9/22/09 at 3457: The Court: "[F]or the wire fraud, what you are citing to as the basis for the—for this false to fraudulent statement is the press release?" Assistant U.S. Attorney Ioana Petrou: "Yes, your honor."). In particular, the Government claimed that certain statements in the 2002 press release were false and misleading: "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF"; Actimmune "Reduces Mortality by 70% in Patients With Mild to Moderate Disease"; and "Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials." Ex. B (press release); Ex. D (RT 5/20/09 at 10-14); Ex. E (RT 8/18/09 at 270-71, 277-82). According to the Government, these statements were false because the Phase III trial's endpoints were not met within FDA's guidelines for statistical significance, and because the Press Release did not state that the subgroup was retrospectively defined. Ex. F (RT 9/23/09 at 3568-69, 3597).

The Government conceded, however, that the Press Release accurately reported the trial data and statistics. For example, during a pretrial conference, Ms. Petrou agreed that the test results were not "transposed or changed in any way." Ex. G (RT 6/24/09 at 28). And during her closing argument, Ms. Petrou stated: "I don't need to spend any time on the numbers in [the Press Release]. We all know the numbers are correct." Ex. H (RT 9/23/09 at 3697).

The Government's witnesses likewise stated that Dr. Harkonen did not falsify the test results. Dr. Marc Walton, an FDA scientist and a chief witness for the Government, testified that he (and FDA) were not aware of any falsifications or distortions in the reporting of the trial results. Ex. I (RT 8/19/09 at 527-28). Dr. Steven Porter, an Intermune scientist, testified that the "actual numbers in the Press Release" were "correct." Ex. J (RT 9/2/09 at 1535–36); *see also* Ex. K (RT 9/1/09 at 1442-43, 1470). Dr. Michael Crager, InterMune's Chief Biostatistician, testified that there were no incorrect "numbers in the press release . . . ." Ex. L (RT 9/10/09 at 2238); *see also* Ex. M (RT 9/10/09 at 2317–18). And James Weiss, who was involved in the drafting of the Press Release, testified that he had no reason "to doubt the absolute correctness and integrity of those results" reflected in the release. Ex. N (RT 9/15/09 at 2661). Defense witnesses also testified that the test results reported in the Press Release were accurate. *See, e.g.*,

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Ex. O (RT 9/18/09 at 3393: Stephen Rosenfield, the then-General Counsel for Intermune, testified that he "never heard that there's a misstatement of any data in this press release.").

Instead, the Government disputed the *conclusions* that Dr. Harkonen derived from the trial results and reported in the Press Release. *See* Ex. P (RT 9/23/09 at 3570: in its closing, the Government argued: "what you can't do is take the p-values that you get from that subgroup analysis, and make conclusions based on those p-values. You can't make definitive conclusions about whether a drug works or not based on those p-values."). Thus, Dr. Harkonen was convicted for drawing a conclusion that the Government claimed the test results did not support; he was not convicted for having falsified the test results themselves.

The Government's assertion in the DOJ press release that Dr. Harkonen "falsif[ied] test results" thus misrepresents what the Government sought to prove in the case and misleads the public as to what the jury actually found, and as to why Dr. Harkonen was convicted. It is also unfair to Dr. Harkonen for the Government to state falsely that he engaged in fraudulent activity beyond what the evidence at trial sought to prove, especially where the Government conceded at trial that such fraudulent activity did not occur. Finally, the Government's false statement will damage Dr. Harkonen's reputation in the medical community, even beyond his conviction. For example, under California law, the falsification of test results can be a separate violation of medical ethical rules apart from a criminal conviction. *See* Cal. Bus. & Prof. Code § 2236(a) (noting that a criminal conviction can "constitute[] unprofessional conduct"); *id.* § 2262 (noting separately that "creating any false medical record, with fraudulent intent, constitutes unprofessional conduct.").

Dr. Harkonen thus requests the following: (1) the Government issue a retraction of the statement in the September 29, 2009 press release that Dr. Harkonen "falsif[ied] test results," and publish that retraction in the same manner that the Government distributed the September 29 press release to the public; and (2) the Government remove the original September 29 press release from all official Government websites. Such an approach is the only reasonable measure by which the Government can mitigate the harm caused by the public dissemination of its false statement.

We look forward to your response within sixty calendar days of receipt of this letter.

SIDLEY AUSTIN LLP
SIDLEY

Very truly yours,

Mark E. Haddad /RBM

Coleen Klasmeier /RBM

Mark E. Haddad

Coleen Klasmeier

Enclosures

cc: Gary Grindler, Acting Deputy Attorney General
Lee J. Lofthus, Assistant Attorney General for Administration, Justice Management Division
Ioana Petrou, Assistant United States Attorney
Marcus S. Topel, Kasowitz, Benson, Torres & Friedman LLP

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EXHIBIT A

United States Department of Justice

United States Attorney Joseph P. Russoniello
Northern District of California

11th Floor, Federal Building
450 Golden Gate Avenue, Box 36055
San Francisco, California 94102
(415) 436-7200
FAX. (415) 436-7234

FOR IMMEDIATE RELEASE
SEPTEMBER 29, 2009
WWW.USDOJ.GOV/USAO/CAN

CONTACT: Jack Gillund
(415) 436-6599
Jack.Gillund@usdoj.gov

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This case is being prosecuted by Assistant U.S. Attorney Ioana Petrou of the Northern District of California and Trial Attorney Allan Gordus of the Office of Consumer Litigation in the Civil Division in Washington, D.C., with the assistance of Associate Chief Counsel Anne Walsh of the FDA Office of Chief Counsel, Paralegal Specialists Matthew McCrobie and Matthew Robinson, and Legal Technician Jennifer Hiwa. The prosecution is the result of a multi-year investigation by the Federal Bureau of Investigation; the Food and Drug Administration's Office of Criminal Investigations; the U.S. Department of Veterans Affairs, Office of Inspector General; and the Office of Personnel Management, Office of the Inspector General.

Further Information:

Case #: 08-164 MHP

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Judges' calendars with schedules for upcoming court hearings can be viewed on the court's website at www.cand.uscourts.gov.

All press inquiries to the U.S. Attorney's Office should be directed to Jack Gillund at (415) 436-6599 or by email at Jack.Gillund@usdoj.gov.

This site does not contain all press releases or court filings and is not an official record of

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proceedings. Please contact the Clerk of Courts for the United States District Court for official copies of documents and public information.

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EXHIBIT B

INTERMUNE®

Investor contact: Myesha Edwards, InterMune, Inc., 415-466-2242, medwards@intermune.com
Media contact: Jim Weiss, InterMune, Inc., 415-362-5018, weisscomm@earthlink.net

INTERMUNE ANNOUNCES PHASE III DATA DEMONSTRATING SURVIVAL BENEFIT OF ACTIMMUNE IN IPF

- Reduces Mortality by 70% in Patients with Mild to Moderate Disease -

BRISBANE, Calif., August 28, 2002 – InterMune, Inc. (Nasdaq: ITMN) announced today that preliminary data from its Phase III clinical trial of Actimmune® (Interferon gamma-1b) injection for the treatment of idiopathic pulmonary fibrosis (IPF), a debilitating and usually fatal disease for which there are no effective treatment options, demonstrate a significant survival benefit in patients with mild to moderate disease randomly assigned to Actimmune versus control treatment ($p = 0.004$). These data confirm the survival benefit seen in the Phase II trial presented earlier this year at the 98th Annual Conference of the American Thoracic Society. There was also approximately a 10% relative reduction in the rate of progression-free survival associated with Actimmune versus placebo, the trial's primary endpoint, but this was not a statistically significant difference.

The company will hold a conference call at 9:00 a.m. EDT today to discuss these results (details below).

"We are extremely pleased with these results, which indicate Actimmune may extend the lives of patients suffering from this debilitating disease," said W. Scott Harkonen, M.D., President and CEO of InterMune. "Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials. 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."

"The mortality benefit is very compelling and represents a major breakthrough in this difficult disease," said Ganesh Raghu, M.D., Professor of Medicine, University of Washington in Seattle, and the Phase III study's lead principal investigator. "Interferon gamma-1b is the first treatment ever to show any meaningful clinical impact in this disease in rigorous clinical trials, and these results would indicate that Actimmune should be used early in the course of this disease in order to realize the most favorable long-term survival benefit."

Study Details and Results

A total of 330 patients were randomized into this double-blind, placebo-controlled trial conducted at 58 centers around the United States and Europe. Patients received either placebo or 200 micrograms of Actimmune injected subcutaneously three times per week. All patients remained in the trial until the last patient received 48 weeks of therapy. Median treatment duration was 60 weeks. The primary endpoint was progression free survival time defined as either one of the following: (i) a decrease in forced vital capacity (FVC) of >10 percent, (ii) an increase in A-a gradient of 5 mmHg, or (iii) death. While this endpoint did not reach statistical significance, there was a trend in favor of Actimmune-treated patients, representing an approximately 10% relative reduction in the rate of progression-free survival versus placebo.

Importantly, Actimmune also demonstrated a strong positive trend in increased survival in the overall patient population, and a statistically significant survival benefit in patients with mild to moderate IPF. In the overall population, there were 16/162 deaths in the Actimmune-treated group (9.9%) compared to 28/168 deaths in the placebo group (16.7%), representing a 40% decrease in mortality in favor of Actimmune vs. placebo ($p = 0.084$). Further, of the 254 patients with mild to moderate disease (FVC >= 55 percent), there were 6/126 deaths in the Actimmune-treated group (4.8%) and 21/128 deaths in the placebo group (16.4%), representing a 70% decrease in mortality in favor of Actimmune versus placebo ($p = 0.004$).

There were also trends later in the course of the study in favor of Actimmune in terms of improved breathing (i.e., dyspnea) and reduced need for supplemental oxygen. Actimmune treatment was also very well tolerated with the most common side effects reported being flu-like symptoms.

These data appear to confirm long-term follow-up data, reported earlier this year at the ATS meeting, which involved 18 patients from a randomized, controlled, open-label trial of Actimmune, in which 16 patients received one or more doses of Actimmune following study completion. The Kaplan Meier estimate of survival at five years was 77.8% and 16.7% in the Actimmune and control groups, respectively ($p = 0.009$).

Tracking Longer Term Outcomes

InterMune plans to transition all remaining Phase III trial patients in the active and placebo groups into an open-label clinical trial in which all patients receive Actimmune to track longer-term outcomes with Actimmune for a minimum of one year.

"We felt we had an ethical obligation to get this important news out about the survival benefit of Actimmune so physicians can evaluate it when making treatment decisions for their patients," said James E. Pennington, M.D., InterMune's Executive Vice President of Clinical and Medical Affairs. "We now have two well-controlled trials in IPF patients supporting a survival benefit, providing what we believe is compelling rationale for consideration of Actimmune for the treatment of patients with this disease."

About Actimmune

Interferon gamma-1b is a naturally occurring protein that stimulates the immune system. InterMune markets Actimmune for the treatment of life-threatening congenital diseases chronic granulomatous disease and severe, malignant osteopetrosis. InterMune is also conducting a Phase III study of Actimmune in ovarian cancer and a Phase II study of Actimmune for the treatment of severe liver fibrosis, or cirrhosis, caused by hepatitis C virus (HCV).

About Idiopathic Pulmonary Fibrosis

Idiopathic pulmonary fibrosis (IPF) is the most common form of idiopathic interstitial pneumonia. Once symptoms appear, there is a relentless deterioration of pulmonary function and death three to five years after diagnosis. The most common treatment is steroids; however, previously published studies suggest that fewer than 20 percent of patients with IPF respond to steroids. In patients having failed treatment with steroids, cytotoxic drugs such as azathioprine or cyclophosphamide are sometimes added to the steroid treatment. However, a large number of studies have shown little or no benefit from treatments involving steroids and other cytotoxic drugs. There are currently no drugs approved by the FDA for the treatment of IPF.

Conference Call Details

To access the live teleconference, dial 888-799-0528 (U.S.) or 706-634-0154 (international). A replay of the webcast and teleconference will be available approximately three hours after the call for two

business days. To access the replay, please call 1-800-642-1687 (U.S.) or 706-645-9291 (international), and enter the conference ID# 5479918. To access the webcast, please log on to the company's website at www.intermune.com at least 15 minutes prior to the start of the call to ensure adequate time for any software downloads that may be required.

These data will be presented in more detail at the European Respiratory Society meeting in Stockholm at a symposium on Sept. 15, 2002, and later this year at the American College of Chest Physicians meeting in November in San Diego, Calif.

About InterMune

InterMune is a commercially driven biopharmaceutical company focused on the marketing, development and applied research of life-saving therapies for pulmonary disease, infectious disease and cancer. For additional information about InterMune, please visit www.intermune.com.

Except for the historical information contained herein, this press release contains certain forward-looking statements that involve risks and uncertainties, including without limitation the statements indicating that the company believes that these results will: (i) support use of Actimmune for the treatment of IPF, (ii) lead to $400-$500 million in peak Actimmune sales, (iii) enable the company to achieve profitability in 2004, and (iv) provide compelling rationale for consideration of Actimmune for the treatment of patients with IPF. All forward-looking statements and other information included in this press release are based on information available to InterMune as of the date hereof, and InterMune assumes no obligation to update any such forward-looking statements or information. InterMune's actual results could differ materially from those described in InterMune's forward- looking statements. Factors that could cause or contribute to such differences include, but are not limited to those discussed under the heading "Risk Factors" and the risks and factors discussed in InterMune's 10-K report filed with the SEC on March 21, 2002, and other periodic reports (i.e., 10-Q and 8- K) filed with the SEC. The risks and other factors that follow, concerning the forward-looking statements in this press release, should be considered only in connection with the fully discussed risks and other factors discussed in detail in the 10-K report and InterMune's other periodic reports filed with the SEC. The forward-looking statements that the company believes that these results will: (i) support use of Actimmune for the treatment of IPF, (ii) lead to $400-$500 million in peak Actimmune sales, (iii) enable the company to achieve profitability in 2004, and (iv) provide compelling rationale for consideration of Actimmune for the treatment of patients with IPF, are subject to the uncertainties and risks of a continuing increase in sales of Actimmune for IPF, an indication for which Actimmune has not been approved by the FDA; reimbursement risks associated with third-party payors; and regulation by the FDA with respect to InterMune's communications with physicians concerning Actimmune for the treatment of IPF.

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EXHIBIT C

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA TUESDAY SEPTEMBER 22, 2009 2:00 P.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

NOT WHAT THE GOVERNMENT CHARGED. WHEN WE HAD THE ARGUMENT, IN OUR -- WE LAID OUT IN DETAIL IN OUR BRIEF, WHEN YOU ASKED THE GOVERNMENT ON THE FIRST AMENDMENT MOTION, "WHAT ARE THE FALSE STATEMENTS FOR THE FRAUD"?

AND THAT MOTION WAS DIRECTED TO BOTH MISBRANDING AND WIRE FRAUD. THEY WENT THROUGH A LITANY OF STATEMENTS THAT WERE MADE; NOT HALF-TRUTHS, NOT OMISSIONS.

THE ONLY OMISSION THEY MENTIONED -- WELL, SUBGROUP ANALYSIS; BUT THEY CONCEDED THAT WAS LATER DISCUSSED IN THE PRESS RELEASE.

SO IT'S OUR POSITION, THOUGH THEY MAY IN THE ABSTRACT BE LEGALLY PERMISSIBLE, THEY ARE NOT CHARGED IN THIS INDICTMENT. AND IT WOULD BE A FATAL VARIANCE OF CONSTRUCTIVE AMENDMENT TO ALLOW HALF-TRUTH OR OMISSIONS AT THIS POINT.

THE COURT: WELL, AS I UNDERSTAND IT, FOR THE WIRE FRAUD, WHAT YOU ARE CITING TO AS THE BASIS FOR THE -- FOR THIS FALSE TO FRAUDULENT STATEMENT IS THE PRESS RELEASE?

MS. PETROU: YES, YOUR HONOR.

THE COURT: THAT'S IT? JUST THE PRESS RELEASE?

MS. PETROU: THE SCHEME TO DEFRAUD CERTAINLY GOES BEYOND THE PRESS RELEASE. AS FAR AS WHAT UNDERLIES THAT PARTICULAR COUNT, IT IS THE PRESS RELEASE.

THE COURT: AND ITS STATEMENT IN THE PRESS RELEASE, CORRECT?

MS. PETROU: YES, YOUR HONOR.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-164 MHP SAN FRANCISCO, CALIFORNIA WEDNESDAY MAY 20, 2009 10:00 O'CLOCK A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVE.
SAN FRANCISCO, CALIFORNIA 94102
BY: IOANA PETROU, ASSISTANT UNITED STATES ATTORNEY
AND NICHOLAS BAGLEY,
ASSISTANT UNITED STATES ATTORNEY AND

ALLAN GORDUS
OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, DC 20044

FURTHER APPEARANCES ON NEXT PAGE

REPORTED BY: KATHERINE WYATT, CSR 9866, RMR, RPR
OFFICIAL REPORTER - US DISTRICT COURT
COMPUTERIZED TRANSCRIPTION BY ECLIPSE

"I THINK THIS INDICATES OR SUGGESTS" -- THAT WAS THEIR WORD: "SUGGEST" -- WE WOULDN'T BE HERE.

THE THING THAT THEY ARE SAYING MAKES THIS FRAUD IS HE SAID "DEMONSTRATES."

AND WE SAY THAT CANNOT BE. IT CANNOT BE UNDER NOT ONLY THE LONG LINE OF SUPREME COURT CASES THAT DEAL WITH THE DIFFERENCE BETWEEN OPINION AND FACT, WHICH IS FRAUD, AND THE CASES -- AND IT IS UP TO YOU TO MAKE THAT DETERMINATION IN THE FIRST INSTANCE.

THERE IS NO QUESTION THAT AS GATEKEEPER WE HAVE RAISED THIS CONTENTION. THE CONTENTION IS IS THIS PRESS RELEASE, WHICH GIVES THE DETAILED DATA -- I'VE BLOWN UP -- IT'S IN OUR BRIEF, SO YOU HAVE IT.

BUT THIS IS THE DETAILED DATA OF THE STUDY. THERE IS NO CONTENTION THAT THE DETAILED DATA IS NOT THE DETAILED DATA. THE CONTENTION IS IS THAT HARKONEN OVERSTATED OR INTERMUNE OVERSTATED THAT.

AND OUR CONTENTION BACK IS:

"SO WHAT? THAT'S HIS OPINION."

AND WE HAVE ON THE ONE --

THE COURT: WELL, LET'S JOIN THE ISSUE RIGHT NOW.

WHAT IS YOUR POSITION AS TO WHAT STATEMENT OR STATEMENTS IN THIS PRESS RELEASE ARE FALSE OR MISLEADING?

MR. BAGLEY: GREAT. I GUESS WE CAN START WITH THE HEADLINE. THEY PULLED IT DOWN. I'LL JUST REFER TO IT.

THE COURT: NO, I THINK IT'S BEHIND THERE.

MR. TOPEL: IT'S RIGHT BEHIND IT.

THE COURT: IT'S RIGHT BEHIND.

MR. BAGLEY: GREAT.

THE COURT: MR. TOPEL WILL BE KIND ENOUGH TO HOLD THE EXHIBIT FOR YOU.

MR. TOPEL: ALLOW ME TO ASSIST THE GOVERNMENT IN THE ARGUMENT, EVEN THOUGH I FEEL THAT IT'S UTTERLY SPECIOUS.

MR. BAGLEY: "INTERMUNE ANNOUNCES PHASE III DATA DEMONSTRATING SURVIVAL BENEFIT OF ACTIMMUNE IN IPF."

THE STUDY, IN FACT -- AND AS WE'RE PREPARED TO PROVE AT TRIAL -- SHOWED ENTIRELY TO THE CONTRARY.

AND IT GOES ON, ANNOUNCES THE RESULTS OF THE STUDY --

THE COURT: WHAT ABOUT THE SUBHEADLINE THERE?

MR. BAGLEY: "REDUCES MORTALITY BY 70 PERCENT IN PATIENTS."

THE COURT: IS THAT -- DO YOU CONTEND THAT THAT IS INACCURATE?

MR. BAGLEY: THERE'S A MATERIAL OMISSION, WHICH IS TO SAY THAT THAT'S NOT A STATISTICALLY SIGNIFICANT FINDING. THEY DO CLARIFY THAT IN THE BALANCE OF PRESS RELEASE.

WE'RE FOCUSING ON THE STATEMENTS ABOUT THE EFFICACY OF ACTIMMUNE IN TREATING MILD TO MODERATE FORMS OF IPF.

"DEMONSTRATE A SIGNIFICANT SURVIVAL BENEFIT IN

PATIENTS WITH MILD TO MODERATE DISEASE, RANDOMLY ASSIGNED TO ACTIMMUNE VERSUS CONTROLLED TREATMENT."

AND THEY OFFER A P VALUE THERE OF .004, WHICH, AGAIN, IS SORT OF A STATISTICAL SHORTHAND FOR:

"WE'RE NOT MAKING THIS UP. THIS IS A TRUE RESULT. THIS ISN'T JUST RANDOM CHANCE."

NOW, AS A MATTER OF STATISTICS THIS WAS FALSE. WHAT THEY DID WAS THEY TOOK A WHOLE LOT OF DATA. IT WAS A BIG WASH OF DATA THAT SHOWED GENERALLY THAT ACTIMMUNE WAS INEFFECTIVE. AND THEY SLICED AND DICED --

THE COURT: ALL RIGHT. I DON'T WANT YOU TO GO INTO THE BASES FOR YOUR STATEMENT THAT IT'S INACCURATE.

MR. BAGLEY: FAIR ENOUGH.

THE COURT: BUT THE PARTS OF IT THAT YOU CONTEND ARE FALSE OR MISLEADING, OKAY?

MR. BAGLEY: GREAT. I'LL KEEP GOING THROUGH IT, IF YOU LIKE.

THE COURT: AND THEN, I WILL GIVE MR. TOPEL BACK THE FLOOR, SINCE IT'S HIS MOTION.

MR. BAGLEY: SO LET ME PULL MY COPY, BECAUSE IT GOES ON. THERE ARE A COUPLE OF OTHER STATEMENTS I CAN POINT TO.

I SHOULD NOTE THAT THESE STATEMENTS WERE REPEATED, NOT ONLY IN THE PRESS RELEASE, BUT ALSO IN THE FAX BLAST OF 2000 PULMONOLOGISTS. THE CONTENT OF THIS WAS ALSO DISTRIBUTED TO ACTIMMUNE PATIENTS ALL UNDER DEFENDANT'S CONTROL.

THE COURT: WELL, BUT WHAT YOU'RE SAYING IS THAT THESE OTHER -- THESE OTHER TRANSMISSIONS THAT YOU'VE REFERRED TO ESSENTIALLY ARE NO DIFFERENT FROM, YOU KNOW, IN SUBSTANCE FROM THE PRESS RELEASE.

MR. BAGLEY: SURE. THEY SAID THE STUDY WORKED --

THE COURT: THEY SAID THE SAME THING.

MR. BAGLEY: -- WHEN THE STUDY DIDN'T. SURE.

THEY SAID THEY WOULD BELIEVE THESE RESULTS WOULD SUPPORT THE USE OF ACTIMMUNE. THEY SAID THE DATA CONFIRMED THE SURVIVAL BENEFIT SHOWN BY A PREVIOUS STUDY. THAT, AGAIN, WAS FALSE.

THEY HAVE QUOTES FROM EMPLOYEES THAT SAY:

"WE BELIEVE THESE RESULTS INDICATE THAT ACTIMMUNE SHOULD BE USED EARLY IN THE COURSE OF THIS DISEASE IN ORDER TO REALIZE THE MOST FAVORABLE LONG-TERM SURVIVAL BENEFIT."

THEY SAY THAT THERE WAS A STATISTICALLY SIGNIFICANT SURVIVAL BENEFIT IN PATIENTS WITH MILD TO MODERATE IPF.

AGAIN, AS A MATTER OF MATH THERE IS SOMETHING TO THIS. AS A MATTER OF STATISTICAL INFERENCE THIS WAS FALSE. THIS IS A MATERIAL OMISSION OF FACT ABOUT THE WAY YOU SPECIFY SUBGROUPS IN A STUDY. WE'RE PREPARED TO PUT ON EXPERTS AT TRIAL THAT WILL TESTIFY TO THAT EFFECT. I'M SURE THEY HAVE THEIR OWN EXPERTS. BUT THAT'S A --

THE COURT: OKAY. LET'S GET TO THE STATEMENTS

THEMSELVES RATHER THAN JUST THE BACKUP. YOU'LL GET YOUR CHANCE WHEN IT'S YOUR TURN.

MR. BAGLEY: SURE. I THINK WE'RE PRETTY MUCH THROUGH THE PRESS RELEASE, BUT WE'RE REALLY PUSHING VERY HARD ON THE STATEMENT THAT THE STUDY DEMONSTRATED THE EFFICACY OF A DRUG WHEN, IN FACT, IT DIDN'T.

AND THE P VALUE IS A STATEMENT TO THE SCIENTIFIC COMMUNITY THAT THIS IS A TRUE, VALID STUDY THAT DEMONSTRATED THIS DRUG WORKED.

"WE'RE NOT, AGAIN, MAKING THIS UP."

THE COURT: OKAY. SO WITH THAT UNDERSTANDING.

MR. TOPEL: YES, I'M A LITTLE CONFUSED ABOUT THE P VALUE. THE P VALUE, AS I UNDERSTAND IT -- AND I DON'T UNDERSTAND THE GOVERNMENT IS CONTENDING DIFFERENTLY -- IS THE P VALUE THAT AROSE FROM THE POST HOC SUBGROUP ANALYSIS, NOT FROM THE STUDY AT LARGE, BECAUSE THE PRESS RELEASE VERY CLEARLY SAID THAT THE STUDY DID NOT MEET ITS END POINT AND DID NOT REACH STATISTICAL SIGNIFICANCE.

SO I'M GOING TO ASSUME THAT'S WHAT THE -- I DON'T WANT TO TALK TO HIM, BUT I'M ASSUMING THAT THAT'S WHAT THEY ARE COMPLAINING ABOUT HERE. AND, OF COURSE, THAT P VALUE IS ABSOLUTELY TRUE.

BUT THAT'S NOT THE POINT. THE THRUST OF THEIR --

THE COURT: WELL, THE THRUST OF IT IS NOT, YOU KNOW, THE INTERPRETATION OF THIS TO THE PUBLIC AT LARGE FOR --

EXHIBIT E

VOLUME 3

PAGES 240 - 405

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. CR 08-0164-MHP
	)	
W. SCOTT HARKONEN,	)	
	)	SAN FRANCISCO, CALIFORNIA
DEFENDANT.	)	TUESDAY
	)	AUGUST 18, 2009
	)	8:36 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

LIVES, WHEN, IN FACT, THERE WAS NO PROOF THAT THAT WAS TRUE. IT'S A CASE ABOUT WANTING TO MAKE BELIEVE THAT A FAILED CLINICAL TRIAL WAS ACTUALLY A SUCCESS. THIS IS A CASE ABOUT A CEO AND DOCTOR WHO CARED MORE ABOUT THE HEALTH OF HIS COMPANY THAN HE DID ABOUT THE HEALTH OF PATIENTS WITH A FATAL DISEASE. THAT CEO AND DOCTOR IS THE DEFENDANT IN THIS CASE.

W. SCOTT HARKONEN.

THIS IS A SIMPLE CASE. YOU WILL NEED TO LEARN A LITTLE BIT ABOUT STATISTICS. YOU'LL NEED TO LEARN A LITTLE BIT ABOUT CLINICAL-TRIAL DESIGN IN ORDER TO UNDERSTAND WHAT HAPPENED; BUT IT'S NOT A CASE ABOUT STATISTICS, AND IT'S NOT A CASE ABOUT CLINICAL TRIALS OR TRIAL DESIGN. THIS IS REALLY A CASE ABOUT FRAUD, AND IT'S REALLY A CASE ABOUT CHOICES: THE DEFENDANT'S CHOICES.

DR. HARKONEN BUILT HIS COMPANY ON THE SALES OF ONE DRUG: ACTIMMUNE; A DRUG THAT COSTS $50,000 PER YEAR PER PATIENT.

AND IN AUGUST OF 2002 HE RECEIVED THE RESULTS FROM A CLINICAL TRIAL; A TRIAL THAT HAD FAILED. IT WAS VERY CLEAR THAT THE TRIAL HAD FAILED. DR. HARKONEN KNEW IT FAILED. HE WAS TOLD IT FAILED BY PEOPLE IN HIS COMPANY, OUTSIDE OF HIS COMPANY, AND BY F.D.A. -- THE FOOD AND DRUG ADMINISTRATION.

AND DESPITE KNOWING THIS, AND INSTEAD OF PUTTING OUT A TRIAL -- EXCUSE ME -- INSTEAD OF PUTTING OUT A PRESS RELEASE THAT CLEARLY SAID, HEADLINE, "FAILED TRIAL," DR. HARKONEN CHOSE

TO PUT OUT A PRESS RELEASE THAT SAID ACTIMMUNE SAVED LIVES. HE CHOSE TO PUT OUT A PRESS RELEASE WITHOUT LETTING THE PEOPLE IN HIS COMPANY MOST FAMILIAR WITH THE TRIAL SEE IT. AND HE CHOSE TO IGNORE THE F.D.A.

AFTER HE PREPARED A PRESS RELEASE THAT HE KNEW WOULD GO UP ON THE COMPANY'S WEBSITE, AND IT WOULD BE SENT ACROSS THE COUNTRY THROUGH THE WIRE SERVICE, HE CHOSE TO IGNORE COMPLAINTS ABOUT THE FALSE AND MISLEADING STATEMENTS IN THE PRESS RELEASE. HE CHOSE TO IGNORE THE PERSON THAT HE HAD HIRED TO BE IN CHARGE OF SAFEGUARDING THE PATIENTS' INTERESTS IN THE TRIAL. HE CHOSE TO IGNORE AN F.D.A. DOCTOR. HE CHOSE TO IGNORE HIS OWN COMPANY'S CONSULTANT. AND, WHILE CHOOSING TO IGNORE ALL OF THESE PEOPLE, HE CHOSE TO KEEP HIS COMPANY'S BOARD OF DIRECTORS IN THE DARK.

WHY DID HE DO ALL OF THIS?

HE DID THIS TO MAKE MONEY FOR HIS COMPANY, PLAIN AND SIMPLE.

WHO IS DR. HARKONEN? NOW, NATURALLY, MUCH OF THE EVIDENCE IN THIS CASE IS GOING TO FOCUS ON HIM. WHO IS HE?

WHAT DID HE KNOW?

WHAT DID HE DO AND NOT DO?

WHAT DID HE SAY AND NOT SAY?

WHAT DID HE WRITE AND NOT WRITE?

AND, PERHAPS MOST IMPORTANTLY, WHY DID HE DO THESE THINGS?

THE TRIAL, AND WHAT WOULD BE SOME GOOD NEXT STEPS GOING FORWARD.

AND ON AUGUST 27TH OF 2002, LITERALLY HOURS BEFORE DR. HARKONEN SENT OUT THE PRESS RELEASE ABOUT THE TRIAL, THE F.D.A. TOLD DR. HARKONEN THE TRIAL FAILED, AND PROVED NOTHING.

THE F.D.A. ALSO TOLD HIM THAT SOME ANALYSES DR. HARKONEN HAD PROVIDED ABOUT A POSSIBLE MORTALITY BENEFIT -- ABOUT A POSSIBILITY THAT MAYBE THIS DRUG HELPED SOME OF THESE PATIENTS LIVE LONGER -- WERE INTERESTING ANALYSES, BUT THAT INTERMUNE WAS GOING TO HAVE TO DO A SECOND TRIAL, ANOTHER TRIAL, TO SEE WHETHER THESE ANALYSES WERE TRUE.

THEY WERE SAYING, YES, WE SEE SOME DIFFERENCES IN THE NUMBERS, BUT BASED ON THIS KIND OF DATA, WE CAN'T TELL IF THAT'S REAL. IS IT REALLY BECAUSE THESE PATIENTS TOOK THIS DRUG, OR IS IT WHAT WE SEE BY CHANCE, AND NOT REAL?

AND, IN FACT, YOU'LL HEAR THAT WITHIN A FEW WEEKS, INTERMUNE STARTED PLANNING THAT NEXT CLINICAL TRIAL.

SO THE TRIAL RESULTS WERE IN. DR. HARKONEN HAD SPOKEN TO THE F.D.A. AND IT WAS TIME GET THE PRESS RELEASE OUT.

AND YOU'LL HEAR DR. HARKONEN, AS WITH ALL THINGS AT INTERMUNE, WAS COMPLETELY IN CONTROL OF THE PRESS RELEASE. HE WAS IN CONTROL OF WHAT IT SAID, AND HE WAS IN CONTROL OF WHO WAS ALLOWED TO SEE IT BEFORE IT WENT OUT.

AND, DESPITE THE CLEAR RESULTS, DESPITE THE CLEAR

FEEDBACK OF THE F.D.A., AND DESPITE PLENTY OF PEOPLE TELLING DR. HARKONEN WHAT HE ALREADY KNEW -- THAT THE TRIAL FAILED -- THIS IS THE PRESS RELEASE THAT HE CHOSE TO WRITE AND PUT UP ON HIS WEBSITE AND SEND ACROSS THE NATION.

INTERMUNE ANNOUNCES PHASE III DATA DEMONSTRATING SURVIVAL BENEFIT OF ACTIMMUNE AND IPF. REDUCES MORTALITY BY 70 PERCENT IN PATIENTS WITH MILD TO MODERATE DISEASE.

NOW, WHERE DO THOSE HEADLINES COME FROM, WHEN I'VE BEEN STANDING HERE TELLING YOU THAT THIS WAS A FAILED TRIAL?

REMEMBER, I TOLD YOU DR. HARKONEN RECEIVED THE TRIAL RESULTS A COUPLE OF WEEKS BEFORE THIS: AUGUST 16TH OF 2002.

THERE WERE TWO OTHER DOCTORS AT INTERMUNE WHO RECEIVED THE TRIAL RESULTS AS WELL: DR. PENNINGTON, AND DR. CRAGER. YOU'LL LEARN THAT DR. PENNINGTON WAS THE CHIEF MEDICAL OFFICER AT THE COMPANY, AT INTERMUNE; BUT AS YOU'LL ALSO LEARN, HE WAS NOT ONE OF THE DOCTORS MOST FAMILIAR WITH THE TRIAL, AND HE WAS NOT SOMEONE DR. HARKONEN EVER RELIED ON TO UNDERSTAND ANYTHING, LET ALONE THIS CLINICAL TRIAL.

DR. CRAGER WAS THE BIOSTATISTICIAN AT THIS COMPANY. DR. CRAGER, AS A BIOSTATISTICIAN, WAS THE PERSON IN CHARGE OF USING STATISTICS TO ANALYZE THE DATA AND HELP FIGURE OUT: WHAT IS THE DATA; AND, MOST IMPORTANTLY, IS IT REAL? ARE THE NUMBERS WE'RE SEEING REAL, OR DUE TO CHANCE?

IN THE DAYS AFTER GETTING THE RESULTS, IN THE DAYS

AFTER AUGUST 16TH, DR. HARKONEN INSTRUCTED DR. CRAGER TO TAKE THE TRIAL DATA ON MORTALITY -- HOW LONG PEOPLE WERE LIVING -- AND RUN THE NUMBERS DIFFERENT WAYS; RUN THE NUMBERS BY BREAKING UP THE PATIENTS INTO DIFFERENT GROUPS.

NOW, DR. CRAGER, KNOWING IN HIS OWN MIND, AS HE WILL TELL YOU, THAT HE WAS SURE THEY WERE GOING TO HAVE TO DO ANOTHER TRIAL, A TRIAL ABOUT MORTALITY, HE THOUGHT HE WAS DOING THESE ANALYSES IN ORDER TO GET READY FOR THE NEXT TRIAL. HE HAD NO IDEA THERE WAS A PRESS RELEASE COMING.

SO WHEN DR. CRAGER AND OTHERS WERE TALKING TO DR. HARKONEN ABOUT THE DATA ON MORTALITY, THEY MADE IT CLEAR THAT THESE AFTER-THE-FACT ANALYSES -- ANALYSES THAT WERE NOT PART OF THE TRIAL DESIGN, ANALYSES THAT WERE NOT FOCUSED ON WHAT THE TRIAL WAS DESIGNED TO TEST -- COULD NOT BE RELIED ON TO ACTUALLY PROVE ANYTHING; THAT ANOTHER TRIAL WOULD BE NEEDED, WHICH IS, OF COURSE, WHAT THE F.D.A. HAD ALREADY TOLD DR. HARKONEN. THE DATA IS NOT RELIABLE. YOU NEED TO DO ANOTHER TRIAL, AND LET'S SEE IF IT'S REAL.

DR. HARKONEN WAS EXPERIENCED, AND KNEW WHAT THEY KNEW. AND HE KNEW WHAT HE WAS BEING TOLD; THAT YOU CAN'T SLICE AND DICE THE NUMBERS, PICK WHAT LOOKS BEST, GET RID OF THE STUFF THAT DOESN'T LOOK AS GOOD, AND HOLD OUT THE BEST NUMBER TO MAKE BELIEVE SOMETHING HAS BEEN PROVEN. IT'S FINE TO LOOK AT DATA TO DESIGN THE NEXT TRIAL. IT'S FINE TO SHARE ALL OF YOUR INFORMATION WITH OTHER SCIENTISTS AND HAVE A GOOD, ROBUST,

SCIENTIFIC DISCUSSION; BUT DON'T MAKE BELIEVE, BY PICKING A NUMBER OUT OF A HAT, THAT THAT'S WHAT THE TRIAL SHOWED, AND THAT THAT'S WHAT WAS PROVEN.

BUT WHAT DR. HARKONEN DID WAS JUST THAT. HE RAN A BUNCH OF DIFFERENT ANALYSES. HE PICKED THE BEST NUMBER THAT MADE IT LOOK LIKE PATIENTS LIVED LONGER. HE LEFT OUT THE OTHER NUMBERS THAT DIDN'T LOOK ANYWHERE NEAR AS GOOD. AND HE MADE IT SOUND LIKE THE TRIAL PROVED SOMETHING IT DIDN'T ACTUALLY PROVE.

THIS IS THE PRESS RELEASE THAT DR. HARKONEN PUT OUT BASED ON A FAILED TRIAL.

INTERMUNE ANNOUNCES PHASE III DATA DEMONSTRATING SURVIVAL BENEFIT OF ACTIMMUNE IN IPF REDUCES MORTALITY BY 70 PERCENT IN PATIENTS WITH MILD TO MODERATE DISEASE.

AND THIS IS THE VERY FIRST SENTENCE OF THE PRESS RELEASE.

"INTERMUNE, INC. NASDAQ" --

SO THAT'S THE TRADING SYMBOL FOR TRADING STOCK ON THE COMPANY.

INTERMUNE, INC., NASDAQ I.T.M.N., ANNOUNCED TODAY THAT PRELIMINARY DATA FROM ITS PHASE III CLINICAL TRIAL OF ACTIMMUNE INTERFERON GAMMA-1B INJECTION FOR THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS, IPF, A DEBILITATING AND USUALLY FATAL

DISEASE FOR WHICH THERE ARE NO EFFECTIVE TREATMENT OPTIONS, DEMONSTRATES A SIGNIFICANT SURVIVAL BENEFIT IN PATIENTS WITH MILD TO MODERATE DISEASE.

AND THIS IS HOW THE DEFENDANT CHOOSES TO QUOTE HIMSELF, W. SCOTT HARKONEN, M.D., PRESIDENT AND CEO OF INTERMUNE.

ACTIMMUNE IS THE ONLY AVAILABLE TREATMENT DEMONSTRATED TO HAVE CLINICAL BENEFIT IN IPF. WE BELIEVE THESE RESULTS WILL SUPPORT USE OF ACTIMMUNE, AND WE NEED TO KEEP SALES IN THE RANGE OF $400 MILLION TO $500 MILLION PER YEAR.

NOW, YOU'LL ALSO SEE A QUOTE -- BECAUSE, OF COURSE, YOU'LL GET ACCESS TO THE ENTIRE PRESS RELEASE VERY SOON. YOU'LL ALSO SEE A QUOTE IN THE PRESS RELEASE FROM A DOCTOR WHO DIDN'T WORK FOR INTERMUNE: DR. GANESH RAGHU. HE WAS A TRIAL INVESTIGATOR INVOLVED WITH THE TRIAL, BUT DIDN'T WORK FOR INTERMUNE. AND, AS DR. RAGHU WILL COME HERE AND TELL YOU HIMSELF, HE DIDN'T EVEN HAVE THE TRIAL DATA. THE DATA -- THIS PRESS RELEASE CAME OUT. AND THE ONLY INFORMATION HE HAD ABOUT THE TRIAL RESULTS WAS INFORMATION THAT WAS GIVEN TO HIM DIRECTLY AND SOLELY BY W. SCOTT HARKONEN.

SO BY NOW YOU'RE PROBABLY ASKING YOURSELVES: WHERE IN THE PRESS RELEASE DOES IT SAY THAT THE TRIAL HAS FAILED?

BECAUSE IT HAS TO SAY IT SOMEWHERE IN THERE.

AND IF YOU LOOK LONG ENOUGH, YOU GO PAST THE GLOWING HEADLINES, PAST THE FIRST PAGE OF THE PRESS RELEASE, ABOUT FIVE PARAGRAPHS IN, THIS IS WHAT YOU GET. AFTER THE CLEAR HEADLINES UP FRONT ABOUT SUCCESS, HERE IS HOW HE CHOOSES TO SAY THAT THE TRIAL FAILED.

> WHILE THIS ENDPOINT DID NOT REACH STATISTICAL SIGNIFICANCE, THERE WAS A TREND IN FAVOR OF ACTIMMUNE-TREATED PATIENTS REPRESENTING AN APPROXIMATELY 10 PERCENT RELATIVE REDUCTION IN THE RATE OF PROGRESSION-FREE SURVIVAL VERSUS PLACEBO.

THAT'S HOW HE CHOSE TO LET THE WORLD -- IT'S NOT JUST TO SCIENTISTS. THIS IS A PRESS RELEASE TO EVERYONE. THIS IS HOW HE CHOSE TO LET THE WORLD KNOW THAT THE TRIAL HAD FAILED.

AND ON THE SAME DAY AS THE PRESS RELEASE CAME OUT, DR. HARKONEN WAS INTERVIEWED BY C.N.B.C. AND YOU'LL GET TO SEE HIS PART OF THAT INTERVIEW ON VIDEO. AND IN THAT INTERVIEW, HE SAID, "WE'RE IN THE PROCESS" -- ACTUALLY WHAT HE SAID FIRST WAS,

> WE ACTUALLY REDUCED MORTALITY OVER THREEFOLD, BY 70 PERCENT, IN THESE PATIENTS.

AND HE ALSO SAID,

> WE'RE IN THE PROCESS OF SUBMITTING THE

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA WEDNESDAY SEPTEMBER 23, 2009 8:35 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

GET. THIS IS THE MARKET THAT HE WANTS ACTIMMUNE TO CAPTURE. IT'S THE IPF MARKET. AND AGAIN, THIS IS A SLIDE FROM THE DEFENDANT'S PRESENTATION AT THAT SAME NATIONAL SALES MEETING. AND YOU SAW HIM GIVING THE PRESENTATION IN THE TAPE WHICH IS EXHIBIT 34. AND HE TALKS ABOUT THIS SLIDE. AND HE TALKS ABOUT HOW HE TELLS INVESTORS WHO WERE POTENTIALLY GOING TO INVEST IN INTERMUNE THAT THERE ARE 50,000 IPF PATIENTS OUT THERE A YEAR, AND THE COST OF ACTIMMUNE IS $50,000 A YEAR. AND THEN HE SITS BACK, AND HE LET THEM DO THE MATH. AND THE MATH IS TWO AND A HALF BILLION DOLLARS. THAT'S THE IPF MARKET THAT HE'S TRYING TO GET ACTIMMUNE INTO; THAT HE'S TRYING TO CAPTURE.

SO LET'S GO BACK TO THE PRESS RELEASE. THIS IS EXHIBIT 1. AND WE'VE ALL SEEN IT MANY TIMES.

THE EVIDENCE IS CLEAR. THE PRESS RELEASE IS FALSE AND MISLEADING. THE RESULTS OF THE TRIAL, WITHOUT QUESTION, SHOW THE TRIAL FAILED. PRIMARY ENDPOINT FAILED. ALL OF THE SECONDARY ENDPOINTS FAILED. IT'S A FAILED TRIAL.

AND THIS IS THE PRESS RELEASE THAT GOES OUT. THIS IS THE PRESS RELEASE THAT'S WRITTEN TO CONVINCE READERS THAT THE RESULTS OF THE TRIAL SHOWED THAT ACTIMMUNE SAVES IPF PATIENTS; IT HAS A SURVIVAL BENEFIT; IT HELPS IPF PATIENTS LIVE LONGER. AND THAT'S JUST FALSE.

WE LISTENED TO DR. FLEMING, DR. PORTER, DR. CRAGER, AND DR. WALTON. ALL OF THEM TESTIFIED THAT THE RESULTS OF THIS TRIAL -- THE RESULTS THAT ARE IN THIS PRESS RELEASE -- YOU

CANNOT CONCLUDE THAT ACTIMMUNE HAS A SURVIVAL BENEFIT. THERE'S NO WAY TO KNOW IF THE SUBGROUP ANALYSIS IS REAL. THEY ALL SAID THAT. THAT IS -- THERE'S NO TESTIMONY TO THE CONTRARY. SO THIS PRESS RELEASE THAT'S WRITTEN TO CONVINCE PEOPLE THAT THE SUBGROUP ANALYSIS SHOWS THAT THERE IS A SURVIVAL BENEFIT FOR ACTIMMUNE IS FALSE. THERE'S NO SUPPORT FOR IT.

IT'S ALSO MISLEADING, BECAUSE IT DOES NOT MENTION THAT ALL OF THE SECONDARY ENDPOINTS FAILED. THAT'S NOT IN THE PRESS RELEASE. IT DOESN'T MENTION THE SUBGROUP ANALYSIS THAT THEY'RE USING TO TOUT THE DRUG DOESN'T PROVE ANYTHING. IT'S PUT UP THERE AS IF IT'S THE PRIMARY ENDPOINT OF THE TRIAL. IT DOESN'T HAVE THE P-VALUE FOR THE PRIMARY ENDPOINT. THE ONLY P-VALUE IN THE ENTIRE TRIAL THAT MEANS SOMETHING.

SO LET'S TALK ABOUT P-VALUES. AND MY APOLOGIES, BUT WE'VE HEARD A LOT ABOUT P-VALUES, SO WE HAVE TO TALK ABOUT P-VALUES.

AS YOU HEARD DR. FLEMING, DR. PORTER, DR. CRAGER, AND DR. WALTON ALL TESTIFY, THE ONLY MEANINGFUL P-VALUE FOR THIS TRIAL IS THE P-VALUE FOR THE PRIMARY ENDPOINT. AND THAT P-VALUE WAS 0.5; NOWHERE NEAR STATISTICAL SIGNIFICANCE.

WHAT THAT P-VALUE MEANS, THEY ALL EXPLAINED, WAS THAT YOU CAN'T DRAW ANY CONCLUSIONS FROM THIS TRIAL. IT'S JUST AS LIKELY THAT THE DRUG HAD NO EFFECT; NONE WHATSOEVER. A P-VALUE OF .5 MEANS IT'S JUST AS LIKELY THAT THE RESULTS OF THIS TRIAL ARE COMPLETELY DUE TO CHANCE.

KNOW IF THE SURVIVAL BENEFIT IS REAL OR SIMPLY A RESULT OF CHANCE.

HE WAS TOLD BY F.D.A. THE SAME THING: NO WAY TO KNOW IF THIS SURVIVAL BENEFIT IS REAL, OR SIMPLY THE RESULT OF CHANCE.

LET'S ALSO LOOK AT THE REST OF THE PRESS RELEASE.

HE DOESN'T PUT IN THE FAILED SECONDARY ENDPOINTS. HE DOESN'T PUT IN THE ONLY P-VALUE THAT HAS ANY MEANING: THE P-VALUE ON THE PRIMARY ENDPOINT. HE PUTS THE SUBGROUP ANALYSIS UP FRONT IN THE PRESS RELEASE. BASICALLY, THE WHOLE PRESS RELEASE IS BASED ON THE SUBGROUP ANALYSIS MAKING THE CONCLUSION THAT ACTIMMUNE REDUCES MORTALITY BY 70 PERCENT FOR MILD TO MODERATE IPF PATIENTS. NOWHERE IN THE PRESS RELEASE DOES IT MENTION THAT THIS IS EXPLORATORY, AFTER-THE-FACT SUBGROUP ANALYSIS.

NOW LET'S TALK ABOUT DR. RAGHU'S QUOTE VERY QUICKLY.

AS I MENTIONED, DR. RAGHU WAS ONE OF THE DOCTORS ON THE STEERING-COMMITTEE CALL ON AUGUST 27TH, 2002, WHO ACTUALLY KNEW THE PRESS RELEASE, OR KNEW SOME OF THE RESULTS OF THE PRESS, OR OF THE TRIAL. AND THAT'S BECAUSE AS DR. RAGHU TESTIFIED THE DEFENDANT CALLED HIM AND TOLD HIM THAT WE HAVE PROVEN A SURVIVAL BENEFIT. DO YOU REMEMBER DR. RAGHU TESTIFYING HE WAS TALKING ON HIS CELL PHONE, AND THE DEFENDANT CALLED HIM AND SAID, "WE'VE PROVEN A SURVIVAL BENEFIT"? AND, OF COURSE, DR. RAGHU WAS ECSTATIC. SO DR. RAGHU HAD THAT

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

United States of America, Plaintiff, vs. W. Scott Harkonen, Defendant.	NO. CR 08-0164-MHP San Francisco, California Wednesday June 24, 2009 2:35 p.m.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

For Plaintiff: Office of the United States Attorney
450 Golden Gate Avenue, Box 36055
San Francisco, CA 94102
(415) 436-7232
BY: IOANA PETROU

For Plaintiff: Office of Consumer Litigation
United States Department of Justice
Post Office Box 386
Washington, D.C. 20044
BY: ALLAN GORDUS

(Appearances continued on next page)

Reported By: **Lydia Zinn, CSR #9223, RPR**
Official Reporter - U.S. District Court

THE COURT: Not going forward.

MR. TOPEL: The point, for further clarification, which may or may not be needed, the -- is there is no allegation here in the indictment that the data is under dispute as to what the data was; for instance, how many people died.

THE COURT: In other words, it wasn't transposed or changed in any way.

MR. TOPEL: No. We're not talking about jiggling the data, which would be fraud.

We're talking about how you interpret the data. And we have a fight between biostatisticians and pulmonary interstitial disease pulmonologists.

MS. PETROU: And, your Honor, I think --

THE COURT: Is that correct?

MS. PETROU: Yeah, but what I was about to say is that I feel like I'm about to completely derail this *in limine* discussion. A lot of these issues are going to the expert disclosures and what they're going to say and what role Dr. Fleming's letter is going to play.

And if your Honor wants to hear that, I'm more than happy to address it. If you'd rather stay on track with the *in limine* --

THE COURT: Let's stay on track right now. And we'll get to some of these issues, and what the experts will testify

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. CR 08-0164-MHP
	)	
W. SCOTT HARKONEN,	)	
	)	SAN FRANCISCO, CALIFORNIA
DEFENDANT.	)	WEDNESDAY
	)	SEPTEMBER 23, 2009
	)	8:35 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

SIMPLE ONE, WHICH IS THAT YOU HAVE TO TELL THE TRUTH. WE DON'T NEED TO LOOK INTO A CFR. WE DON'T NEED TO LOOK INTO THE E9 PRINCIPLES OF STATISTICS.

THIS PERSON, THE DEFENDANT, W. SCOTT HARKONEN, NEEDED TO TELL THE TRUTH. HE NEEDED TO TELL THE TRUTH TO, AS MR. TOPEL SAID, DYING PATIENTS.

THESE PATIENTS ARE DYING, AND THEY ARE GOING TO TAKE A DRUG BASED ON ANY HOPE AT ALL, INCLUDING BASED ON FALSE HOPE.

DR. RAGHY TOLD YOU HIMSELF, EVEN BEFORE THIS CLINICAL TRIAL TOOK PLACE HE WAS PRESCRIBING IT TO SOME PEOPLE ON A COMPASSIONATE BASIS, BECAUSE THERE'S SIMPLY NOTHING ELSE OUT THERE. AND DYING PATIENTS WILL TAKE A DRUG ON FALSE HOPE, EVEN WHEN IT COSTS THEM $50,000 A YEAR, AND EVEN IF IT COSTS THEM $50,000 A YEAR OUT OF THEIR OWN POCKET.

IT'S NOT COMPLICATED. HE NEEDED TO TELL THEM THE TRUTH. DR. HARKONEN COULD HAVE TOLD THE TRUTH, BECAUSE HE KNEW IT. HE WAS TOLD IT TIME AND AGAIN BEFORE THE PRESS RELEASE CAME OUT, AND AFTER THE PRESS RELEASE CAME OUT.

HE WAS TOLD TIME AND AGAIN THAT THE TRIAL DID NOT DEMONSTRATE A SURVIVAL BENEFIT. I DON'T NEED TO SPEND ANY TIME ON THE NUMBERS IN THERE. WE ALL KNOW THE NUMBERS ARE CORRECT.

DR. FLEMING CAME IN HERE AND TOLD YOU:

"THIS WAS A REALLY, REALLY WELL-RUN TRIAL. IT WAS DONE EXTREMELY WELL. WE COULD RELY ON THE NUMBERS. AND THAT, IN PART, IS WHEN I SAW A .5 ON

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA,	)	
	)	
PLAINTIFF,	)	
	)	
VS.	)	NO. CR 08-0164-MHP
	)	
W. SCOTT HARKONEN,	)	
	)	SAN FRANCISCO, CALIFORNIA
DEFENDANT.	)	WEDNESDAY
	)	AUGUST 19, 2009
	)	8:30 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR #9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

Q. -- WAS ESTABLISHED, WAS IT NOT, SIR?

A. YOU MEAN THE DATA THAT WERE ANALYZED AND KNOWN?

Q. YES.

A. YES.

Q. YES.

A. YEAH.

Q. AND, JUST SO IT'S CLEAR TO THIS JURY, THERE IS NO DISPUTE, IS THERE, AS TO HOW MANY PEOPLE BEFORE JUNE 26TH DIED WHO TOOK ACTIMMUNE, AND PEOPLE WHO DIED THAT WERE TAKING PLACEBO? THAT'S NOT IN DISPUTE, IS IT?

A. WE ACCEPT THE NUMBERS GIVEN TO US BY INTERMUNE.

Q. MORE THAN THAT, YOU HAVE NO REASON TO DOUBT THE INTEGRITY OF THOSE NUMBERS, DO YOU?

A. OH, YES. CORRECT. WE HAVE NO KNOWLEDGE THAT WOULD MAKE US DOUBT THAT.

Q. ALL RIGHT. SO AS A BASELINE FOR WHAT IS THE CONTINUING DISPUTE, THERE IS NO ARGUMENT HERE THAT -- OF THE NUMBER OF PEOPLE IN THIS STUDY WHO DIED WHO TOOK ACTIMMUNE, AND WHO DIED WHO TOOK PLACEBO -- WE'RE ALL IN AGREEMENT. ISN'T THAT RIGHT?

A. YES.

Q. AND THERE'S NO EVIDENCE THAT DR. HARKONEN OR ANYBODY ELSE AT INTERMUNE DID ANYTHING TO FALSIFY OR OTHER -- OTHERWISE DISTORT THOSE NUMBERS, IS THERE?

A. WE ARE NOT AWARE OF ANY --

Q. ALL RIGHT.

A. -- SUCH DISTORTIONS.
Q. RIGHT. THE ISSUE IS -- IS WHETHER OR NOT --
WELL, STRIKE THAT.
YOU ALSO TESTIFIED SOMEWHAT BRIEFLY ABOUT THE CONDITION OF IPF OR A DISTINCTION BETWEEN SEVERE IPF, AND MILD TO MODERATE IPF. DO YOU RECOLLECT THOSE QUESTIONS, DOCTOR?
A. YES. GENERAL CATEGORIZATIONS.
Q. RIGHT. THEY ARE GENERAL CATEGORIZATIONS WHICH HAVE A -- A DEMARCATION LINE THAT ISN'T EXACT. ISN'T THAT CORRECT?
A. YES.
Q. ALL RIGHT. AND THAT'S A FAIR STATEMENT BY ME. ISN'T THAT RIGHT?
A. YES.
Q. ALL RIGHT. NOW, BACK IN 2002, AT THE TIME OF THIS, DO YOU KNOW, JUST IN YOUR INVOLVEMENT IN THIS, DR. KEVIN BROWN? IS THAT A NAME THAT'S AT ALL FAMILIAR TO YOU? HE'S A PULMONOLOGIST AT DENVER JEWISH HOSPITAL.
A. WE MAY HAVE HAD INTERACTIONS WITH HIM, BUT I DO NOT RECALL THAT SPECIFICALLY.
Q. HOW ABOUT A DR. DAVID SCHWARZ? I DON'T KNOW. I THINK HE MAY BE AT U.C.S.F. IS HE A NAME THAT YOU'RE FAMILIAR --
A. AGAIN, I DO NOT RECALL THAT NAME SPECIFICALLY.
Q. ALL RIGHT. I WON'T --
IF PULMONOLOGISTS IN 2002 SAID THAT THE DEMARCATION LINE BETWEEN MILD TO MODERATE IPF AND SEVERE IPF WAS BETWEEN 50

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA WEDNESIDAY SEPTEMBER 2, 2009 8:30 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: **LYDIA ZINN, CSR #9223**
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

PRESENTATIONS TO THE STEERING COMMITTEE OR OTHERS, DID YOU TELL THEM THE P-VALUE?

A YES.

Q LET'S GO TO THE NEXT PARAGRAPH BEGINNING "IMPORTANTLY."

SECOND LINE SAYS:

"IN THE OVERALL POPULATION" -- AND MS. MOORMAN ASKED YOU ABOUT THIS AT LENGTH ABOUT THE 16 VERSUS 162 DEATHS. DO YOU SEE THAT IN THERE?

A I DO.

Q "IN THE OVERALL POPULATION THERE WERE 16 VERSUS 162 DEATHS IN THE ACTIMMUNE-TREATED GROUP REPRESENTING A 40 PERCENT DECREASE IN MORTALITY."

ONE SECOND HERE. OKAY. LET'S NOT -- LET'S JUST MOVE ON.

WELL, LET ME ASK YOU THIS, THOUGH, ON THIS ONE PARAGRAPH, AGAIN, WHERE IT'S TALKING ABOUT MILD TO MODERATE DISEASE AND THE ANALYSES THAT WERE DONE, DOES IT EXPLAIN THAT IT WAS A POST HOC SUBGROUP ANALYSIS?

A NO.

Q AND YOU'VE BEEN ASKED REPEATEDLY BY MS. MOORMAN ABOUT NUMBERS IN HERE AND IN OTHER PLACES:

"IS THE NUMBER RIGHT HERE?

"IS THE .004 RIGHT?

"IS THE .055 RIGHT?"

I JUST WANT TO BE VERY CLEAR. YOU DO NOT HAVE -- YOU

DO NOT THINK THAT THE ACTUAL NUMBERS IN THE PRESS RELEASE ARE INCORRECT; IS THAT RIGHT?

A I BELIEVE THEY ARE ALL CORRECT.

Q OKAY. AND SO WHEN YOU TESTIFIED THAT YOU WERE SURPRISED BY THE CONTENT, WHAT WERE YOU REFERRING TO?

A THE CONCLUSION AND INTERPRETATION OF THOSE NUMBERS.

Q "CONCLUSION" BEING WHAT?

A AS WE ALLUDED TO A MINUTE AGO: DEMONSTRATION OF A SURVIVAL BENEFIT, AMONG OTHER --

Q OKAY. SO LET ME SHOW YOU -- WHAT THE HECK IS THE EXHIBIT NUMBER? I THINK IT'S EXHIBIT 288 WAS THE LAST THING THAT MS. MOORMAN SHOWED YOU?

AND I THINK IT'S THIS, THIS THING (INDICATING).

IS THIS THE 2006 STUDY REPORT?

A IT IS.

Q ALL RIGHT. LET'S JUST START. IF YOU LOOK AT THE VERY FIRST PAGE AT THE TOP, HOW MANY PAGES DOES IT SAY THAT THIS REPORT IS?

A 959.

Q AND SIMILAR QUESTION TO THE PACKET GIVEN TO THE STEERING COMMITTEE: IS THAT 959 PAGES ABOUT THE SUBGROUP ANALYSES?

A THEY ARE CONTAINED WITHIN THOSE 959, BUT, OBVIOUSLY, IT'S ALL THE DATA FROM THE TRIAL THAT WAS ANALYZED.

Q OKAY. WHAT'S THE PURPOSE -- THIS IS CALLED "A CLINICAL STUDY REPORT."

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA TUESDAY SEPTEMBER 1, 2009 8:35 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

NOT, BUT YOU DO RECALL AT THE STEERING COMMITTEE, SIR, DR. BRADFORD DESCRIBING THE SUBGROUP OF PATIENTS AS BEING MILD TO MODERATE, AS THAT DEFINITION WAS -- OR THAT DESCRIPTION WAS PREMISED ON AN F.V.C. PERCENTAGE OF EQUAL TO OR GREATER THAN 55 PERCENT, CORRECT?

A. I RECALL THAT HE PRESENTED THE SUBGROUP ANALYSES. SO IN TERMS OF HIS SPECIFIC USE OF MILD TO MODERATE, I DON'T RECALL; BUT THE ANALYSIS THAT WE HAD AT THAT TIME WAS A 55 PERCENT CUTOFF.

Q. AND YOU DO RECALL HIM USING THE TERM "MILD TO MODERATE" IN CONJUNCTION WITH THAT SUBGROUP OF PATIENTS?

A. NOT SPECIFICALLY AT THAT MEETING. I DON'T RECALL.

Q. AT OTHER TIMES?

A. YES.

Q. ALL RIGHT. AND THAT'S DR. BRADFORD I USED IN THAT SENTENCE.

DO YOU RECALL HIM USING THAT TERM IN CONJUNCTION WITH THAT SUBSET OF PATIENTS? CORRECT?

A. YES.

Q. AND DR. CRAGER AS WELL?

A. NO.

Q. ALL RIGHT. NOW -- AND THE P-VALUE RENDERED FROM THE DATA TAKEN FROM THAT SUBSET OF PATIENTS WAS A P -- P .004. YOU DO RECALL THAT?

A. I DO. YES.

Q. AND THAT'S THE SAME P NUMBER IN THE PRESS RELEASE FROM AUGUST 28TH, CORRECT?

A. THAT IS CORRECT.

Q. SO THE DATA IN THE PRESS RELEASE, AT LEAST WITH RESPECT TO THAT P-VALUE NUMBER, WAS ACCURATE?

A. THAT'S CORRECT.

Q. NOW, THE -- ON THE F.D.A. TELECONFERENCE WHICH OCCURRED, APPARENTLY, EARLIER IN THE DAY ON AUGUST 27TH, YOU -- YOU WERE PRESENT FOR THAT, CORRECT?

A. YES.

Q. AND COUNSEL SHOWED YOU A REPORT -- A REPORT -- OR IT'S A MEMORANDUM OF NOTES, CORRECT? OF -- WRITTEN BY DR. ARMSTRONG THAT SUMMARIZED WHAT HAD TAKEN PLACE ON THE CALL?

A. YES.

Q. AND THE -- DR. ARMSTRONG -- YOU MENTIONED THAT SHE -- ONE OF HER ROLES AT THE TIME, ANYWAY, WAS THAT SHE WAS INVOLVED IN THE REGULATORY DIVISION AT INTERMUNE?

A. CORRECT.

Q. AND WITH RESPECT TO THE RESULTS OF THE GIPF-001 TRIAL, SHE -- HER PURPOSE WAS TO ASSIST IN COMMUNICATIONS WITH THE F.D.A., CORRECT?

A. YES.

MS. MOORMAN: THANK YOU.

Q. AND SHE HAD BEEN UNBLINDED -- AT LEAST, BASED ON YOUR OBSERVATIONS, ANYWAY -- PRIOR TO THE F.D.A. CALL ON THE 27TH?

AS BY PERCENTAGE?

A. YES.

Q. AND IN THE ACTIMMUNE-TREATED -- ACTIMMUNE-TREATED GROUP OF PATIENTS THAT FELL WITHIN THIS MILD TO MODERATE CATEGORY, THERE HAD BEEN SIX DEATHS, CORRECT?

A. YES.

Q. WHEREAS IN THE PLACEBO-TREATED CATEGORY OF THESE MILD TO MODERATE PATIENTS, THERE WERE 21, CORRECT?

A. YES.

Q. AND IT RENDERED A P-VALUE OF .004?

A. CORRECT.

Q. AND THIS IS THE NUMBER THAT WAS USED -- OR ONE OF THE NUMBERS THAT WAS USED IN THE AUGUST 28TH PRESS RELEASE, CORRECT?

A. I BELIEVE THAT'S CORRECT, YES.

Q. AND ON THIS DATA TABLE, YOU DON'T -- YOU DON'T SQUABBLE WITH THE ACCURACY OF THE DATA PRESENTED, RIGHT?

A. NO.

Q. AND YOU NOTE, SIR, THAT IT DOESN'T SAY POST HOC ANALYSIS ON THE TOP OF THE TABLE, RIGHT?

A. NO, IT DOES NOT.

Q. BUT YOU KNEW THAT, RIGHT?

A. YES.

Q. YOU KNEW IT WAS POST HOC ANALYSIS?

A. YES.

EXHIBIT L

VOLUME 13

PAGES 2103 - 2335

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA THURSDAY SEPTEMBER 10, 2009 8:37 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

YOU MAY ANSWER.

THE WITNESS: I KIND OF WINCED WHEN I SAW THE -- THE OPENING LINE.

MR. TOPEL: MOVE TO STRIKE.

THE COURT: ANSWER -- THE MOTION IS DENIED.

MS. PETROU: CAN WE PUT UP THE EXHIBIT 1? LET ME JUST HAND IT TO THE WITNESS.

Q. DR. CRAGER, I'M HANDING YOU EXHIBIT 1, WHICH IS THE PRESS RELEASE WE WERE JUST TALKING ABOUT; THE FINAL VERSION.

NOW, WITHOUT GOING THROUGH THIS WHOLE PRESS RELEASE WITH YOU, CAN YOU -- IF YOU NEED TO, YOU'RE CERTAINLY WELCOME TO DO SO. OKAY? I JUST WANT TO BE CLEAR THAT --

ARE THERE NUMBERS IN THE PRESS RELEASE THAT ARE WRONG; THAT ARE JUST INCORRECT CALCULATIONS?

A. NO.

Q. SO WHEN YOU SAY THAT YOU WINCED, IT WASN'T BECAUSE THERE WAS A WRONG P-VALUE OR WRONG NUMBER IN THE PRESS RELEASE?

MR. TOPEL: OBJECTION. LEADING. COME ON.

THE COURT: THE OBJECTION IS OVERRULED.

YOU MAY ANSWER.

THE WITNESS: THAT IS CORRECT.

BY MS. PETROU

Q. SO WHY DID YOU?

A. BECAUSE I FELT THAT IT WAS -- THE RESULTS WERE OVERINTERPRETED, AND THE CONCLUSIVENESS OF THE RESULTS WAS

EXHIBIT M

VOLUME 13

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA THURSDAY SEPTEMBER 10, 2009 8:37 A.M.

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OFFICIAL REPORTERS - U.S. DISTRICT COURT

Q DID YOU EVER CALL HIM BACK?

A NO.

Q DID YOU EVER CALL SCOTT?

A NO, I NEVER CALLED SCOTT. I CALLED JIM.

Q ALL RIGHT. BUT DID YOU EVER CALL SCOTT?

A NO.

Q OKAY. AND YOU, OF COURSE, DON'T --

MR. TOPEL: WELL, STRIKE THAT.

BY MR. TOPEL

Q ALL RIGHT. SO IN ANY EVENT, THE NEXT DAY THE PRESS RELEASE COMES OUT. AND YOU HAVE TOLD US HERE THAT YOU KIND OF WINCED BECAUSE IT WAS SORT OF OVERSTATED. YOU THOUGHT THAT THE RESULTS WERE OVERSTATED, THE INTERPRETATION WAS A LITTLE AGGRESSIVE?

A YES, THEY ARE DEFINITELY OVERSTATED.

Q YES. ALL RIGHT. BUT YOU NEVER WENT TO SCOTT HARKONEN AND TOLD HIM THAT, DID YOU?

A NO, I DIDN'T.

Q AND YOU KNEW, DID YOU NOT, THAT -- WELL NOW, IN THE PRESS RELEASE -- IN THE PRESS RELEASE --

MR. TOPEL: CAN WE HAVE THE FIRST PAGE OF THE PRESS RELEASE? NUMBER ONE. AND THE FIRST PARAGRAPH, PLEASE.

BY MR. TOPEL

Q NOW, YOU'VE TOLD US THAT THERE'S NOTHING WRONG WITH THE NUMBERS. IT'S THE INTERPRETATION THAT YOU DON'T LIKE, CORRECT?

A THAT'S CORRECT.

Q ALL RIGHT. BUT THERE IS HERE A P-VALUE OF .004 ASSOCIATED WITH THE STATEMENTS CONCERNING THE MILD TO MODERATE DISEASE GROUP; ISN'T THAT CORRECT?

A YES, IT IS.

Q AND RIGHT IN THAT FIRST PARAGRAPH THERE IS --

MR. TOPEL: CAN WE GO DOWN HERE TO THE DISCUSSION WHERE IT SAYS:

"THE TRIAL'S PRIMARY ENDPOINT. THERE WAS A TEN PERCENT RELATIVE REDUCTION IN PROGRESSION FREE SURVIVAL ASSOCIATED WITH ACTIMMUNE VERSUS PLACEBO, BUT THIS WAS NOT A STATISTICALLY SIGNIFICANT DIFFERENCE."

BY MR. TOPEL

Q DO YOU SEE THAT?

A YES, I DO.

Q RIGHT. AND THAT'S TRUE; IS IT NOT?

A IT'S TRUE THAT IT IS NOT A STATISTICALLY SIGNIFICANT DIFFERENCE.

Q RIGHT. AND THAT THE PRIMARY ENDPOINT DID NOT MEET STATISTICAL SIGNIFICANCE, AS YOU DEFINE IT, .05?

A THAT IS CORRECT.

Q ALL RIGHT.

MR. TOPEL: ALL RIGHT. CAN WE GO TO THE SECOND PAGE FOR A MOMENT?

EXHIBIT N

VOLUME 15

PAGES 2547 - 2775

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA TUESDAY SEPTEMBER 15, 2009 8:30 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

Q OKAY. DO YOU HAVE ANY REASON, OR DID YOU AT THE TIME, HAVE ANY REASON TO DOUBT THE ABSOLUTE CORRECTNESS AND INTEGRITY OF THOSE RESULTS?

A NO.

MR. TOPEL: THANK YOU.

I HAVE NOTHING FURTHER.

THE COURT: OKAY. MAY THIS WITNESS BE EXCUSED WITHOUT BEING SUBJECT TO BEING RECALLED?

MS. PETROU: YES, YOUR HONOR.

THE COURT: OKAY. YOU ARE EXCUSED, MR. WEISS. AGAIN, DO NOT DISCUSS YOUR TESTIMONY WITH ANY OTHER PERSONS WHO MAY BE WITNESSES. BUT YOU ARE FREE TO LEAVE.

MS. PETROU: YOUR HONOR, MAY I RETRIEVE THE EXHIBITS?

THE COURT: YES, YOU MAY.

MR. GORDUS: YOUR HONOR, AT THIS TIME THE GOVERNMENT MOVES TO ADMIT SOME STIPULATIONS OF FACT.

THE COURT: YES.

MR. GORDUS: THE EXHIBITS NUMBER 300, 301 AND 304.

MR. TOPEL: MAY I HAVE ONE MOMENT?

THE COURT: AND THAT IS A STIPULATION TO ADMIT THE EXHIBITS. THERE'S NO OTHER INFORMATION IN THE STIPULATION?

MR. GORDUS: I WAS GOING TO READ THE STIPULATIONS OF FACT, YOUR HONOR.

THE COURT: OH, THERE ARE SOME STIPULATIONS OF FACT. OKAY.

EXHIBIT O

VOLUME 18

PAGES 3214 - 3440

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA FRIDAY SEPTEMBER 18, 2009 8:38 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF:

OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF:

OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: **LYDIA ZINN, CSR #9223**
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

Q RIGHT. BUT IF YOU LEARNED THAT HE HAD SEEN THE PRESS RELEASE AND MADE SOME CORRECTIONS TO THE DATA THAT WOULD HAVE BEEN OKAY WITH YOU, RIGHT?

A THAT WOULD HAVE BEEN A PLUS, YES.

Q IN FACT, YOU'VE NEVER LEARNED, SIR, HAVE YOU, THAT IN THIS PRESS RELEASE THERE'S A MISSTATEMENT OF DATA, HAVE YOU?

A NO.

Q IN FACT, THERE IS NO MISSTATEMENT OF DATA IN THIS PRESS RELEASE, IS THERE?

A I HAVE NEVER HEARD THAT THERE'S A MISSTATEMENT OF ANY DATA IN THIS PRESS RELEASE.

Q AND THAT THE DATA THAT'S BEEN ANNOUNCED BECAUSE --

MS. MOORMAN: I'LL WITHDRAW THE QUESTION, YOUR HONOR.

BY MS. MOORMAN

Q THE HEADLINE OF THE PRESS RELEASE IS:

"INTERMUNE ANNOUNCES PHASE III DATA DEMONSTRATING A SURVIVAL BENEFIT OF ACTIMMUNE."

THAT'S THE HEADLINE, CORRECT?

A CORRECT.

Q AND THAT'S WHAT THIS DOCUMENT DID IS ANNOUNCE DATA KNOWN AT THE MOMENT THAT THE DOCUMENT WENT OUT, CORRECT?

A CORRECT.

Q AND THAT HEADLINE IS CONSISTENT WITH WHAT YOU LEARNED IN YOUR DIRECT DISCUSSION WITH DR. CRAGER AND DR. PENNINGTON, CORRECT?

EXHIBIT P

VOLUME 20

PAGES 3533 - 3734

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA WEDNESDAY SEPTEMBER 23, 2009 8:35 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

NOW, THE P-VALUES -- YOU CAN CALCULATE P-VALUES FOR THE SECONDARY ENDPOINTS AFTER YOU LOOK AT THE P-VALUE FOR THE PRIMARY ENDPOINT; BUT IF THE PRIMARY ENDPOINT FAILS, THOSE P-VALUES FOR THE SECCONDARY ENDPOINTS -- YOU CAN'T MAKE ANY CONCLUSIONS BASED ON THOSE P-VALUES. YOU CAN CALCULATE THEM. YOU CAN SEE WHAT THEY LOOK LIKE, BUT YOU CAN'T MAKE ANY CONCLUSIONS BASED ON THOSE P-VALUES.

WELL, FOR THIS TRIAL, EVEN IF YOU CALCULATED P-VALUES FOR THE SECONDARY ENDPOINTS -- AND THEY DID -- THEY ALL FAILED. NONE OF THEM WERE EVEN CLOSE TO 0.05.

NOW, ONE OTHER THING ABOUT P-VALUES. AND YOU'VE HEARD A LOT ABOUT SUBGROUP ANALYSIS: POST-HOC, AFTER-THE-FACT SUBGROUP ANALYSIS. YOU CAN DO SUBGROUP ANALYSIS ON THE DATA ONCE YOU GET IT. YOU CAN LOOK AT THE DATA. AND YOU CAN SEE SAY TO YOURSELF, "OKAY. WHAT LOOKS INTERESTING? LET'S LOOK AT THE DATA. LET'S CUT IT HERE. LET'S CUT IT THERE. LET'S SEE WHAT WE CAN FIND." THAT IS JUST FINE. THERE'S NOTHING WRONG WITH THAT. THE EVIDENCE IS UNDISPUTED THAT COMPANIES ALL THE TIME DO SUBGROUP ANALYSIS, EXPLORATORY ANALYSIS OF THE DATA FROM THEIR PHASE III TRIALS. IT'S PERFECTLY APPROPRIATE. IT'S DONE ALL THE TIME.

WELL, WHAT YOU CAN'T DO IS TAKE THE P-VALUES THAT YOU GET FROM THAT SUBGROUP ANALYSIS, AND MAKE CONCLUSIONS BASED ON THOSE P-VALUES. YOU CAN'T MAKE DEFINITIVE CONCLUSIONS ABOUT WHETHER A DRUG WORKS OR NOT BASED ON THOSE P-VALUES.

EXHIBIT 4

U.S. Department of Justice

Executive Office for United States Attorneys

Office of the Director

Room 2261, RFK Main Justice Building
950 Pennsylvania Avenue, NW
Washington, DC 20530

(202) 514-2121

MAR 15 2010

Mark E. Haddad, Esquire
Sidley Austin LLP
555 West Fifth Street
Los Angeles, CA 90013

Dear Mr. Haddad:

This responds to your letter dated February 11, 2010, to the United States Attorney for the Northern District of California, a copy of which you provided to the Acting Deputy Attorney General, concerning your Request for Correction pursuant to the Department of Justice's Information Quality Guidelines. You seek a retraction of a statement contained in a press release issued by the United States Attorney's Office for the Northern District of California (USAO) on September 29, 2009, regarding the conviction of your client, W. Scott Harkonen. Because your request falls outside the scope of the Department's guidelines, we are unable to accommodate your request. Moreover, regardless of the guidelines' application, we do not believe a retraction is warranted under the circumstances.

Section 515 of the Treasury and General Appropriations Act for Fiscal Year 2001 required the Office of Management and Budget (OMB) to issue government-wide guidelines for ensuring and maximizing the quality of information disseminated by federal agencies. It also required federal agencies to promulgate their own implementing guidelines consistent with those established by OMB. The OMB guidelines apply only to information that is "disseminated." Under the OMB guidelines, "dissemination" means "agency initiated or sponsored distribution of information to the public," but excludes certain distributions, including press releases. (67 FR 8460.) Similarly, the DOJ guidelines apply to all "DOJ initiated or sponsored dissemination of information," subject to specific exceptions. The exceptions include information disseminated in "press releases[,] fact sheets, press conferences, or similar communications (in any medium) that announce, support or give public notice of information in DOJ." Because the statement of which you complain was disseminated in a press release, the guidelines do not apply.

Even if the guidelines applied, no retraction is necessary because the statement at issue is correct. As you know, Mr. Harkonen was convicted of wire fraud for the creation and dissemination of false and misleading information about the efficacy of a certain drug for the treatment of a fatal disease. Following his trial and conviction, the USAO issued a press release containing the following statement:

> "Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval," said FBI Special Agent in Charge Stephanie Douglas.

You contend this statement is false because Mr. Harkonen did not alter the clinical trial data but instead drew unsupported conclusions from the data. While we agree that Mr. Harkonen did not change the data, he nevertheless used it to support his false and misleading conclusions. Because data alone is meaningless without analysis and conclusions, Mr. Harkonen's false statements regarding the data's meaning were part and parcel of the results. Thus, it was accurate to say that he falsified the results.

Thank you for raising your concerns with the Department.

Sincerely,

H. Marshall Jarrett
Director

cc: Joseph P. Russoniello
United States Attorney
Northern District of California

EXHIBIT 5

SIDLEY AUSTIN LLP
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SIDLEY AUSTIN LLP
555 WEST FIFTH STREET
LOS ANGELES, CA 90013
(213) 896 6000
(213) 896 6600 FAX

mhaddad@sidley.com
(213) 896 6604

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FOUNDED 1866

April 20, 2010

By Federal Express

The Honorable Joseph P. Russoniello
United States Attorney, Northern District of California
United States Attorney's Office
450 Golden Gate Avenue, 11th Floor
San Francisco, California 94102

Re: *United States v. Harkonen*, No. CR 08-0164 MHP (N.D. Cal.)
Request for Reconsideration under Information Quality Guidelines

Dear Mr. Russoniello:

On behalf of W. Scott Harkonen, and pursuant to the Information Quality Guidelines promulgated by the U.S. Department of Justice ("DOJ Guidelines")[1] under the Information Quality Act, Pub. L. No. 106-554, Appendix C § 515(a), 114 Stat. 2763A-154 (2000) (codified at 44 U.S.C. § 3516 note) ("the Act"), we submit this letter as a Request for Reconsideration concerning Dr. Harkonen's earlier-filed Request for Correction, dated February 11, 2010. The Department of Justice denied the Request for Correction by letter dated March 15, 2010 ("Response"), a copy of which is attached as Exhibit A. We submit this Request for Reconsideration to you as the "disseminating DOJ component" pursuant to the DOJ Guidelines.

In the Request for Correction, Dr. Harkonen asserted that the following statement, contained in a September 29, 2009 press release issued by the U.S. Attorney's Office of the Northern District of California, is false and thus violates the DOJ Guidelines: "'Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval,' said FBI Special Agent in Charge Stephanie Douglas."[2] In particular, the statement that Dr. Harkonen "falsif[ied] test results" is untrue, because the Government at trial conceded

[1] The DOJ Guidelines are available at www.justice.gov/iqpr/dojinformationqualityguidelines.htm.
[2] The press release is available at www. justice.gov/usao/can/press/2009/2009_09_29harkonen.convicted.press.html.

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that Dr. Harkonen did not falsify any test results. In its Response, the Government again "agree[s] that [Dr.] Harkonen did not change the data."

The Government's false statement in its press release is not merely a semantic error. There is a profound difference between falsifying clinical test results – an allegation never even made let alone proven here – and drawing allegedly unsupported conclusions from clinical test results. The DOJ's statement that Dr. Harkonen falsified test results is causing ongoing and severe injury to Dr. Harkonen's reputation in the medical community and to Dr. Harkonen in his personal and professional life. It should be corrected immediately.

Rather than owning up to its obvious error and taking responsibility for it, DOJ has now offered two excuses for inaction. Each is transparently meritless. It is precisely in a situation such as this that the agency, in the exercise of its statutory duty to review the case independently on rehearing, should step in, assess the situation dispassionately and see it for what it is, and correct the public record.

1. First, the Response argues that DOJ can say anything it wants to say, including false statements, so long as it utters those false statements in the medium of a press release. That DOJ would even advance such an argument in this case – where it seeks to treat an alleged misstatement in a press release as felonious conduct warranting 30 years imprisonment – is astonishing and bitterly ironic. The argument is all the more surprising as it conflicts with the plain language of DOJ's own guidelines.

The DOJ Guidelines expressly cover material disseminated on DOJ's web site, as well as DOJ's press releases. The DOJ "guidelines apply to all information disseminated by DOJ . . . , [including] any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. It includes information that an agency disseminates from a web page . . . ." The guidelines further state that "[t]he information DOJ disseminates includes: Departmental briefs in major cases, regulations, business review letters, memoranda, *press releases*, opinions, research, statistical and special reports, newsletters, and general publications." (emphasis added).

Nevertheless, the Response contends the following exemption in the DOJ Guidelines applies to the press release at issue: "[T]he guidance does not apply to information disseminated in the following contexts: . . . press releases [sic] fact sheets, press conferences or similar communications (in any medium) that announce, support or give public notice *of information in DOJ*." DOJ Guidelines, note 1 *supra* (emphasis added). That exemption has no application to information posted on web pages, and applies only to those press releases that "announce, support or give public notice of information in DOJ." *Id.* In contrast, the press release at issue here announced the verdict of a criminal trial in federal court; the press release thus did not give

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"public notice of information in DOJ." The exemption is thus inapplicable by its terms, and the Response's assertion to the contrary is incorrect and arbitrary.

The Response also cites to the OMB Guidelines. The OMB guidelines, however, require federal agencies (including DOJ) to "issue their own implementing guidelines" consistent with the objectives of the Act. 67 Fed. Reg. 8452, 8452 (Feb. 22, 2002) (attached as Exhibit B). The OMB guidelines thus do not and cannot supplant, but instead only reinforce, the applicability of DOJ's own guidelines.

Nonetheless, the Response cites to a provision of the OMB guidelines that purports to exclude "dissemination" by "press release." *See id.* at 8460 ("'Dissemination' means agency initiated or sponsored distribution of information to the public. Dissemination . . . does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." (internal citation omitted)). This exemption does not apply here.

First, the OMB's guidelines merely provide guidance for federal agencies generally to use in developing their own guidelines. Where, as here, an agency has promulgated its own guidelines, and those guidelines specifically address an issue that is treated only more generally in the OMB guidelines, the agency's own, more specific guidelines control.

Second, the OMB guidelines on their face do not exempt the DOJ press release at issue, because the purported exemption is for "distribution limited to . . . press releases," and the distribution here was not so "limited." DOJ not only sent out the press release in September 2009, but posted this press release on its web site, where it remains to this day, more than six months after the trial, readily accessible to the public via an internet search, and continuing to mislead all who see it on an issue of public importance. The distinction between a press release and information on a web site is material, because DOJ's own guidelines recognize and separately address the fact that information "disseminate[d] from a web page" is covered by the IQA.

Third, the OMB Guidelines are designed "to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate (meaning to share with, or give access to, the public). It is crucial that information Federal agencies disseminate meet these guidelines." 67 Fed. Reg. at 8452. Here, that calls for applying the IQA to the DOJ's press releases, because unlike other federal agencies that communicate primarily with the public through other means, such as rulemaking processes, "[t]he use of a press release . . . is the usual method to release public information to the media by Department of Justice components and investigative agencies." U.S. Attorneys' Manual 1-7.401(A) (2003) (attached as Exhibit C). Because of the importance of press releases to DOJ's public mission, it was

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appropriate for the DOJ Guidelines to limit any exemption for press releases only to those that "announce, support or give public notice of information in DOJ." DOJ Guidelines, note 1 *supra*. As explained above, that exemption does not apply to the press release at issue, and the DOJ Guidelines thus apply in full force here.

It is inconsistent with DOJ's public mission for DOJ to insulate itself from any responsibility for disseminating false or misleading statements about the results of criminal trial through press releases. It particularly undermines public faith and trust in DOJ's integrity for DOJ to do so here, where the same DOJ seeks to imprison Dr. Harkonen for his alleged false statement in a press release. The DOJ's double standard is arbitrary and unreasonable, and we urge you to reject it.

2. Second, the Response attempts, in the alternative, to defend the merits of the challenged statement. Although the Response "agree[s] that [Dr.] Harkonen did not change the data," the Response argues that Dr. Harkonen used the data "to support his false and misleading conclusions. Because data alone is meaningless without analysis and conclusions, [Dr.] Harkonen's false statements regarding the data's meaning were part and parcel of the results. Thus, it was accurate to say that he falsified the results." Response at 2.

This explanation, upon examination, is sleight-of-hand. It arbitrarily ignores the well-recognized distinction between scientific *data* and scientific *analysis*. Data are separate from, and precede, analysis. *See, e.g.*, Webster's II New College Dictionary 293 (3d ed. 2005) ("Data" is defined as "information organized for analysis or used as the basis for making a decision."). If data are falsified, the integrity of any subsequent analysis is immediately compromised for that reason alone. The falsification of results is thus easily distinguishable from a dispute over the meaning of accurately reported data.

The distinction between data and analysis is readily apparent in both science and the law. Scientific articles separate the reporting of test results from the analysis of those results, as review of a respected medical journal like the *New England Journal of Medicine* reveals. *See, e.g.*, Supachai Rerks-Ngarm, M.D., et al., *Vaccination with ALVAC and AIDSVAX to Prevent HIV-1 Infection in Thailand*, N. Engl. J. Med. 2009, at 4–8 (Nov. 9, 2009) (attached as Exhibit D) (setting forth test "Results"); *id.* at 8–10 (setting forth "Discussion" and analysis). And the same is true in the law, where judicial opinions commonly distinguish between the facts of the case, and the analysis of the law as applied to those facts. Even the OMB Guidelines recognize that scientific data are separate from analysis: "In a scientific . . . context, the original and supporting data shall be generated, *and* the analytic results shall be developed, using sound statistical and research methods." 67 Fed. Reg. at 8459 (emphasis added).

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Thus, the Response's conclusion that the "false statements regarding the data's meaning were part and parcel of the results" (Response at 2) is nonsensical. A summary of a clinical study can set forth accurate results; interpretation and analysis of those results may vary. Similarly, a legal opinion may accurately recite the facts of a case, yet prompt one or more dissenting opinions interpreting and analyzing the law in light of those same facts.[3] The Government's theory of prosecution here was never about falsifying test data or results; instead, the Government disputed the analysis and conclusions that Dr. Harkonen drew from those results.

The clinical results, accurately reported in the InterMune press release, included the facts that, of those treated with Actimmune in the Phase III trial, 40% fewer patients died than of those given placebo. In human terms, 16 patients died on Actimmune, but 28 died while being treated with placebo. The chances of this benefit occurring independently of Actimmune were 8% (p-value .084). Additional subgroup analyses showed an even stronger benefit (and at a lower p-value of .004) for those whose disease was not too far advanced. The Government never disputed the accuracy of those data.

Instead, the Government argued at trial that Dr. Harkonen drew a false conclusion from that data by claiming the trial data "demonstrate[ed a] survival benefit of Actimmune in IPF," even though the Government admitted before trial that the data "suggested" a survival benefit. In post-trial motions, we explain why the Government's attempt to draw a line between what the Government conceded was a permissible conclusion (that the data "suggested" a survival benefit) and what it claims was a felonious conclusion (that the data "demonstrated" a survival benefit) lacks any merit whatsoever.

This Request, however, does not require the Government to address the validity of the conclusion that Dr. Harkonen drew from the clinical results. That is for the District Court. This Request raises a separate dispute over the Government's description in *its* press release of the charges it proved against Dr. Harkonen is false. Those charges never included claims that he "falsif[ied] test results," and this point has now been conceded by the Government in the Response. As a result, the statement in the Government's press release that Dr. Harkonen was guilty of falsifying test results is, itself, a false statement. Under the IQA, the Government has a legal duty to correct that statement.

---

[3] For example, as the government is aware, the only remaining issues in dispute in Dr. Harkonen's criminal case relate to the reporting of clinical trials to the public. Nonetheless, the government's press release suggests by "falsifying test results," Dr. Harkonen "undermine[d] public trust in our system for drug approval." And yet the jury acquitted Dr. Harkonen of the misbranding charge alleging that he unlawfully marketed a drug. Thus, even assuming the basis of the argument was true (*i.e.*, that Dr. Harkonen falsified test results), which it is not, the government's conclusion that the falsified test results "undermined public trust in our system for drug approval" is false, separate, and independent from the truth or falsity of the basis of the argument.

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We urge DOJ to correct the public record now. As we noted in the Request for Correction, "the falsification of test results can be a separate violation of medical ethical rules apart from a criminal conviction." *See* Request for Correction at 3 (citing California law). Although scientists regularly differ over the conclusions to be drawn from data, no one condones the falsification of the data itself. The latter is widely understood to involve serious wrongdoing. Indeed, since the issuance of the press release, Dr. Harkonen has lost professional employment and research opportunities attributable to the Government's claim that he falsified test results. Given that the Government "agree[s] that [Dr.] Harkonen did not change the data" (Response at 2), these injuries are unnecessary, unfair, and must be remedied.

For these reasons, and those set for in our initial Request, the Government should withdraw its earlier Response and correct the press release as set forth in the Request for Correction.

We look forward to your response within forty-five calendar days of receipt of this letter.

Very truly yours,

Mark E. Haddad

Coleen Klasmeier

Enclosures

cc: H. Marshall Jarrett, Director, Executive Office for United States Attorneys
Ioana Petrou, Assistant United States Attorney
Marcus S. Topel, Kasowitz, Benson, Torres & Friedman LLP

Exhibit A

U.S. Department of Justice

Executive Office for United States Attorneys

Office of the Director

Room 2261, RFK Main Justice Building
950 Pennsylvania Avenue, NW
Washington, DC 20530

(202) 514-2121

MAR 15 2010

Mark E. Haddad, Esquire
Sidley Austin LLP
555 West Fifth Street
Los Angeles, CA 90013

Dear Mr. Haddad:

This responds to your letter dated February 11, 2010, to the United States Attorney for the Northern District of California, a copy of which you provided to the Acting Deputy Attorney General, concerning your Request for Correction pursuant to the Department of Justice's Information Quality Guidelines. You seek a retraction of a statement contained in a press release issued by the United States Attorney's Office for the Northern District of California (USAO) on September 29, 2009, regarding the conviction of your client, W. Scott Harkonen. Because your request falls outside the scope of the Department's guidelines, we are unable to accommodate your request. Moreover, regardless of the guidelines' application, we do not believe a retraction is warranted under the circumstances.

Section 515 of the Treasury and General Appropriations Act for Fiscal Year 2001 required the Office of Management and Budget (OMB) to issue government-wide guidelines for ensuring and maximizing the quality of information disseminated by federal agencies. It also required federal agencies to promulgate their own implementing guidelines consistent with those established by OMB. The OMB guidelines apply only to information that is "disseminated." Under the OMB guidelines, "dissemination" means "agency initiated or sponsored distribution of information to the public," but excludes certain distributions, including press releases. (67 FR 8460.) Similarly, the DOJ guidelines apply to all "DOJ initiated or sponsored dissemination of information," subject to specific exceptions. The exceptions include information disseminated in "press releases[,] fact sheets, press conferences, or similar communications (in any medium) that announce, support or give public notice of information in DOJ." Because the statement of which you complain was disseminated in a press release, the guidelines do not apply.

Even if the guidelines applied, no retraction is necessary because the statement at issue is correct. As you know, Mr. Harkonen was convicted of wire fraud for the creation and dissemination of false and misleading information about the efficacy of a certain drug for the treatment of a fatal disease. Following his trial and conviction, the USAO issued a press release containing the following statement:

> "Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval," said FBI Special Agent in Charge Stephanie Douglas.

You contend this statement is false because Mr. Harkonen did not alter the clinical trial data but instead drew unsupported conclusions from the data. While we agree that Mr. Harkonen did not change the data, he nevertheless used it to support his false and misleading conclusions. Because data alone is meaningless without analysis and conclusions, Mr. Harkonen's false statements regarding the data's meaning were part and parcel of the results. Thus, it was accurate to say that he falsified the results.

Thank you for raising your concerns with the Department.

Sincerely,

H. Marshall Jarrett

H. Marshall Jarrett
Director

cc: Joseph P. Russoniello
United States Attorney
Northern District of California

Exhibit B

Federal Register

Friday,
February 22, 2002

Part IX

Office of Management and Budget

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication

OFFICE OF MANAGEMENT AND BUDGET

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication

Editorial Note: Due to numerous errors, this document is being reprinted in its entirety. It was originally printed in the **Federal Register** on Thursday, January 3, 2002 at 67 FR 369–378 and was corrected on Tuesday, February 5, 2002 at 67 FR 5365.

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Final guidelines.

SUMMARY: These final guidelines implement section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106–554; H.R. 5658). Section 515 directs the Office of Management and Budget (OMB) to issue government-wide guidelines that ''provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.'' By October 1, 2002, agencies must issue their own implementing guidelines that include ''administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency'' that does not comply with the OMB guidelines. These final guidelines also reflect the changes OMB made to the guidelines issued September 28, 2001, as a result of receiving additional comment on the ''capable of being substantially reproduced'' standard (paragraphs V.3.B, V.9, and V.10), which OMB previously issued on September 28, 2001, on an interim final basis.

DATES: *Effective Date:* January 3, 2002.

FOR FURTHER INFORMATION CONTACT: Brooke J. Dickson, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Telephone (202) 395–3785 or by e-mail to informationquality@omb.eop.gov.

SUPPLEMENTARY INFORMATION: In section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106–554; H.R. 5658), Congress directed the Office of Management and Budget (OMB) to issue, by September 30, 2001, government-wide guidelines that ''provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies * * *'' Section 515(b) goes on to state that the OMB guidelines shall:

''(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

''(2) require that each Federal agency to which the guidelines apply—

''(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

''(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

''(C) report periodically to the Director—

''(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency and;

''(ii) how such complaints were handled by the agency.''

Proposed guidelines were published in the **Federal Register** on June 28, 2001 (66 FR 34489). Final guidelines were published in the **Federal Register** on September 28, 2001 (66 FR 49718). The Supplementary Information to the final guidelines published in September 2001 provides background, the underlying principles OMB followed in issuing the final guidelines, and statements of intent concerning detailed provisions in the final guidelines.

In the final guidelilnes published in September 2001, OMB also requested additional comment on the ''capable of being substantially reproduced'' standard and the related definition of ''influential scientific or statistical information'' (paragraphs V.3.B, V.9, and V.10), which were issued on an interim final basis. The final guidelines published today discuss the public comments OMB received, the OMB response, and amendments to the final guidelines published in September 2001.

In developing agency-specific guidelines, agencies should refer both to the Supplementary Information to the final guidelines published in the **Federal Register** on September 28, 2001 (66 FR 49718), and also to the Supplementary Information published today. We stress that the three ''Underlying Principles'' that OMB followed in drafting the guidelines that we published on September 28, 2001 (66 FR 49719), are also applicable to the amended guidelines that we publish today.

In accordance with section 515, OMB has designed the guidelines to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate (meaning to share with, or give access to, the public). It is crucial that information Federal agencies disseminate meets these guidelines. In this respect, the fact that the Internet enables agencies to communicate information quickly and easily to a wide audience not only offers great benefits to society, but also increases the potential harm that can result from the dissemination of information that does not meet basic information quality guidelines. Recognizing the wide variety of information Federal agencies disseminate and the wide variety of dissemination practices that agencies have, OMB developed the guidelines with several principles in mind.

First, OMB designed the guidelines to apply to a wide variety of government information dissemination activities that may range in importance and scope. OMB also designed the guidelines to be generic enough to fit all media, be they printed, electronic, or in other form. OMB sought to avoid the problems that would be inherent in developing detailed, prescriptive, ''one-size-fits-all'' government-wide guidelines that would artificially require different types of dissemination activities to be treated in the same manner. Through this flexibility, each agency will be able to incorporate the requirements of these OMB guidelines into the agency's own information resource management and administrative practices.

Second, OMB designed the guidelines so that agencies will meet basic information quality standards. Given the administrative mechanisms required by section 515 as well as the standards set forth in the Paperwork Reduction Act, it is clear that agencies should not disseminate substantive information that does not meet a basic level of quality. We recognize that some government information may need to meet higher or more specific information quality standards than those that would apply to other types of government information. The more important the information, the higher the quality standards to which it should be held, for example, in those situations involving ''influential scientific, financial, or statistical information'' (a phrase defined in these guidelines). The guidelines recognize, however, that

information quality comes at a cost. Accordingly, the agencies should weigh the costs (for example, including costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality) and the benefits of higher information quality in the development of information, and the level of quality to which the information disseminated will be held.

Third, OMB designed the guidelines so that agencies can apply them in a common-sense and workable manner. It is important that these guidelines do not impose unnecessary administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and other technologies to disseminate information that can be of great benefit and value to the public. In this regard, OMB encourages agencies to incorporate the standards and procedures required by these guidelines into their existing information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes. The primary example of this is that the guidelines recognize that, in accordance with OMB Circular A–130, agencies already have in place well-established information quality standards and administrative mechanisms that allow persons to seek and obtain correction of information that is maintained and disseminated by the agency. Under the OMB guidelines, agencies need only ensure that their own guidelines are consistent with these OMB guidelines, and then ensure that their administrative mechanisms satisfy the standards and procedural requirements in the new agency guidelines. Similarly, agencies may rely on their implementation of the Federal Government's computer security laws (formerly, the Computer Security Act, and now the computer security provisions of the Paperwork Reduction Act) to establish appropriate security safeguards for ensuring the ''integrity'' of the information that the agencies disseminate.

In addition, in response to concerns expressed by some of the agencies, we want to emphasize that OMB recognizes that Federal agencies provide a wide variety of data and information. Accordingly, OMB understands that the guidelines discussed below cannot be implemented in the same way by each agency. In some cases, for example, the data disseminated by an agency are not collected by that agency; rather, the information the agency must provide in a timely manner is compiled from a variety of sources that are constantly updated and revised and may be confidential. In such cases, while agencies' implementation of the guidelines may differ, the essence of the guidelines will apply. That is, these agencies must make their methods transparent by providing documentation, ensure quality by reviewing the underlying methods used in developing the data and consulting (as appropriate) with experts and users, and keep users informed about corrections and revisions.

Summary of OMB Guidelines

These guidelines apply to Federal agencies subject to the Paperwork Reduction Act (44 U.S.C. chapter 35). Agencies are directed to develop information resources management procedures for reviewing and substantiating (by documentation or other means selected by the agency) the quality (including the objectivity, utility, and integrity) of information before it is disseminated. In addition, agencies are to establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of information disseminated by the agency that does not comply with the OMB or agency guidelines. Consistent with the underlying principles described above, these guidelines stress the importance of having agencies apply these standards and develop their administrative mechanisms so they can be implemented in a common sense and workable manner. Moreover, agencies must apply these standards flexibly, and in a manner appropriate to the nature and timeliness of the information to be disseminated, and incorporate them into existing agency information resources management and administrative practices.

Section 515 denotes four substantive terms regarding information disseminated by Federal agencies: quality, utility, objectivity, and integrity. It is not always clear how each substantive term relates—or how the four terms in aggregate relate—to the widely divergent types of information that agencies disseminate. The guidelines provide definitions that attempt to establish a clear meaning so that both the agency and the public can readily judge whether a particular type of information to be disseminated does or does not meet these attributes.

In the guidelines, OMB defines ''quality'' as the encompassing term, of which ''utility,'' ''objectivity,'' and ''integrity'' are the constituents. ''Utility'' refers to the usefulness of the information to the intended users. ''Objectivity'' focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. ''Integrity'' refers to security—the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. OMB modeled the definitions of ''information,'' ''government information,'' ''information dissemination product,'' and ''dissemination'' on the longstanding definitions of those terms in OMB Circular A–130, but tailored them to fit into the context of these guidelines.

In addition, Section 515 imposes two reporting requirements on the agencies. The first report, to be promulgated no later than October 1, 2002, must provide the agency's information quality guidelines that describe administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of disseminated information that does not comply with the OMB and agency guidelines. The second report is an annual fiscal year report to OMB (to be first submitted on January 1, 2004) providing information (both quantitative and qualitative, where appropriate) on the number, nature, and resolution of complaints received by the agency regarding its perceived or confirmed failure to comply with these OMB and agency guidelines.

Public Comments and OMB Response

Applicability of Guidelines. Some comments raised concerns about the applicability of these guidelines, particularly in the context of scientific research conducted by Federally employed scientists or Federal grantees who publish and communicate their research findings in the same manner as their academic colleagues. OMB believes that information generated and disseminated in these contexts is not covered by these guidelines unless the agency represents the information as, or uses the information in support of, an official position of the agency.

As a general matter, these guidelines apply to ''information'' that is ''disseminated'' by agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)). See paragraphs II, V.5 and V.8. The definitions of ''information'' and ''dissemination'' establish the scope of the applicability of these guidelines. ''Information'' means ''any communication or representation of knowledge such as facts or data * * *'' This definition of information in paragraph V.5 does ''not include opinions, where the agency's presentation makes it clear that what is

being offered is someone's opinion rather than fact or the agency's views.''

''Dissemination'' is defined to mean ''agency initiated or sponsored distribution of information to the public.'' As used in paragraph V.8, ''agency INITIATED * * * distribution of information to the public'' refers to information that the agency disseminates, e.g., a risk assessment prepared by the agency to inform the agency's formulation of possible regulatory or other action. In addition, if an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these guidelines. By contrast, an agency does not ''initiate'' the dissemination of information when a Federally employed scientist or Federal grantee or contractor publishes and communicates his or her research findings in the same manner as his or her academic colleagues, even if the Federal agency retains ownership or other intellectual property rights because the Federal government paid for the research. To avoid confusion regarding whether the agency agrees with the information (and is therefore disseminating it through the employee or grantee), the researcher should include an appropriate disclaimer in the publication or speech to the effect that the ''views are mine, and do not necessarily reflect the view'' of the agency.

Similarly, as used in paragraph V.8., ''agency * * * SPONSORED distribution of information to the public'' refers to situations where an agency has directed a third-party to disseminate information, or where the agency has the authority to review and approve the information before release. Therefore, for example, if an agency through a procurement contract or a grant provides for a person to conduct research, and then the agency directs the person to disseminate the results (or the agency reviews and approves the results before they may be disseminated), then the agency has ''sponsored'' the dissemination of this information. By contrast, if the agency simply provides funding to support research, and it the researcher (not the agency) who decides whether to disseminate the results and—if the results are to be released—who determines the content and presentation of the dissemination, then the agency has not ''sponsored'' the dissemination even though it has funded the research and even if the Federal agency retains ownership or other intellectual property rights because the Federal government paid for the research. To avoid confusion regarding whether the agency is sponsoring the dissemination, the researcher should include an appropriate disclaimer in the publication or speech to the effect that the ''views are mine, and do not necessarily reflect the view'' of the agency. On the other hand, subsequent agency dissemination of such information requires that the information adhere to the agency's information quality guidelines. In sum, these guidelines govern an agency's dissemination of information, but generally do not govern a third-party's dissemination of information (the exception being where the agency is essentially using the third-party to disseminate information on the agency's behalf). Agencies, particularly those that fund scientific research, are encouraged to clarify the applicability of these guidelines to the various types of information they and their employees and grantees disseminate.

Paragraph V.8 also states that the definition of ''dissemination'' does not include ''* * * distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.'' The exemption from the definition of ''dissemination'' for ''adjudicative processes'' is intended to exclude, from the scope of these guidelines, the findings and determinations that an agency makes in the course of adjudications involving specific parties. There are well-established procedural safeguards and rights to address the quality of adjudicatory decisions and to provide persons with an opportunity to contest decisions. These guidelines do not impose any additional requirements on agencies during adjudicative proceedings and do not provide parties to such adjudicative proceedings any additional rights of challenge or appeal.

*The Presumption Favoring Peer-Reviewed Information.*As a general matter, in the scientific and research context, we regard technical information that has been subjected to formal, independent, external peer review as presumptively objective. As the guidelines state in paragraph V.3.b.i: ''If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity.'' An example of a formal, independent, external peer review is the review process used by scientific journals.

Most comments approved of the prominent role that peer review plays in the OMB guidelines. Some comments contended that peer review was not accepted as a universal standard that incorporates an established, practiced, and sufficient level of objectivity. Other comments stated that the guidelines would be better clarified by making peer review one of several factors that an agency should consider in assessing the objectivity (and quality in general) of original research. In addition, several comments noted that peer review does not establish whether analytic results are capable of being substantially reproduced. In light of the comments, the final guidelines in new paragraph V.3.b.i qualify the presumption in favor of peer-reviewed information as follows: ''However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance.''

We believe that transparency is important for peer review, and these guidelines set minimum standards for the transparency of agency-sponsored peer review. As we state in new paragraph V.3.b.i: ''If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance. If agency-sponsored peer review is employed to help satisfy the objectivity standard, the review process employed shall meet the general criteria for competent and credible peer review recommended by OMB–OIRA to the President's Management Council (9/20/01) (http://www.whitehouse.gov/omb/inforeg/oira_review-process.html), namely, 'that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner.'''

The importance of these general criteria for competent and credible peer review has been supported by a number of expert bodies. For example, ''the work of fully competent peer-review panels can be undermined by allegations of conflict of interest and bias. Therefore, the best interests of the Board are served by effective policies and procedures regarding potential conflicts of interest, impartiality, and panel balance.'' (*EPA's Science Advisory*

Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, GAO–01–536, General Accounting Office, Washington, DC, June 2001, page 19.) As another example, ''risk analyses should be peer-reviewed and accessible—both physically and intellectually—so that decision-makers at all levels will be able to respond critically to risk characterizations. The intensity of the peer reviews should be commensurate with the significance of the risk or its management implications.'' (*Setting Priorities, Getting Results: A New Direction for EPA,* Summary Report, National Academy of Public Administration, Washington, DC, April 1995, page 23.)

These criteria for peer reviewers are generally consistent with the practices now followed by the National Research Council of the National Academy of Sciences. In considering these criteria for peer reviewers, we note that there are many types of peer reviews and that agency guidelines concerning the use of peer review should tailor the rigor of peer review to the importance of the information involved. More generally, agencies should define their peer-review standards in appropriate ways, given the nature and importance of the information they disseminate.

Is Journal Peer Review Always Sufficient? Some comments argued that journal peer review should be adequate to demonstrate quality, even for influential information that can be expected to have major effects on public policy. OMB believes that this position overstates the effectiveness of journal peer review as a quality-control mechanism.

Although journal peer review is clearly valuable, there are cases where flawed science has been published in respected journals. For example, the NIH Office of Research Integrity recently reported the following case regarding environmental health research:

> ''Based on the report of an investigation conducted by [XX] University, dated July 16, 1999, and additional analysis conducted by ORI in its oversight review, the US Public Health Service found that Dr. [X] engaged in scientific misconduct. Dr. [X] committed scientific misconduct by intentionally falsifying the research results published in the journal SCIENCE and by providing falsified and fabricated materials to investigating officials at [XX] University in response to a request for original data to support the research results and conclusions report in the SCIENCE paper. In addition, PHS finds that there is no original data or other corroborating evidence to support the research results and conclusions reported in the SCIENCE paper as a whole.'' (66 FR 52137, October 12, 2001).

Although such cases of falsification are presumably rare, there is a significant scholarly literature documenting quality problems with articles published in peer-reviewed research. ''In a [peer-reviewed] meta-analysis that surprised many—and some doubt—researchers found little evidence that peer review actually improves the quality of research papers.'' (*See, e.g., Science,* Vol. 293, page 2187 (September 21, 2001.)) In part for this reason, many agencies have already adopted peer review and science advisory practices that go beyond journal peer review. *See, e.g.,* Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policy Makers,* Cambridge, MA, Harvard University Press, 1990; Mark R. Powell, *Science at EPA: Information in the Regulatory Process.* Resources for the Future, Washington, DC., 1999, pages 138–139; 151–153; *Implementation of the Environmental Protection Agency's Peer Review Program: An SAB Evaluation of Three Reviews,* EPA–SAB–RSAC–01–009, A Review of the Research Strategies Advisory Committee (RSAC) of the EPA Science Advisory Board (SAB), Washington, DC., September 26, 2001. For information likely to have an important public policy or private sector impact, OMB believes that additional quality checks beyond peer review are appropriate.

Definition of ''Influential''. OMB guidelines apply stricter quality standards to the dissemination of information that is considered ''influential.'' Comments noted that the breadth of the definition of ''influential'' in interim final paragraph V.9 requires much speculation on the part of agencies.

We believe that this criticism has merit and have therefore narrowed the definition. In this narrower definition, ''influential'', when used in the phrase ''influential scientific, financial, or statistical information'', is amended to mean that ''the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.'' The intent of the new phrase ''clear and substantial'' is to reduce the need for speculation on the part of agencies. We added the present tense—''or does have''—to this narrower definition because on occasion, an information dissemination may occur simultaneously with a particular policy change. In response to a public comment, we added an explicit reference to ''financial'' information as consistent with our original intent.

Given the differences in the many Federal agencies covered by these guidelines, and the differences in the nature of the information they disseminate, we also believe it will be helpful if agencies elaborate on this definition of ''influential'' in the context of their missions and duties, with due consideration of the nature of the information they disseminate. As we state in amended paragraph V.9, ''Each agency is authorized to define 'influential' in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.''

Reproducibility. As we state in new paragraph V.3.b.ii: ''If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.'' OMB believes that a reproducibility standard is practical and appropriate for information that is considered ''influential'', as defined in paragraph V.9—that ''will have or does have a clear and substantial impact on important public policies or important private sector decisions.'' The reproducibility standard applicable to influential scientific, financial, or statistical information is intended to ensure that information disseminated by agencies is sufficiently transparent in terms of data and methods of analysis that it would be feasible for a replication to be conducted. The fact that the use of original and supporting data and analytic results have been deemed ''defensible'' by peer-review procedures does not necessarily imply that the results are transparent and replicable.

Reproducibility of Original and Supporting Data. Several of the comments objected to the exclusion of original and supporting data from the reproducibility requirements. Comments instead suggested that OMB should apply the reproducibility standard to original data, and that OMB should provide flexibility to the agencies in determining what constitutes ''original and supporting'' data. OMB agrees and asks that agencies consider, in developing their own guidelines, which categories of original and supporting data should be subject to the reproducibility standard and which should not. To help in resolving this issue, we also ask agencies to consult directly with relevant scientific and technical communities on the feasibility of having the selected categories of original and supporting data subject to the reproducibility standard. Agencies are encouraged to address ethical, feasibility, and confidentiality issues

with care. As we state in new paragraph V.3.b.ii.A, ''Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints.'' Further, as we state in our expanded definition of ''reproducibility'' in paragraph V.10, ''If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (*e.g.,* standards for replication of laboratory data).'' OMB urges caution in the treatment of original and supporting data because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data. For example, it may not be ethical to repeat a ''negative'' (ineffective) clinical (therapeutic) experiment and it may not be feasible to replicate the radiation exposures studied after the Chernobyl accident. When agencies submit their draft agency guidelines for OMB review, agencies should include a description of the extent to which the reproducibility standard is applicable and reflect consultations with relevant scientific and technical communities that were used in developing guidelines related to applicability of the reproducibility standard to original and supporting data.

It is also important to emphasize that the reproducibility standard does not apply to all original and supporting data disseminated by agencies. As we state in new paragraph V.3.b.ii.A, ''With regard to original and supporting data related [to influential scientific, financial, or statistical information], agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement.'' In addition, we encourage agencies to address how greater transparency can be achieved regarding original and supporting data. As we also state in new paragraph V.3.b.ii.A, ''It is understood that reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (*i.e.,* a new experiment, test, or sample) shall not be required prior to each dissemination.'' Agency guidelines need to achieve a high degree of transparency about data even when reproducibility is not required.

Reproducibility of Analytic Results. Many public comments were critical of the reproducibility standard and expressed concern that agencies would be required to reproduce each analytical result before it is disseminated. While several comments commended OMB for establishing an appropriate balance in the ''capable of being substantially reproduced'' standard, others considered this standard to be inherently subjective. There were also comments that suggested the standard would cause more burden for agencies.

It is not OMB's intent that each agency must reproduce each analytic result before it is disseminated. The purpose of the reproducibility standard is to cultivate a consistent agency commitment to transparency about how analytic results are generated: the specific data used, the various assumptions employed, the specific analytic methods applied, and the statistical procedures employed. If sufficient transparency is achieved on each of these matters, then an analytic result should meet the ''capable of being substantially reproduced'' standard.

While there is much variation in types of analytic results, OMB believes that reproducibility is a practical standard to apply to most types of analytic results. As we state in new paragraph V.3.b.ii.B, ''With regard to analytic results related [to influential scientific, financial, or statistical information], agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies.'' We elaborate upon this principle in our expanded definition of ''reproducibility'' in paragraph V.10: ''With respect to analytic results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.''

Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard. For example, a qualified party, operating under the same confidentiality protections as the original analysts, may be asked to use the same data, computer model or statistical methods to replicate the analytic results reported in the original study. *See, e.g.,* ''Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality,'' A Special Report of the Health Effects Institute's Particle Epidemiology Reanalysis Project, Cambridge, MA, 2000.

The primary benefit of public transparency is not necessarily that errors in analytic results will be detected, although error correction is clearly valuable. The more important benefit of transparency is that the public will be able to assess how much an agency's analytic result hinges on the specific analytic choices made by the agency. Concreteness about analytic choices allows, for example, the implications of alternative technical choices to be readily assessed. This type of sensitivity analysis is widely regarded as an essential feature of high-quality analysis, yet sensitivity analysis cannot be undertaken by outside parties unless a high degree of transparency is achieved. The OMB guidelines do not compel such sensitivity analysis as a necessary dimension of quality, but the transparency achieved by reproducibility will allow the public to undertake sensitivity studies of interest.

We acknowledge that confidentiality concerns will sometimes preclude public access as an approach to reproducibility. In response to public comment, we have clarified that such concerns do include interests in ''intellectual property.'' To ensure that the OMB guidelines have sufficient flexibility with regard to analytic transparency, OMB has, in new paragraph V.3.b.ii.B.i, provided agencies an alternative approach for classes or types of analytic results that cannot practically be subject to the reproducibility standard. ''[In those situations involving influential scientific, financial, or statistical information * * *] making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections. '' Specifically, in cases where reproducibility will not occur due to other compelling interests, we expect agencies (1) to perform robustness checks appropriate to the importance of the information involved, e.g., determining whether a specific statistic is sensitive to the choice of analytic method, and, accompanying the information disseminated, to document their efforts to assure the needed robustness in information quality, and (2) address in their guidelines the

degree to which they anticipate the opportunity for reproducibility to be limited by the confidentiality of underlying data. As we state in new paragraph V.3.b.ii.B.*ii,* ''In situations where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken. Agency guidelines shall, however, in all cases, require a disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed.''

Given the differences in the many Federal agencies covered by these guidelines, and the differences in robustness checks and the level of detail for documentation thereof that might be appropriate for different agencies, we also believe it will be helpful if agencies elaborate on these matters in the context of their missions and duties, with due consideration of the nature of the information they disseminate. As we state in new paragraph V.3.b.ii.B.ii, ''Each agency is authorized to define the type of robustness checks, and the level of detail for documentation thereof, in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.''

We leave the determination of the appropriate degree of rigor to the discretion of agencies and the relevant scientific and technical communities that work with the agencies. We do, however, establish a general standard for the appropriate degree of rigor in our expanded definition of ''reproducibility'' in paragraph V.10: '' 'Reproducibility' means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased).'' OMB will review each agency's treatment of this issue when reviewing the agency guidelines as a whole.

Comments also expressed concerns regarding interim final paragraph V.3.B.iii, ''making the data and models publicly available will assist in determining whether analytic results are capable of being substantially reproduced,'' and whether it could be interpreted to constitute public dissemination of these materials, rendering moot the reproducibility test. (For the equivalent provision, see new paragraph V.3.b.ii.B.*i.*) The OMB guidelines do not require agencies to reproduce each disseminated analytic result by independent reanalysis. Thus, public dissemination of data and models *per se* does not mean that the analytic result has been reproduced. It means only that the result should be CAPABLE of being reproduced. The transparency associated with this capability of reproduction is what the OMB guidelines are designed to achieve.

We also want to build on a general observation that we made in our final guidelines published in September 2001. In those guidelines we stated: ''... in those situations involving influential scientific[, financial,] or statistical information, the substantial reproducibility standard is added as a quality standard above and beyond some peer review quality standards'' (66 FR 49722 (September 28, 2001)). A hypothetical example may serve to illustrate this point. Assume that two Federal agencies initiated or sponsored the dissemination of five scientific studies after October 1, 2002 (see paragraph III.4) that were, before dissemination, subjected to formal, independent, external peer review, i.e., that met the presumptive standard for ''objectivity'' under paragraph V.3.b.i. Further assume, at the time of dissemination, that neither agency reasonably expected that the dissemination of any of these studies would have ''a clear and substantial impact'' on important public policies, *i.e.,* that these studies were not considered ''influential'' under paragraph V.9, and thus not subject to the reproducibility standards in paragraphs V.3.b.ii.A or B. Then assume, two years later, in 2005, that one of the agencies decides to issue an important and far-reaching regulation based clearly and substantially on the agency's evaluation of the analytic results set forth in these five studies and that such agency reliance on these five studies as published in the agency's notice of proposed rulemaking would constitute dissemination of these five studies. These guidelines would require the rulemaking agency, prior to publishing the notice of proposed rulemaking, to evaluate these five studies to determine if the analytic results stated therein would meet the ''capable of being substantially reproduced'' standards in paragraph V.3.b.ii.B and, if necessary, related standards governing original and supporting data in paragraph V.3.b.ii.A. If the agency were to decide that any of the five studies would not meet the reproducibility standard, the agency may still rely on them but only if they satisfy the transparency standard and—as applicable—the disclosure of robustness checks required by these guidelines. Otherwise, the agency should not disseminate any of the studies that did not meet the applicable standards in the guidelines at the time it publishes the notice of proposed rulemaking.

Some comments suggested that OMB consider replacing the reproducibility standard with a standard concerning ''confirmation'' of results for influential scientific and statistical information. Although we encourage agencies to consider ''confirmation'' as a relevant standard—at least in some cases—for assessing the objectivity of original and supporting data, we believe that ''confirmation'' is too stringent a standard to apply to analytic results. Often the regulatory impact analysis prepared by an agency for a major rule, for example, will be the only formal analysis of an important subject. It would be unlikely that the results of the regulatory impact analysis had already been confirmed by other analyses. The ''capable of being substantially reproduced'' standard is less stringent than a ''confirmation'' standard because it simply requires that an agency's analysis be sufficiently transparent that another qualified party could replicate it through reanalysis.

Health, Safety, and Environmental Information. We note, in the scientific context, that in 1996 the Congress, for health decisions under the Safe Drinking Water Act, adopted a basic standard of quality for the use of science in agency decisionmaking. Under 42 U.S.C. 300g–1(b)(3)(A), an agency is directed, ''to the degree that an Agency action is based on science,'' to use ''(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).''

We further note that in the 1996 amendments to the Safe Drinking Water Act, Congress adopted a basic quality standard for the dissemination of public information about risks of adverse health effects. Under 42 U.S.C. 300g–1(b)(3)(B), the agency is directed, ''to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable.'' The agency is further directed, ''in a document made available to the public in support of a regulation [to] specify, to the extent practicable—(i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of

risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data.''

As suggested in several comments, we have included these congressional standards directly in new paragraph V.3.b.ii.C, and made them applicable to the information disseminated by all the agencies subject to these guidelines: ''With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g–1(b)(3)(A) & (B)).'' The word ''adapt'' is intended to provide agencies flexibility in applying these principles to various types of risk assessment.

Comments also argued that the continued flow of vital information from agencies responsible for disseminating health and medical information to medical providers, patients, and the public may be disrupted due to these peer review and reproducibility standards. OMB responded by adding to new paragraph V.3.b.ii.C: ''Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations (*e.g.,* imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines.''

Administrative Correction Mechanisms. In addition to commenting on the substantive standards in these guidelines, many of the comments noted that the OMB guidelines on the administrative correction of information do not specify a time period in which the agency investigation and response must be made. OMB has added the following new paragraph III.3.i to direct agencies to specify appropriate time periods in which the investigation and response need to be made. ''Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.''

Several comments stated that the OMB guidelines needed to direct agencies to consider incorporating an administrative appeal process into their administrative mechanisms for the correction of information. OMB agreed, and added the following new paragraph III.3.ii: ''If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration.'' Recognizing that many agencies already have a process in place to respond to public concerns, it is not necessarily OMB's intent to require these agencies to establish a new or different process. Rather, our intent is to ensure that agency guidelines specify an objective administrative appeal process that, upon furthercomplaint by the affected person, reviews an agency's decision to disagree with the correction request. An objective process will ensure that the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement. In addition, the agency guidelines should specify that if the agency believes other agencies may have an interest in the resolution of any administrative appeal, the agency should consult with those other agencies about their possible interest.

Overall, OMB does not envision administrative mechanisms that would burden agencies with frivolous claims. Instead, the correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes. Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB.

OMB's issuance of these final guidelines is the beginning of an evolutionary process that will include draft agency guidelines, public comment, final agency guidelines, development of experience with OMB and agency guidelines, and continued refinement of both OMB and agency guidelines. Just as OMB requested public comment before issuing these final guidelines, OMB will refine these guidelines as experience develops and further public comment is obtained.

Dated: December 21, 2001.

John D. Graham,

Administrator, Office of Information and Regulatory Affairs.

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

I. OMB Responsibilities

Section 515 of the Treasury and General Government Appropriations Act for FY2001 (Public Law 106–554) directs the Office of Management and Budget to issue government-wide guidelines that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies.

II. Agency Responsibilities

Section 515 directs agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)) to—

1. Issue their own information quality guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency no later than one year after the date of issuance of the OMB guidelines;

2. Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines; and

3. Report to the Director of OMB the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines concerning the quality, objectivity, utility, and integrity of information and how such complaints were resolved.

III. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

1. Overall, agencies shall adopt a basic standard of quality (including objectivity, utility, and integrity) as a performance goal and should take appropriate steps to incorporate information quality criteria into agency information dissemination practices. Quality is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated. Agencies shall adopt

specific standards of quality that are appropriate for the various categories of information they disseminate.

2. As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information.

3. To facilitate public review, agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines. These administrative mechanisms shall be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices.

i. Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.

ii. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration.

4. The agency's pre-dissemination review, under paragraph III.2, shall apply to information that the agency first disseminates on or after October 1, 2002. The agency's administrative mechanisms, under paragraph III.3., shall apply to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information.

IV. Agency Reporting Requirements

1. Agencies must designate the Chief Information Officer or another official to be responsible for agency compliance with these guidelines.

2. The agency shall respond to complaints in a manner appropriate to the nature and extent of the complaint. Examples of appropriate responses include personal contacts via letter or telephone, form letters, press releases or mass mailings that correct a widely disseminated error or address a frequently raised complaint.

3. Each agency must prepare a draft report, no later than April 1, 2002, providing the agency's information quality guidelines and explaining how such guidelines will ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency. This report must also detail the administrative mechanisms developed by that agency to allow affected persons to seek and obtain appropriate correction of information maintained and disseminated by the agency that does not comply with the OMB or the agency guidelines.

4. The agency must publish a notice of availability of this draft report in the **Federal Register**, and post this report on the agency's website, to provide an opportunity for public comment.

5. Upon consideration of public comment and after appropriate revision, the agency must submit this draft report to OMB for review regarding consistency with these OMB guidelines no later than July 1, 2002. Upon completion of that OMB review and completion of this report, agencies must publish notice of the availability of this report in its final form in the **Federal Register**, and post this report on the agency's web site no later than October 1, 2002.

6. On an annual fiscal-year basis, each agency must submit a report to the Director of OMB providing information (both quantitative and qualitative, where appropriate) on the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines and how such complaints were resolved. Agencies must submit these reports no later than January 1 of each following year, with the first report due January 1, 2004.

V. Definitions

1. ''Quality'' is an encompassing term comprising utility, objectivity, and integrity. Therefore, the guidelines sometimes refer to these four statutory terms, collectively, as ''quality.''

2. ''Utility'' refers to the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the perspective of the agency but also from the perspective of the public. As a result, when transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information.

3. ''Objectivity'' involves two distinct elements, presentation and substance.

a. ''Objectivity'' includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.

b. In addition, ''objectivity'' involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods.

i. If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance. If agency-sponsored peer review is employed to help satisfy the objectivity standard, the review process employed shall meet the general criteria for competent and credible peer review recommended by OMB–OIRA to the President's Management Council (9/20/01) (http://www.whitehouse.gov/omb/inforeg/oira_review-process.html), namely, ''that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and

institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner.''

ii. If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.

A. With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicable be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints. It is understood that reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination.

B. With regard to analytic results related thereto, agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies.

i. Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.

ii. In situations where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken. Agency guidelines shall, however, in all cases, require a disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed. Each agency is authorized to define the type of robustness checks, and the level of detail for documentation thereof, in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

C. With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g–1(b)(3)(A) & (B)). Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations (*e.g.,* imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines.

4. ''Integrity'' refers to the security of information—protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

5. ''Information'' means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views.

6. ''Government information'' means information created, collected, processed, disseminated, or disposed of by or for the Federal Government.

7. ''Information dissemination product'' means any books, paper, map, machine-readable material, audiovisual production, or other documentary material, regardless of physical form or characteristic, an agency disseminates to the public. This definition includes any electronic document, CD–ROM, or web page.

8. ''Dissemination'' means agency initiated or sponsored distribution of information to the public (see 5 CFR 1320.3(d) (definition of ''Conduct or Sponsor'')). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.

9. ''Influential'', when used in the phrase ''influential scientific, financial, or statistical information'', means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions. Each agency is authorized to define ''influential'' in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

10. ''Reproducibility'' means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased). If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (*e.g.,* standards for replication of laboratory data). With respect to analytic results, ''capable of being substantially reproduced'' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

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Editorial Note: Due to numerous errors, this document is being reprinted in its entirety. It was originally printed in the **Federal Register** on Thursday, January 3, 2002 at 67 FR 369–378 and was corrected on Tuesday, February 5, 2002 at 67 FR 5365.

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Exhibit C

1-7.000 MEDIA RELATIONS

1-7.001 Purpose

The purpose of this policy statement is to establish specific guidelines consistent with the provisions of 28 CFR 50.2 governing the release of information relating to criminal and civil cases and matters by all components (FBI, DEA, INS, BOP, USMS, USAO, and DOJ divisions) and personnel of the Department of Justice. These guidelines are: 1) fully consistent with the underlying standards set forth in this statement and with 28 CFR 50.2; 2) in addition to any other general

Budget). OPC should be consulted for guidance prior to commenting on new policies and initiatives, legislative proposals or budgetary issues of the Department. This should not be interpreted to preclude recitation of existing well-established Departmental policies or approved budgets.

[cited in USAM 1-3.000; 1-7.401]

1-7.400 Coordination With United States Attorneys—Issuance of Press Releases

By OPA or Headquarters. In instances where OPA or the headquarters of any division, component or agency of the Department issues a news release or conducts a news conference which may affect an office or the United States Attorney, such division, component, or agency will coordinate that effort with the appropriate United States Attorney.

Issuance of Press Release by Field Officers of Any Division. In instances where local field officers of any division or component plans to issue a news release, schedule a news conference or make contact with a member of the media relating to any case or matter which may be prosecuted by the United States Attorney's office, such release, scheduling of a news conference or other media contact shall be approved by the United States Attorney. See the DOJ Organizations and Functions Manual at 28 for a discussion of press releases in cases involving the Internal Revenue Service.

[Added November 2003] [cited in USAM 1-3.000; USAM 1-7.401]

1-7.401 Guidance for Press Conferences and Other Media Contacts

The following guidance should be followed when Department of Justice components or investigative agencies consider conducting a press conference or other media contact:

A. The use of a press release which conforms to the approval requirements of USAM 1-7.400 is the usual method to release public information to the media by Department of Justice components and investigative agencies. Press conferences should be held only for the most significant and newsworthy actions, or if a particularly important deterrent or law enforcement purpose would be served. Prudence and caution should be exercised in the conduct of any press conference or other media contact.

B. Press conferences about pending cases or investigations that may result in an indictment by all Department of Justice components and investigative agencies must be approved by the appropriate Assistant Attorney General or by the United States Attorney responsible for the case. In joint or multi-district cases the approving official should consult with other districts or divisions affected. If it is a national case, press conferences must be approved by the Director, Office of Public Affairs. *See* USAM 1-7.320 to 1-7.330.

C. There are exceptional circumstances when it may be appropriate to have press

conferences or other media outreach about ongoing matters before indictment or other formal charge. These include cases where: 1) the heinous or extraordinary nature of the crime requires public reassurance that the matter is being promptly and properly handled by the appropriate authority; 2) the community needs to be told of an imminent threat to public safety; or 3) a request for public assistance or information is vital. *See* USAM 1-7.530 to 1-7.550 and 28 C.F.R. 50.2.

D. There are also circumstances involving substantial public interest when it may be appropriate to have media contact about matters after indictment or other formal charge but before conviction. In such cases, any communications with press or media representatives should be limited to the information contained in an indictment or other charging instrument, other public pleadings or proceedings, and any other related non-criminal information, within the limits of USAM 1-7.520, .540, .550, .500 and 28 C.F.R. 50.2.

E. Any public communication by any Department component or investigative agency or their employees about pending matters or investigations that may result in a case, or about pending cases or final dispositions, must be approved by the appropriate Assistant Attorney General, the United States Attorney, or other designate responsible for the case. In joint or multi-district cases, the approving official should consult with other districts or divisions affected. If it is a national case, press conferences must be approved by the Director, Office of Public Affairs.

F. The use of displays or handouts in either press conferences or other media outreach when it involves a pending case or an investigation that may lead to an indictment requires separate and specific approval by the officials authorizing approval as set forth in section B.

G. All Department personnel must avoid any public oral or written statements or presentations that may violate any Department guideline or regulation, or any legal requirement or prohibitions, including case law and local court rules.

H. Particular care must be taken to avoid any statement or presentation that would prejudice the fairness of any subsequent legal proceeding. See also 28 C.F.R. 16.26(b). In cases where information is based directly or indirectly on tax records, care should be taken to comply with any applicable disclosure provisions in the Tax Reform Act, section 6103 of the Internal Revenue Code of 1986. The fact of conviction, sentences and guilty pleas may be reported in a press release based on information uttered in court as opposed to waiting for the publicly filed documents relating to the fact of conviction, plea or sentence. If you have any questions please contact the Tax Division. Special rules apply and should be closely followed to ensure that the identity of minors directly or indirectly is not revealed in juvenile proceedings.

I. For press releases or other public comment concerning the filing of a request for commutation of a federal death sentence or whether such a sentence

should be commuted, special rules apply. In clemency matters, the Department acts both as prosecutor and as advisor to the President on the issue of clemency. In order to ensure clarity about the role in which the Department is making a public comment and to ensure that there is no potential for infringement upon the President's prerogative in exercising his clemency powers or conflict in the Department's role in such matters, press releases or other comment to the press concerning the issue of clemency should be transmitted through the Office of Public Affairs to the Deputy Attorney General for final approval.

J. Prior to conducting a press conference or making comments on a pending investigation regarding another DOJ component, the U.S. Attorney shall coordinate any comments, including any written statements, with the affected component.

K. The Office of Inspector General is exempt from any approval requirement for media contacts. However, the Office of Inspector General should inform the Office of Public Affairs on public or other media issues.

[Added November 2003] [cited in USAM 1-7.401]

1-7.500 Release of Information in Criminal and Civil Matters— Non-Disclosure

At no time shall any component or personnel of the Department of Justice furnish any statement or information that he or she knows or reasonably should know will have a substantial likelihood of materially prejudicing an adjudicative proceeding.

1-7.520 Release of Information in Criminal and Civil Matters— Disclosable Information

Department personnel, subject to specific limitations imposed by law or court rule or order and consistent with the provisions of these guidelines, may make public the following information in any criminal case in which charges have been brought:

The defendant's name, age, residence, employment, marital status, and similar background information;

A. The substance of the charge, limited to that contained in the complaint, indictment, information, or other public documents;

B. The identity of the investigating and/or arresting agency and the length and scope of an investigation;

C. The circumstances immediately surrounding an arrest, including the time and place of arrest, resistance, pursuit, possession and use of weapons, and a description of physical items seized at the time of arrest. Any such disclosures shall not include subjective observations; and

Exhibit D

The NEW ENGLAND JOURNAL of MEDICINE

Vaccination with ALVAC and AIDSVAX to Prevent HIV-1 Infection in Thailand

Supachai Rerks-Ngarm, M.D., Punnee Pitisuttithum, M.D., D.T.M.H., Sorachai Nitayaphan, M.D., Ph.D., Jaranit Kaewkungwal, Ph.D., Joseph Chiu, M.D., Robert Paris, M.D., Nakorn Premsri, M.D., Chawetsan Namwat, M.D., Mark de Souza, Ph.D., Elizabeth Adams, M.D., Michael Benenson, M.D., Sanjay Gurunathan, M.D., Jim Tartaglia, Ph.D., John G. McNeil, M.D., Donald P. Francis, M.D., D.Sc., Donald Stablein, Ph.D., Deborah L. Birx, M.D., Supamit Chunsuttiwat, M.D., Chirasak Khamboonruang, M.D., Prasert Thongcharoen, M.D., Ph.D., Merlin L. Robb, M.D., Nelson L. Michael, M.D., Ph.D., Prayura Kunasol, M.D., and Jerome H. Kim, M.D., for the MOPH–TAVEG Investigators*

ABSTRACT

BACKGROUND

The development of a safe and effective vaccine against the human immunodeficiency virus type 1 (HIV-1) is critical to pandemic control.

METHODS

In a community-based, randomized, multicenter, double-blind, placebo-controlled efficacy trial, we evaluated four priming injections of a recombinant canarypox vector vaccine (ALVAC-HIV [vCP1521]) plus two booster injections of a recombinant glycoprotein 120 subunit vaccine (AIDSVAX B/E). The vaccine and placebo injections were administered to 16,402 healthy men and women between the ages of 18 and 30 years in Rayong and Chon Buri provinces in Thailand. The volunteers, primarily at heterosexual risk for HIV infection, were monitored for the coprimary end points: HIV-1 infection and early HIV-1 viremia, at the end of the 6-month vaccination series and every 6 months thereafter for 3 years.

RESULTS

In the intention-to-treat analysis involving 16,402 subjects, there was a trend toward the prevention of HIV-1 infection among the vaccine recipients, with a vaccine efficacy of 26.4% (95% confidence interval [CI], −4.0 to 47.9; P=0.08). In the per-protocol analysis involving 12,542 subjects, the vaccine efficacy was 26.2% (95% CI, −13.3 to 51.9; P=0.16). In the modified intention-to-treat analysis involving 16,395 subjects (with the exclusion of 7 subjects who were found to have had HIV-1 infection at baseline), the vaccine efficacy was 31.2% (95% CI, 1.1 to 51.2; P=0.04). Vaccination did not affect the degree of viremia or the CD4+ T-cell count in subjects in whom HIV-1 infection was subsequently diagnosed.

CONCLUSIONS

This ALVAC-HIV and AIDSVAX B/E vaccine regimen may reduce the risk of HIV infection in a community-based population with largely heterosexual risk. Vaccination did not affect the viral load or CD4+ count in subjects with HIV infection. Although the results show only a modest benefit, they offer insight for future research. (ClinicalTrials.gov number, NCT00223080.)

From the Department of Disease Control, Ministry of Public Health, Nonthaburi (S.R.-N., R.P., C.N., S.C., C.K., P.T., P.K.); Vaccine Trials Center (P.P.) and Data Management Unit (J.K.), Faculty of Tropical Medicine, Mahidol University, Bangkok; Thai Component (S.N.) and U.S. Army Medical Component (J.C., R.P., M.S., M.B.), Armed Forces Research Institute of Medical Sciences, Bangkok — all in Thailand; the Division of AIDS, National Institutes of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD (E.A.); Sanofi Pasteur, Swiftwater, PA (S.G., J.T., J.G.M.); Global Solutions for Infectious Diseases, South San Francisco, CA (D.P.F.); the Emmes Corporation, Rockville, MD (D.S.); the Global AIDS Program, Centers for Disease Control and Prevention, Atlanta (D.L.B); U.S. Military HIV Research Program, Walter Reed Army Institute of Research, Rockville, MD (M.L.R., N.L.M., J.H.K); and U.S. Army Medical Materiel Development Activity, Ft. Detrick, MD (J.H.K.). Address reprint requests to Dr. Kim at the U.S. Military HIV Research Program, Walter Reed Army Institute of Research, 1600 E. Gude Dr., Rockville, MD 20850, or at jkim@hivresearch.org.

*The names and affiliations of the Ministry of Public Health–Thai AIDS Vaccine Evaluation Group (MOPH–TAVEG) investigators are listed in the Appendix.

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In the late 1980s in Thailand, there was a dramatic increase in the prevalence of infection with the human immunodeficiency virus type 1 (HIV-1) in sentinel surveillance cohorts.[1-3] Initially, these groups consisted of injection-drug users and commercial sex workers; they were subsequently expanded to include persons in the general population. By 1995, the overall seroprevalence of HIV-1 reached a peak of 3.7% among conscripts in the Royal Thai Army and of 12.5% among conscripts from Northern Thailand.[2,4,5] The Thai Ministry of Public Health responded with an effective HIV-prevention campaign, and the number of new HIV-1 infections per year decreased from an estimated 143,000 in 1990 to 14,000 in 2007.[2,4,6-9] The persistence of new infection despite these measures led public health officials to conclude that an HIV vaccine, within the context of a broader HIV-prevention program, was needed for better control of the epidemic.

A number of trials of various subtype B canarypox–HIV vector primes and boosters containing subunit glycoprotein 120 or 160 (gp120 or gp160) established the prime–boost concept as a candidate for advanced testing.[10-13] Canarypox-based prime–boost regimens induced both cellular and humoral responses, but CD8+ responses on enzyme-linked immunosorbent spot (ELISPOT) assay were low,[12] and the presence of primary isolate neutralizing antibody was not consistently detected.[14-18]

A series of phase 1 and 2 trials of HIV vaccines involving more than 1000 Thai volunteers was undertaken, with products matching the circulating HIV-1 subtypes B and CRF01_AE.[8,17-22] Although a phase 3 trial of VaxGen bivalent gp120 AIDSVAX B/E vaccine alone involving injection-drug users showed no effect on HIV-1 acquisition,[21] a phase 2 trial of an ALVAC-HIV (vCP1521) prime with an AIDSVAX B/E boost showed induction of prespecified cellular and humoral immune responses and was consistent with criteria for advancement to a large test-of-concept study.[17] In October 2003, our study was initiated in a population at community risk for HIV infection.[8]

METHODS

STUDY DESIGN AND POPULATION

This study was a community-based, randomized, multicenter, double-blind, placebo-controlled efficacy trial of the prime–boost combination of vaccines containing ALVAC-HIV (vCP1521) (Sanofi Pasteur) and AIDSVAX B/E (Global Solutions for Infectious Diseases). For details regarding the vaccines and placebo, see the Supplementary Appendix, available with the full text of this article at NEJM.org. The study was designed to evaluate two coprimary end points: the prevention of HIV-1 infection and the effect of vaccination on the early viral load after infection. The trial was conducted through facilities of the Thai Ministry of Public Health in Rayong and Chon Buri provinces. From September 2003 through December 2005, a total of 16,402 volunteers were enrolled.

Thai men and women who were between the ages of 18 and 30 years and who were not infected with HIV were recruited from the community without regard to HIV risk (i.e., community risk). Written informed consent was obtained from all volunteers, who were required to pass a written test of understanding. Women were counseled to practice effective contraception until 3 months after the last vaccination; pregnant and breast-feeding women were excluded.

STUDY OVERSIGHT

The protocol was reviewed by the ethics committees of the Ministry of Public Health, the Royal Thai Army, Mahidol University, and the Human Subjects Research Review Board of the U.S. Army Medical Research and Materiel Command. It was also independently reviewed and endorsed by the World Health Organization and the Joint United Nations Program on HIV/AIDS and by the AIDS Vaccine Research Working Group of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. The manufacturers were full trial collaborators and were a part of the phase 3 trial steering committee.

STUDY PROCEDURES

The study vaccines were administered at baseline (day 0), 4 weeks (prespecified range, 3 to 7), 12 weeks (range, 10 to 15), and 24 weeks (range, 21 to 28). The ALVAC-HIV (vCP1521) vaccine was administered at each of the four visits. Boosting with AIDSVAX B/E occurred at weeks 12 and 24. For 3 days after each dose of vaccine, subjects reported local and systemic vaccine reactions on a diary card. All other adverse and serious adverse events were documented at each visit and were graded on a scale that is used for rating adverse events associated with vaccines, as recommended by the Division of Acquired Immunodeficiency

Syndrome of the National Institute of Allergy and Infectious Diseases (http://rcc.tech-res.com/safetyandpharmacovigilance). All subjects who underwent randomization were included in the safety analysis.

Women underwent urine testing for pregnancy throughout the vaccination phase. Pregnant volunteers did not receive further vaccinations. All volunteers were followed with the use of HIV testing at day 0, at 24 and 26 weeks, and every 6 months during the 3-year follow-up phase. Peripheral-blood mononuclear cells were isolated and archived in liquid nitrogen at 0, 6, 12, and 42 months. Assessment of behavior associated with an increased risk of HIV infection occurred at baseline, at week 26, and at each 6-month follow-up visit. HIV-prevention counseling was provided during each vaccination and post-test counseling visit.

PRIMARY END POINTS

We established the presence of HIV infection on the basis of repeated positive results on enzyme immunoassay and Western blotting, with two confirmatory HIV nucleic acid tests: the Amplicor HIV Monitor (version 1.5) assay (Roche) in Thailand and the Procleix HIV discriminatory assay (Novartis) in the United States. We performed three measurements of HIV-1 RNA within 6 weeks after serodiagnosis to determine the mean postinfection viral load. Infection time was defined as the midpoint between the last negative result and the first positive result of testing. An independent endpoints monitoring committee whose members were unaware of study-group assignments verified the accuracy of all diagnoses.

ASSESSMENT OF RISK

We assessed subjects' risk of HIV infection using a self-administered behavioral questionnaire at baseline and every 6 months thereafter. First, volunteers categorized themselves as being at high, moderate, or low risk for HIV infection. A second approach categorized subjects as being at high risk if they reported being at high risk or reported any high-risk behavior (e.g., needle sharing, multiple sex partners, commercial sex work, and symptoms of sexually transmitted disease). Volunteers were considered to be at low risk if they perceived their risk as low; if they reported that in the previous 6 months they had had no more than one sex partner and no sexual contact with a commercial sex worker, a partner of the same sex, an HIV-infected partner, a partner who used injection drugs, or a partner who had multiple partners; and if they reported having had no symptoms of a sexually transmitted disease or incarceration within 6 months before study entry. Moderate-risk subjects were considered to be at neither low nor high risk.

IMMUNOGENICITY ANALYSES

We analyzed plasma and cells from volunteers who did not have HIV infection at various time points after vaccination to evaluate immunogenicity. After removal of a small subgroup of samples for future matched case–control studies, we identified random samples and provided them in a blinded fashion to the Armed Forces Research Institute of Medical Sciences laboratory at a ratio of samples from the vaccine group to samples from the placebo group of approximately 4:1. The immunogenicity of the vaccine regimen was measured with the use of the following validated assays: interferon-γ ELISPOT and CD4+ and CD8+ intracellular cytokine staining for interferon-γ and interleukin-2 to Gag and Env; binding antibody to gp120 in the MN strain, gp120 in the A244 strain (CM244), and p24 Gag; and lymphoproliferation to gp120 MN, gp120 A244, and p24 (for details, see the Supplementary Appendix).[17,18,22-25]

STATISTICAL ANALYSIS

According to the study protocol, we conducted both intention-to-treat and per-protocol analyses. The intention-to-treat analysis included all subjects who underwent randomization. Because of the time between screening and vaccination and the possibility of acquiring HIV-1 infection during this interval, the protocol specified look-back testing of baseline plasma for HIV-1 RNA if the sample that was collected on the day of the fourth vaccination was HIV-seropositive. Seven persons who were enrolled and vaccinated were found to be positive for HIV-1 RNA at baseline. The per-protocol analysis included a subgroup of subjects in the intention-to-treat analysis who received the entire series of vaccinations within the defined time period, who remained eligible to participate in the study, and who did not have HIV infection at the time of the fourth vaccination. A separate subgroup analysis, called the modified intention-to-treat analysis, excluded the seven volunteers who were found to have HIV infection at baseline. This was used as the primary analysis

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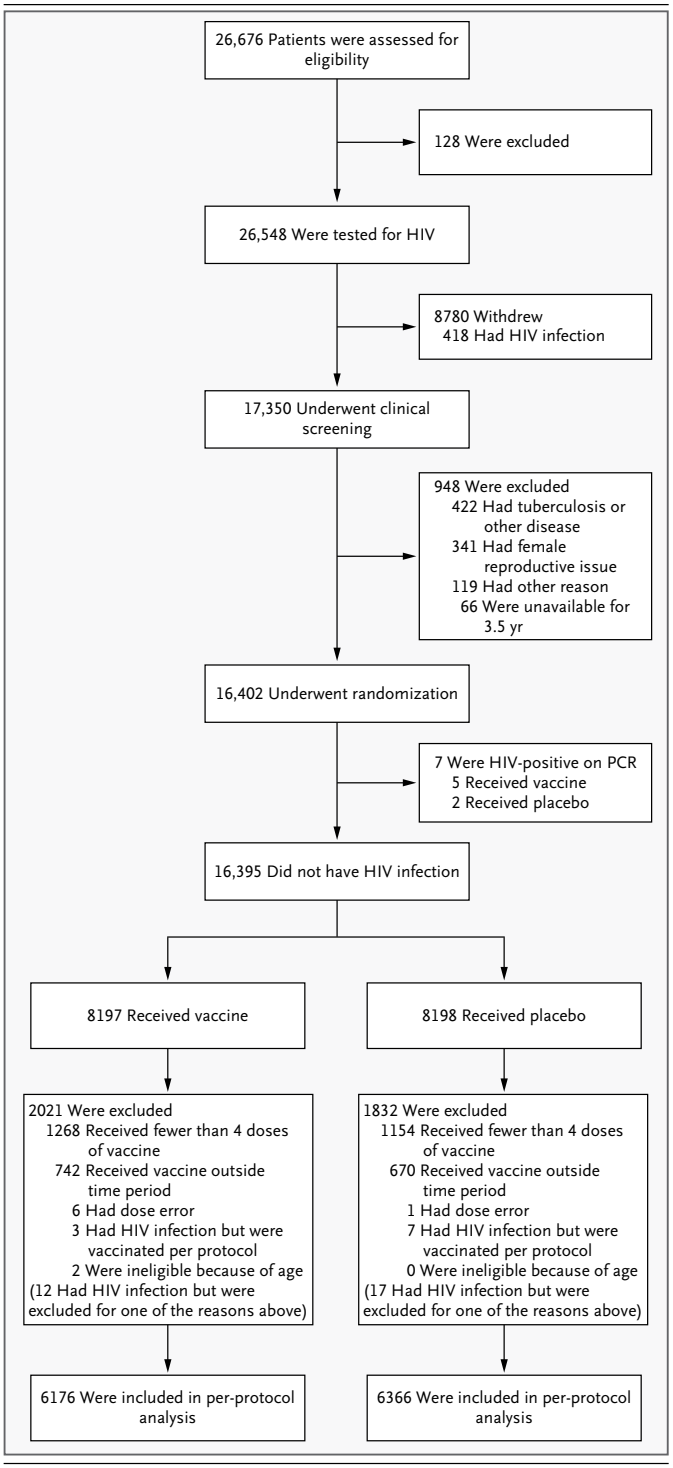

Figure 1. Enrollment and Outcomes.

During the course of the study, there were 15 HIV-1 infections in the vaccine group and 24 in the placebo group that were excluded from the final analysis. This left 12,542 volunteers (6176 in the vaccine group and 6366 in the placebo group) who received all four doses of vaccine within the prespecified time period, who were not excluded for the other reasons, and who did not have HIV-1 infection at visit 7 (per-protocol population).

at the time of the interim and final analyses and was prespecified in the final data-analysis plan that was approved 5 months before the unblinding of the study. (For details regarding the sample size calculation, randomization procedures, and calculation of vaccine efficacy, see the Supplementary Appendix.)

After the initiation of the trial, the effect of vaccination on early viral load was included as a coprimary end point, and the mean postinfection viral load was compared between vaccine and placebo recipients at the 1% level with the Wilcoxon statistic. The effect of selection bias was considered.[26]

The trial was monitored by an independent, international data and safety monitoring board, which met every 6 to 12 months (eight times during the trial) and reviewed the trial for safety and futility. At the interim analysis, the trial was reviewed for efficacy, safety, and futility. Statistical futility for the acquisition end point was examined with a trigger for early termination if the conditional power was less than 10%. All reported P values are two-tailed and have not been adjusted for multiple testing. A P value of less than 0.05 was considered to indicate statistical significance.

RESULTS

STUDY POPULATION

A total of 26,676 volunteers were screened and 16,402 were enrolled (intention-to-treat group) (Fig. 1). The 12,542 subjects who completed all vaccination visits on schedule and were not found to have HIV-1 infection after receiving the full vaccination regimen were included in the per-protocol analysis. Seven volunteers who were found to

Table 1. Baseline Characteristics of the Subjects (Modified Intention-to-Treat Population).

Variable	Vaccine (N=8197)	Placebo (N=8198)	All Subjects (N=16,395)
		number (percent)	
Sex			
Male	5033 (61.4)	5031 (61.4)	10,064 (61.4)
Female	3164 (38.6)	3167 (38.6)	6,331 (38.6)
Age group			
≤20 yr	2297 (28.0)	2246 (27.4)	4,543 (27.7)
21–25 yr	3633 (44.3)	3708 (45.2)	7,341 (44.8)
≥26 yr	2267 (27.7)	2244 (27.4)	4,511 (27.5)
Province			
Chon Buri	4107 (50.1)	4107 (50.1)	8,214 (50.1)
Rayong	4090 (49.9)	4091 (49.9)	8,181 (49.9)
Marital status			
Single	3353 (40.9)	3338 (40.7)	6,691 (40.8)
Married	4110 (50.1)	4169 (50.9)	8,279 (50.5)
Divorced	602 (7.3)	541 (6.6)	1,143 (7.0)
Widowed	50 (0.6)	64 (0.8)	114 (0.7)
Separated	82 (1.0)	86 (1.0)	168 (1.0)
No. of sex partners			
0	1864 (22.7)	1801 (22.0)	3,665 (22.4)
1	5428 (66.2)	5495 (67.0)	10,923 (66.6)
>1	619 (7.6)	620 (7.6)	1,239 (7.6)
Did not answer	280 (3.4)	273 (3.3)	553 (3.4)
Missing data	6 (0.1)	9 (0.1)	15 (0.1)
Risk group			
Low	3865 (47.2)	3924 (47.9)	7,789 (47.5)
Medium	2369 (28.9)	2292 (28.0)	4,661 (28.4)
High	1963 (23.9)	1982 (24.2)	3,945 (24.1)
Behavioral risk			
Needle sharing	68 (0.8)	65 (0.8)	133 (0.8)
No condom use			
With casual partner	497 (6.1)	439 (5.4)	936 (5.7)
With commercial sex worker	33 (0.4)	29 (0.4)	62 (0.4)
With same-sex partner	79 (1.0)	90 (1.1)	169 (1.0)
With HIV-infected partner	16 (0.2)	13 (0.2)	29 (0.2)
With partner who injects drugs	12 (0.1)	6 (0.1)	18 (0.1)
With multiple sex partners	128 (1.6)	130 (1.6)	258 (1.6)
Condom use with HIV-infected partner	113 (1.4)	114 (1.4)	227 (1.4)
Symptoms of an STD within past 6 mo*	246 (3.0)	233 (2.8)	479 (2.9)
Drug injection in jail	23 (0.3)	15 (0.2)	38 (0.2)
Occupation as a commercial sex worker	42 (0.5)	44 (0.5)	86 (0.5)
Occupation in the entertainment business	233 (2.8)	237 (2.9)	470 (2.9)

* STD denotes sexually transmitted disease.

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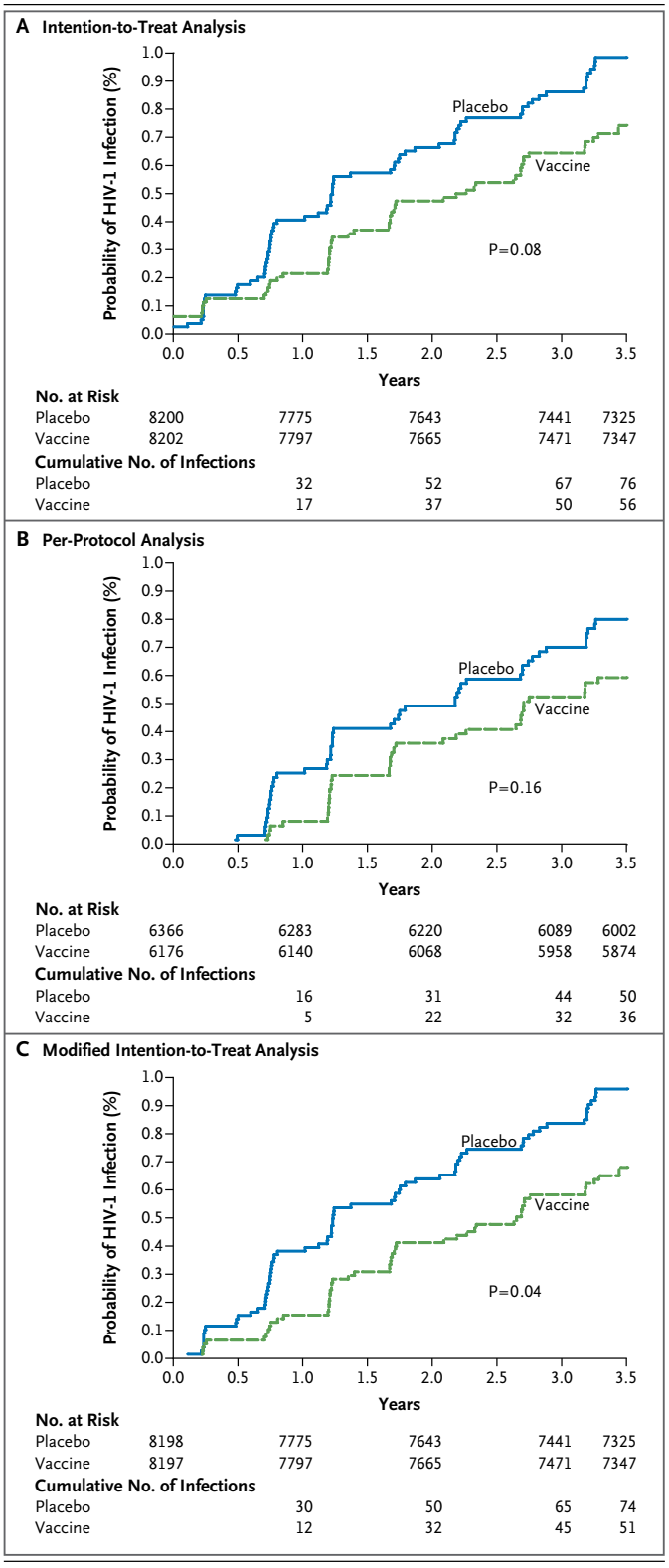

Figure 2. Kaplan–Meier Cumulative Rates of Infection, According to Type of Analysis.

The vaccination regimen was completed approximately 6 months after the first dose was administered. In the intention-to-treat analysis involving 16,402 subjects, the vaccine efficacy was 26.4% (95% confidence interval [CI], −4.0 to 47.9; P=0.08) (Panel A). In the per-protocol analysis involving 12,542 subjects, the vaccine efficacy was 26.2% (95% CI, −13.3 to 51.9; P=0.16) (Panel B). In the modified intention-to-treat analysis involving 16,395 subjects (excluding 7 subjects who were found to have had HIV infection at baseline), the vaccine efficacy was 31.2% (95% CI, 1.1 to 51.2; P=0.04) (Panel C).

be seropositive for HIV-1 on the first test after vaccination were determined by RNA testing to have been infected at enrollment and were not included in the modified intention-to-treat analysis, leaving 16,395 volunteers: 8197 in the vaccine group and 8198 in the placebo group. This group consisted of 10,064 men (61.4% of the subjects) and 6331 women (38.6%). Baseline characteristics were similar for selected variables, and there was no imbalance between the two groups in self-described risk behavior (Table 1).

There were no substantive changes in serial self-reports of risk behavior during the trial. No data were collected on the status of male circumcision or on serologic analyses for adenovirus type 5 or herpes simplex virus type 2.

There were 52,985 person-years of follow-up (15% more than planned). At 42 months, 14,672 of the volunteers (89.5%) had completed the trial and were HIV-seronegative.

ADVERSE EVENTS

Most local and systemic reactions to the vaccine were mild to moderate and reflected the findings of studies on the safety of these products that have been reported previously[12,17,27-29] (Fig. 1 in the Supplementary Appendix). Most reactions were mild to moderate and resolved within 3 days after vaccination. At least one adverse event was reported in 69.4% of subjects in the two study groups. The number of deaths and the frequency and severity of adverse events and serious adverse events were similar in the two groups (Table 1 in the Supplementary Appendix).

PRIMARY END POINTS

HIV-1 Infection

HIV-1 infection was diagnosed in 132 subjects (56 in the vaccine group and 76 in the placebo

Table 2. Rate of HIV Infection and Vaccine Efficacy, According to Selected Baseline Variables (Modified Intention-to-Treat Population).

Variable	Vaccine (N=8197)				Placebo (N=8198)				Vaccine Efficacy
	No. Evaluated	No. with Infection	No. of Person-Years	Rate	No. Evaluated	No. with Infection	No. of Person-Years	Rate	
				no./person-yr				*no./person-yr*	*% (95% CI)*
All subjects	7960	51	26,507	0.192	7988	74	26,478	0.279	31.2 (1.7 to 51.8)
Sex									
Male	4875	32	16,221	0.197	4885	43	16,179	0.266	25.8 (–17.3 to 53.0)
Female	3085	19	10,286	0.185	3103	31	10,300	0.301	38.6 (–8.6 to 65.3)
Age group									
≤20 yr	2228	12	7,358	0.163	2185	11	7,216	0.152	7.1 (–143.0 to 52.7)
21–25 yr	3517	20	11,713	0.171	3610	40	11,946	0.335	49 (12.8 to 70.2)
≥26 yr	2215	19	7,437	0.255	2193	23	7,316	0.314	18.7 (–49.3 to 55.7)
Living with partner									
Yes	4017	19	13,466	0.141	4083	34	13,612	0.25	43.5 (1.0 to 67.8)
No	3943	32	13,041	0.245	3905	40	12,866	0.311	21 (–25.7 to 50.4)
Risk group									
Low	3767	17	12,565	0.135	3837	29	12,798	0.227	40.4 (–8.5 to 67.2)
Medium	2297	12	7,642	0.157	2222	22	7,353	0.299	47.6 (–6.0 to 74.0)
High	1896	22	6,300	0.349	1929	23	6,327	0.364	3.7 (–72.7 to 46.3)

group) during 52,985 person-years of follow-up in the intention-to-treat analysis, in 86 subjects (36 in the vaccine group and 50 in the placebo group) during 36,720 person-years of follow-up in the per-protocol analysis, and in 125 subjects (51 in the vaccine group and 74 in the placebo group) during 52,985 person-years of follow-up in the modified intention-to-treat analysis. One subject in the placebo group who was identified by hospital record as being seropositive for HIV after dying from *Pneumocystis jirovecii* pneumonia was included in the analysis before the unblinding of the study. This diagnosis of HIV-1 infection was the only one that occurred outside planned procedures.

With the use of the Cox proportional-hazards method, the observed vaccine efficacy was 26.4% (95% confidence interval [CI], −4.0 to 47.9; P=0.08) in the intention-to-treat analysis (Fig. 2A); 26.2% (95% CI, −13.3 to 51.9; P=0.16) in the per-protocol analysis (Fig. 2B); and 31.2% (95% CI, 1.1 to 52.1; P=0.04 by the O'Brien–Fleming method) in the modified intention-to-treat analysis (Fig. 2C). Because HIV testing was done at week 24, it is not possible to discern which dose of vaccine might have been associated with an early effect. The overall observed effect in the modified intention-to-treat analysis was evaluated with the use of several different analyses: event rates by Barnard's test (P=0.04), the log-rank test (P=0.04), the Wilcoxon test (P=0.03), modification of the time-to-seroconversion end point (P=0.04), exclusion of the in-hospital diagnosed case (P=0.05), and analysis of interval-censored data (P=0.04).

Covariates were analyzed for the populations with similar results. Simultaneous adjustment for sex, age, living with a partner, and baseline risk factors did not affect estimates of vaccine efficacy, even though between-group differences in age, living with a partner, and baseline risk factors were significant. Subgroup analyses revealed no significant heterogeneity in vaccine efficacy according to baseline variables (Table 2).

There were 86 HIV-1 infections in the per-protocol population and 125 infections in the modified intention-to-treat population. There were three categories into which the 39 subjects with HIV-1 infection who were excluded from the per-protocol population could be organized: 10 subjects (3 in the vaccine group and 7 in the placebo group) were infected during the vaccination phase and received all vaccinations on schedule; 10 subjects (3 in the vaccine group and 7 in

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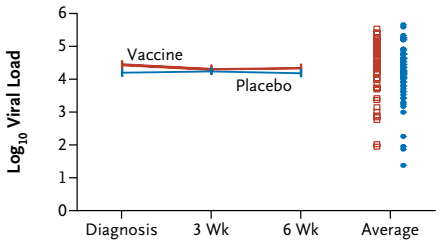

Figure 3. Viral Loads in Subjects with Early HIV-1 Infection.

The receipt of vaccine did not have a significant effect on the viral load in subjects who were found to have early HIV-1 infection. On the left are the mean $\log_{10}$ viral loads at three visits during a 6-week period for subjects who were included in the intention-to-treat analysis. The data points at the right show the distribution of viral loads in the vaccine group (mean, 4.36 $\log_{10}$ copies per milliliter) and the placebo group (mean, 4.21 $\log_{10}$ copies per milliliter) (P=0.09). There was no significant between-group difference in viral load in either the per-protocol analysis (P=0.47) or the modified intention-to-treat analysis (P=0.24).

the placebo group) were infected after the vaccination phase and received all vaccinations, but one or more vaccinations were not administered during the prespecified window; and 19 subjects (9 in the vaccine group and 10 in the placebo group) were infected after the vaccination phase but did not receive all vaccinations.

Postinfection Viral Load and CD4+ T-Cell Count

There was no significant difference in the mean viral load among subjects who were found to have HIV infection in the vaccine group, as compared with those in the placebo group. The mean viral-load values were 4.36 $\log_{10}$ copies per milliliter in the vaccine group and 4.21 $\log_{10}$ copies per milliliter in the placebo group (P=0.09 by the Wilcoxon test) in the intention-to-treat analysis (Fig. 3). The viral-load values were 4.24 $\log_{10}$ copies per milliliter in the vaccine group and 4.19 $\log_{10}$ copies per milliliter in the placebo group in the per-protocol analysis (P=0.47) and 4.30 $\log_{10}$ copies per milliliter and 4.20 $\log_{10}$ copies per milliliter, respectively, in the modified intention-to-treat analysis (P=0.24).

In all three analyses, there were no significant between-group differences in postinfection CD4+ T-cell counts. The mean early postinfection CD4+ T-cell count was 541 cells per microliter in the vaccine group and 568 cells per microliter in the placebo group in the intention-to-treat analysis (P=0.47 by the Wilcoxon test), 572 cells per microliter in the vaccine group and 532 cells per microliter in the placebo group in the per-protocol analysis (P=0.72), and 555 cells per microliter in the vaccine group and 568 cells per microliter in the placebo group in the modified intention-to-treat analysis (P=0.76).

IMMUNOGENICITY

Vaccination induced an HIV-specific response, as measured by the production of interferon-γ by T cells when exposed to either Env or Gag antigen on ELISPOT assay, in 19.7% of volunteers 6 months after the final dose of vaccine was administered (Table 3 and the Supplementary Appendix). This result was similar to the rate of 17% in the phase 2 trial (de Souza MS: personal communication). Response rates for CD4+ Env-specific intracellular cytokine staining were higher in the vaccine group than in the placebo group. Rates of positivity in the gp120 and p24 binding-antibody assays and the lymphoproliferation assay were similar to those in the phase 2 study.[17] Binding antibody for Env was nearly uniformly present, with the reciprocal of the geometric mean titer (GMT^{-1}) of 31,207 for the MN strain and 14,558 for the A244 strain, whereas p24 responses were less frequent (GMT^{-1}, 138) (for details, see the Supplementary Appendix). The median lymphocyte stimulation index (LSI) was 2 for all subjects at baseline and subsequently in placebo recipients. The LSI was significantly higher in vaccine recipients (median LSI, 24 for gp120 MN, 32 for A244, and 4 for p24).

DISCUSSION

In this clinical trial, we evaluated the efficacy of ALVAC-HIV priming and AIDSVAX B/E boosting for the prevention of HIV-1 infection in more than 16,000 young Thai adults at community risk for such infection. In the intention-to-treat group (which included seven subjects who were found to have had HIV-1 infection at baseline), there was a trend toward prevention of infection with the vaccine regimen. In the per-protocol analysis, which excluded 30% of the end points and person-years of follow-up, the results were not significant. However, after the exclusion of the subjects who were infected with HIV-1 before vaccination, the modified intention-to-treat analysis showed a significant, though modest, reduc-

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Table 3. Immunogenicity Analyses at Baseline and 12 Months.*

Assay and Antigen	Baseline	12 Months	
		Vaccine	Placebo
	no. positive/total no. (%)	*no. positive/total no. (%)*	*no. positive/total no. (%)*
ELISPOT			
Gag	7/194 (3.6)	13/156 (8.3)	3/41 (7.3)
Env	7/198 (3.5)	25/157 (15.9)	3/41 (7.3)
Gag or Env	8/198 (4.0)	31/157 (19.7)	3/41 (7.3)
Intracellular cytokine staining			
CD8 Gag	11/200 (5.5)	11/144 (7.6)	4/56 (7.1)
CD8 Env	15/200 (7.5)	16/144 (11.1)	8/56 (14.3)
CD4 Gag	0/200	2/144 (1.4)	0/56
CD4 Env	4/200 (2.0)	49/144 (34.0)†	2/56 (3.6)
Binding antibody‡			
gp120 MN	8/200 (4.0)	140/142 (98.6)†	0/58
gp120 A244	1/200 (0.5)	140/142 (98.6)†	0/58
p24	2/200 (1.0)	74/142 (52.1)†	0/58
Lymphoproliferation‡§			
gp120 MN	23/96 (24.0)	62/71 (87.3)†	5/25 (20.0)
gp120 A244	12/96 (12.5)	64/71 (90.1)†	4/25 (16.0)
p24	19/96 (19.8)	35/71 (49.3)¶	4/25 (16.0)

* All analyses were performed on samples collected at baseline (visit 1) and at 12 months (visit 9), unless otherwise specified.
† P<0.001 for the between-group comparison.
‡ These analyses were performed at 6.5 months (visit 8), 2 weeks after the administration of the fourth dose of vaccine.
§ Lymphoproliferation was measured with the use of the lymphocyte stimulation index (LSI). Values are for subjects who had an LSI of 5 or more.
¶ P=0.001 for the between-group comparison.

tion in the rate of HIV-1 infection, as compared with placebo.

Taken together, these data are consistent with a modest protective effect of vaccine in this study. However, there was no significant difference in the HIV-1 viral load or the postinfection CD4+ count between the two study groups. A simple, combined analysis of phase 1 and 2 ALVAC-HIV and gp120 prime–boost studies showed a rate of HIV-1 infection of 0.59 per 100 person-years in the vaccine group and 1.2 per 100 person-years in the placebo group, for a vaccine efficacy of 50% (95% CI, −39 to 80), a difference that was not significant; the results also showed no effect on viral load.[30] In nonhuman primates, ALVAC-SIV appeared to protect neonatal macaques against infection from milk containing a low dose of simian immunodeficiency virus (SIV).[31] However, ALVAC-SIV did not prevent infection from a more intense challenge exposure, although it did reduce the viral load and delay disease progression.[32,33]

Our trial did not have sufficient power to determine whether there was an effect of risk stratification on either disease acquisition or vaccine efficacy, and none of the observed heterogeneity achieved significance. Previous efficacy trials of HIV vaccines in higher-risk populations have not shown an effect on disease acquisition. Bivalent subtype B AIDSVAX B/B gp120 did not protect high-risk men who have sex with men,[34-36] and AIDSVAX B/E did not protect Thai injection-drug users[21] from infection with HIV-1. The Step trial of Merck recombinant adenovirus type 5 (rAd5) HIV-1 vaccine containing subtype B *gag*, *pol*, and *nef* in high-risk men who have sex with men was stopped because of futility and possibly higher rates of infection in vaccine recipients.[37]

An immunologic correlate with protection from HIV-1 infection has not been determined at this time. Though early studies of canarypox–gp120 subunit prime–boost regimens were promising,[10-13] advanced-phase testing of subtype B ALVAC-HIV (vCP1452) and AIDSVAX B/B was can-

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celed because CD8+ reactivity on ELISPOT was too low.[12] The vaccines that were used in our trial showed a level of immunogenicity that was similar to levels reported previously.[17] Additional studies with the use of more recently developed immunogenicity assays are planned in order to determine their suitability for correlates analyses.[38-41] Further insight may be gained through molecular-sieve analysis of breakthrough infections with the use of single-genome amplification.[42]

Although our study provided preliminary evidence that an HIV vaccine regimen has the potential to prevent infection, it did not have the power to address two intriguing considerations: vaccine efficacy may have decreased over the first year after vaccination, and vaccine efficacy may have been greater in persons at lower risk for infection (Fig. 2 and Table 2). These issues deserve greater attention in future studies. We do not understand the immune mechanisms mediating the results that we observed. The ALVAC-HIV and AIDSVAX B/E prime–boost regimen induces a broad constellation of immune responses against HIV-1, including T-cell–line adapted neutralizing antibody (71% with response), antibody-directed, cell-mediated cytotoxicity, CD4+ lymphoproliferation (61% with response to gp20 MN, 63% with response to gp120 CM244), and CD8+ T cells (24% with response to ^{51}Cr-release cytotoxic T-cell assay; 17% with positive response on ELISPOT),[17,33,43] but these may not be the relevant responses. Understanding the potential immunologic correlates of protection will be a principal research focus. The data also do not answer the related question of whether it was a single vaccine or the combination of vaccines that induced a potentially protective immune response. Previous studies have suggested that prime–boost combinations induce qualitative or quantitative protective immune responses that are not seen with either vaccine alone, but the current data do not address this question.[28,44]

Finally, our study supports the possibility that immunologic mechanisms mediating protection against HIV may be different from those mediating early postinfection control of viral replication.[45,46] Taken together, these considerations underscore the opportunities afforded by the efficacy testing of HIV vaccines in human subjects in providing an objective context for review of existing methods of vaccine design, immunogenicity testing, and animal models.

Supported in part by an Interagency Agreement (Y1-AI-2642-12) between the U.S. Army Medical Research and Materiel Command and the National Institute of Allergy and Infectious Diseases and by a cooperative agreement (W81XWH-07-2-0067) between the Henry M. Jackson Foundation for the Advancement of Military Medicine and the U.S. Department of Defense. Sanofi Pasteur provided the ALVAC-HIV vaccine, and Global Solutions for Infectious Diseases (VaxGen) provided the reagents for the immunogenicity assays.

Drs. Gurunathan, Tartaglia, and McNeil report being employees of Sanofi Pasteur, and Dr. Tartaglia reports having an equity interest in the company. No other potential conflict of interest relevant to this article was reported.

The opinions expressed in this article are those of the authors and do not represent the official views of the Department of Health and Human Services, the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention, the Department of Defense, or Department of the Army.

We thank the volunteers who participated in this study and staff members of the Ministry of Public Health at health centers in Rayong, Chon Buri, and surrounding provinces.

APPENDIX

The following investigators and institutions participated in the MOPH-TAVEG study: **Ministry of Public Health, Thailand:** S. Rerks-Ngarm, S. Chunsuttiwat, N. Premsri, C. Namwat, P. Kunasol, P. Thongcharoen, C. Khamboonruang; **Vaccine Trials Center, Mahidol University:** P. Pitisuttithum, V. Bussaratid, W. Maek-a-nantawat, J. Dhitavat, P. Suntharasamai, S. Pungpak, S. Vanijanonta; **Data Management Unit, Mahidol University:** J. Kaewkunwal, A. Khamsiriwatchara, P. Jarujareet; **Royal Thai Army, Armed Forces Research Institute of Medical Sciences:** S. Nitayaphan, C. Easmila, S, Tabprasit; **U.S. Army Component, Armed Forces Research Institute of Medical Sciences:** J. Chiu, R. Paris, M. Benenson, A. Brown, P. Morgan, M. de Souza, R. Trichavaroj, A. Schuetz, N. Thaitawat; **Sanofi Pasteur:** S. Gurunathan, J. Tartaglia, J.G. McNeil, R. Harkness, C. Meric, R. El Habib, L. Baglyos; **Global Solutions in Infectious Diseases:** D. Francis, C. Lee; **National Institute of Allergy and Infectious Diseases:** E. Adams; **U.S. Military HIV Research Program, Walter Reed Army Institute of Research and U.S. Army Medical Materiel Development Agency, U.S. Army Medical Research and Materiel Command:** J.H. Kim, M.L. Robb, N.L. Michael, M. Milazzo, A. Bolen, B. Wessner, S.R. Kim, M. Marovich, J. Currier; **Global AIDS Program, Centers for Disease Control and Prevention:** D.L. Birx; **Emmes Corporation:** D. Stablein, T. Germanson, L. Dally; **SHI Consulting:** R. Wiley; **International AIDS Vaccine Initiative:** Dr. Jean-Louis Excler; **Tripler Army Medical Center:** Dr. Jeffrey Berenberg.

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EXHIBIT 6

U.S. Department of Justice

Executive Office for United States Attorneys

Office of the Director

Room 2261, RFK Main Justice Building
950 Pennsylvania Avenue, NW
Washington, DC 20530

(202) 514-2121

JUL - 2 2010

Mark E. Haddad, Esq.
Sidley Austin LLP
555 West Fifth Street
Los Angeles, CA 90013

Dear Mr. Haddad:

This responds to your letter dated April 20, 2010, to the United States Attorney for the Northern District of California, concerning your client's Request for Reconsideration under the Department of Justice's Information Quality Guidelines.

As set forth in my letter dated March 15, 2010, the guidelines do not apply because the statement of which you complain was disseminated in a press release. While the guidelines acknowledge that DOJ disseminates information through various sources, including press releases, the guidelines explicitly state that "[n]ot all of this information falls within these guidelines." The exceptions to the guidelines include "press releases ... that announce, support or give public notice of information in DOJ." Your claim that the press release at issue does not fall within this exception because it does not give notice of public information in DOJ is not a reasonable interpretation of such language. One of the primary functions of the Department of Justice is to prosecute violations of federal law. Accordingly, a press release that announces a successful prosecution is clearly public information in the Department of Justice.

Similarly, your argument that the guidelines do not apply because the disputed statement was not limited to a press release, but was disseminated on the Department's website, is also unavailing. The method by which the Department issued the press release is irrelevant. The guidelines make no distinction between a press release that is posted on the Internet and one that is issued any other way (e.g., fax or mail). Rather, it is the very fact that the information is contained in a press release that exempts it from the guidelines.

Because the guidelines do not apply to press releases, the Department was not required to respond substantively to your initial request for a retraction. The guidelines provide that "[t]he Department need not respond substantively ... to requests [for correction] that concern information not covered by the guidelines." As your request for reconsideration relies on the guidelines, your request is misplaced and cannot be accommodated.

Thank you for raising your concerns with the Department.

Sincerely,

H. Marshall Jarrett
Director

cc: Brian Stretch
Acting United States Attorney
Northern District of California

EXHIBIT 7

Pages 1 - 48

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL, JUDGE

UNITED STATES OF AMERICA, Plaintiff, vs. W. SCOTT HARKONEN, Defendant.	No. CR-08-0164 MHP San Francisco, California Monday, November 15, 2010

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF:

OFFICE OF CONSUMER LITIGATION
U.S. DEPARTMENT OF JUSTICE
450 5TH STREET, NW,
6TH FLOOR SOUTH
WASHINGTON D.C., 20001

BY: Allan Gordus, Attorney at Law

UNITED STATES ATTORNEY'S OFFICE
450 GOLDEN GATE AVE., 11TH FLOOR
SAN FRANCISCO, CALIFORNIA 94102

BY: Kyle Waldinger, Attorney at Law

(FURTHER APPEARANCES ON NEXT PAGE.)

REPORTED BY: SARAH L. GOEKLER, CSR NO. 13446
Computerized Technology By Eclipse

FURTHER APPEARANCES: (CONT'D)

SIDLEY AUSTIN BROWN & WOOD
555 WEST FIFTH STREET, SUITE 4000
LOS ANGELES, CALIFORNIA 90013

BY: **Mark E. Haddad, Attorney at Law**
Douglas A. Axel, Attorney at Law
Robert B. Martin, III,
Attorney at Law

applications or whatever.

MR. HADDAD: Well, I would say that whether this case involves the falsification of data as opposed to the inferences to be drawn from data, that's a very important distinction, and it's not drawn in the presentence report, so -- and I think that Dr. Goodman and Dr. Rubin helped the Court make the correct analysis there. So that's a factual issue for the Court's resolution.

MR. GORDUS: Your Honor --

THE COURT: What do you have to say with respect to that?

MR. GORDUS: Just on those two issues --

THE COURT: Just on Dr. Goodman and Dr. Rubin -- are they both doctors? I forget. There's so many doctors in this case.

MR. HADDAD: I would distinguish medical doctors so --

THE COURT: Rubin is not a medical doctor?

MR. HADDAD: Rubin is not a medical doctor.

THE COURT: I apologize to them in absentia for just using the last names, but with respect to Goodman and Rubin, what do you have to say about them? What is your response?

MR. GORDUS: With respect -- Mr. Haddad just mentioned these two witnesses would speak to the falsification of data versus the falsification of inferences that can be made

from the data, and we would agree. The Government has always agreed that there was no falsification of data here, so that fact is not in dispute, and there's no need to have anyone testify on that.

With respect to whether there was a falsification of the conclusions that could be drawn from the data, that was what the trial was all about. That was the central issue in the trial, and that is what the statisticians were extensively cross-examined on, and everything that's in the declarations of Dr. Rubin and Dr. Goodman was at play at trial and defense counsel went over that extensively. We have a record. If they want to supplement it with declarations, that's just fine, but we don't see a need to call them as witnesses.

THE COURT: Or to cross-examine?

MR. GORDUS: Exactly, Your Honor.

MR. HADDAD: Your Honor, I suggest that if the Court would have let those declarations stand, it is very difficult to see how any significant further punishment would be warranted, and I think if the Court has the opportunity to carefully review those declarations, it will see that with the full sentencing record that's now before the Court there would be profound reason to question whether, you know, there's a basis to find that one could not draw reasonably the inference that we're drawing here.

So even though that testimony was not available to

EXHIBIT 8

Pages 1 - 172

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL, JUDGE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	NO. CR 08-00164 MHP
	)	
W. SCOTT HARKONEN,	)	
	)	
Defendant.	)	
	)	

San Francisco, California
Wednesday, April 13, 2011

TRANSCRIPT OF SENTENCING PROCEEDINGS

APPEARANCES:

For Plaintiff:

MELINDA L. HAAG, ESQ.
United States Attorney
450 Golden Gate Avenue
San Francisco, California 94102

BY: **KYLE WALDINGER**
Assistant United States Attorney

U.S. Department of Justice
Office of Consumer Litigation
450 Fifth Street, N.W.
Suite 6400-South
Washington, D.C. 20001

BY: **ALLAN GORDUS**
Trial Attorney

(Appearances continued on following page.)

Reported By: Leo T. Mankiewicz, CSR 5297, RMR, CRR

APPEARANCES: (cont.)

For Defendant:

Sidley Austin, LLP
555 West Fifth Street, Suite 4000
Los Angeles, California 90013-1010
BY: **MARK E. HADDAD**
DOUGLAS A. AXEL
Attorney at Law

Sidley Austin, LLP
555 California Street
San Francisco, California 94104
BY: **ROBERT BROOKS MARTIN III**
R. VAN SWEARINGEN

Kish & Lietz, P.C.
225 Peachtree Street
1700 South Tower
Peachtree Center
Atlanta, Georgia 30303
BY: **W. CARL LEITZ III**

ALSO PRESENT: Sara Rizor Black, U.S.P.O.

press release; and that goes to the government's argument that materiality of the press release in this case was obvious.

This was a fatal disease, uniformly fatal. The defendant distributed this press release to thousands of sites. He wanted to get it to patients. Patients read it, patients wanted Actimmune.

The demonstration of materiality in this case was obvious. Even assuming that not a single doctor would have considered the press release, the defendant's own documents that they're asking the Court to rely upon to find a *Brady* violation demonstrate straight that patients relied upon the press release, and for that reason, I think your Honor can just simply deny this *Brady* motion out of hand.

THE COURT: I will give you a chance to briefly walk through it, okay?

MR. HADDAD: Thank you, your Honor.

THE COURT: But I have my doubts, okay?

MR. HADDAD: All right. I will attempt to dispel them; and let me start, first of all, with the fundamental confusion that the government's first point perpetuates here.

The question is not whether a press release can matter or can have an affect, because the case is not about the press release. The case is about the conclusions that the manufacturer drew in the press release from what the government has repeatedly conceded was accurately stated data.

THE COURT: Okay, and there's no dispute, is there, that the data that's actually referred to in the press release is accurately reflected? Is that correct?

MR. WALDINGER: No dispute. The government says the conclusions were inaccurate, --

THE COURT: It's the interpretation thereof, et cetera.

MR. WALDINGER: -- were false.

THE COURT: It's the interpretation thereof, et cetera. Is that correct? Okay.

MR. HADDAD: And that is the critical overarching point to begin with, because what the question then becomes is, could the conclusions have had an impact on the decision-making of the physicians, who are the ones that have to make the prescription decision.

So even if the patients come in and ask for information, or can I have Actimmune or whatever, because of the press release, they don't get it unless the physician makes the decision. So how does the physician make the decision, and can the conclusions of the manufacturer in a press release affect that? That's the critical question.

And if I can show the Court -- and I will do this expeditiously, what I think are the compelling reasons why the documents matter.

I want to start first, briefly, with a document

EXHIBIT 9

SIDLEY AUSTIN LLP
SIDLEY

SIDLEY AUSTIN LLP
555 WEST FIFTH STREET
LOS ANGELES, CA 90013
(213) 896 6000
(213) 896 6600 FAX

mhaddad@sidley.com
(213) 896 6604

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TOKYO
WASHINGTON, D.C.

FOUNDED 1866

June 8, 2011

By Hand Delivery

Brian J. Stretch
Acting United States Attorney,[1] Northern District of California
United States Attorney's Office
450 Golden Gate Avenue, 11th Floor
San Francisco, California 94102

Re: *United States v. Harkonen*, No. CR 08-0164 MHP (N.D. Cal.)
Request for Correction under Information Quality Guidelines

Dear Mr. Stretch:

We represent W. Scott Harkonen, the defendant in the above-referenced matter. On his behalf, we submit this letter as a Request for Correction under the Information Quality Guidelines ("Guidelines"), promulgated by the U.S. Department of Justice ("DOJ") pursuant to the Information Quality Act, Pub. L. No. 106-554, Appendix C § 515(a), 114 Stat. 2763A-154 (2000) (codified at 44 U.S.C. § 3516 note). *See* www.justice.gov/iqpr/dojinformationqualityguidelines.htm (setting forth DOJ Guidelines).

On September 29, 2009, the U.S. Attorney's Office of the Northern District of California issued a press release titled "W. Scott Harkonen, Former Biotech CEO, Convicted of Wire Fraud." Exh. A. The DOJ press release contains the following statement: "Douglas J. Carver, Special Agent in Charge of the U.S. Department of Veterans Affairs, Office of Inspector General, Western Field Office, stated 'today's verdict, which resulted from a complex and labor-intensive investigation and trial, demonstrates our commitment to work with our law enforcement partners to aggressively pursue all individuals that would jeopardize the integrity and safety of the VA's health care system. *The actions of this defendant served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans.* The VA OIG will continue to aggressively pursue investigations of this type and hold those responsible accountable for their actions.'" (emphasis added.) The press

[1] Pursuant to authority conferred by 28 U.S.C. § 515.

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release remains available on DOJ's website. *See* http://www.justice.gov/usao/can/press/2009/2009_09_29_harkonen.convicted.press.html.[1]

As set forth below, the italicized sentence within Mr. Carver's quotation is not accurate and violates DOJ's Information Quality Guidelines, as well as IQA guidelines issued by the Office of Management and Budget. *See* DOJ Guidelines ("DOJ components will ensure disseminated information, as a matter of substance and presentation, is accurate . . . ."); OMB Guidelines, 67 Fed. Reg. 8452, 8458 (Feb. 22, 2002) ("agencies shall adopt a basic standard of quality (including objectivity, utility, and integrity) as a performance goal and should take appropriate steps to incorporate information quality criteria into agency information dissemination practices."); *id.* at 8459 (defining "objectivity" as whether "disseminated information is being presented in an accurate, clear, complete, and unbiased manner.").[2]

During Dr. Harkonen's trial, the Government challenged statements from an August 28, 2002 press release ("Press Release") that announced the preliminary results of a Phase III clinical trial of the prescription drug Actimmune (interferon gamma-1b) for treating idiopathic pulmonary fibrosis ("IPF"). *See* Exh. B (Aug. 28, 2002 Press Release); Exh. C (9/22/09 RT 3457: The Court: "[F]or the wire fraud, what you are citing to as the basis for the—for this false to fraudulent statement is the press release?" Assistant U.S. Attorney Ioana Petrou: "Yes, your honor."). In particular, the Government claimed that the 2002 press release contained conclusions that were false and misleading, and offered as examples: "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF"; Actimmune "Reduces Mortality by 70% in Patients With Mild to Moderate Disease"; and "Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials." *See* Exh. B; Exh. D (5/20/09 RT 10-14; 8/18/09 RT 270-71, 277-82). According to the Government, these conclusions were false and were not supported by the underlying data also set forth in the Press Release, even though the government conceded that the data were accurately reported in the Press Release. *See, e.g.*, Exh. E (4/13/11 RT 11-12 (Assistant U.S. Attorney Kyle Waldinger agreeing that there is "no dispute . . . that the data that's actually referred to in the press release is accurately reflected," and instead the

[1] DOJ earlier denied Dr. Harkonen's request for correction pursuant to the DOJ Guidelines concerning another statement in the September 29, 2009 press release, namely, the statement by FBI Special Agent in Charge Stephanie Douglas that Dr. Harkonen had "falsif[ied] test results." That statement is not accurate because the government conceded the data in the August 28, 2002 Press Release was accurately reported, and instead based its prosecution upon Dr. Harkonen's interpretation of that data. *See* Exh. H (copies of former IQA correspondence with DOJ). Dr. Harkonen continues to reserve his right to challenge the DOJ's denial of his prior request for correction, including through judicial review.

[2] Dr. Harkonen expressly incorporates into this letter, by reference, pages 2-4 of his letter to The Hon. Joseph P. Russoniello, dated April 20, 2010, which explain why the DOJ 2009 press release is subject to the IQA and covered by the DOJ Guidelines and the OMB Guidelines. *See* Exh. H.

government's position is that "the conclusions [stated in the Press Release] were inaccurate . . . ."); *see also* Exh. F (6/24/09 RT 28 (AUSA Petrou agreeing that the data were not "transposed or changed in any way."); Exh. G (9/23/09 RT 3697 (AUSA Petrou stating: "I don't need to spend any time on the numbers in [the Press Release]. We all know the numbers are correct.").

But even though Mr. Carver stated (and DOJ repeated during the sentencing phase) that the conclusions in the Press Release caused loss to the VA (*i.e.*, "diver[sion]" of "precious financial resources"), the Government was unable, despite multiple opportunities, to prove the accuracy of that statement. First, the Government asked, and the District Court agreed, that the jury would not address the issue of whether the conclusions in the 2002 Press Release caused any loss. Second, during post-trial proceedings, the Government produced 67 pages of documents from the VA, but none of those documents show any loss or harm to the VA resulting from the conclusions in the Press Release.[3] To the contrary, the Government admitted that only one page of those documents mentions the Press Release (Exh. J (ECF 331 at 14)), and that page is evidence that the VA Network that authored the letter "was not persuaded by the Defendant's press release . . . ." Exh. J (ECF 331 at 17).

During an initial sentencing hearing, the District Court criticized the Government for not providing the Court with any "real data" to support its allegation of loss, and gave the Government another opportunity to produce such data. Exh. K (11/16/10 RT 31-32). But at the next sentencing hearing, the Court found that the Government, even after submitting supplemental briefing, still had failed to prove that the conclusions set forth in the Press Release caused any loss to *anyone*. The Court found that under either the clear-and-convincing or the preponderance-of-the-evidence standards, the Government failed to establish that "there is a loss as a result of the conduct reflected in the wire fraud count." Exh. L (4/13/11 RT 116); *see id.* ("there just isn't enough evidence in the record under either burden of proof to satisfy the Court that there is a loss as a result of the press release."); *id.* at 117 (Court concluding that there was no "victim" of the Press Release). Because the Government could not prove that the conclusions in the Press Release caused any loss to any victim, it logically follows that the VA did not suffer any loss from the conclusions in the Press Release.

The Government's assertion in the DOJ press release that Dr. Harkonen's conclusions "divert[ed] precious financial resources" from the VA's mission thus is not accurate. It misrepresents what the Government proved in this case, misleads the public as to what the Court actually found was the result of the offense, and characterizes the offense as having caused the

[3] The Government has admitted repeatedly that the "[t]he Veterans Administration Office of Inspector General was one of the investigating agencies" assisting in the prosecution of Dr. Harkonen. *See* Exh. I (4/13/2011 RT 6; *see also* Exh. A.

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Government adverse financial consequences that it did not cause. The statement, in short, is not accurate, and thus it should be corrected immediately.

Dr. Harkonen thus requests the following: (1) the Government issue a retraction of the statement in the September 29, 2009 press release that Dr. Harkonen "divert[ed] precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans" and publish that retraction in the same manner that the Government distributed the September 29 press release to the public; and (2) the Government remove the original September 29 press release from all official Government websites. Such an approach is the only reasonable measure by which the Government can mitigate the harm caused by the public dissemination of its false statement.

We look forward to your response within sixty calendar days of the date of this letter.

Very truly yours,

Mark E. Haddad /BSM

Coleen Klasmeier /BSM

Mark E. Haddad

Coleen Klasmeier

Enclosures

cc: H. Marshall Jarrett, Executive Office for United States Attorneys
Kyle Waldinger, Assistant United States Attorney

United States Department of Justice

United States Attorney Joseph P. Russoniello
Northern District of California
11th Floor, Federal Building
450 Golden Gate Avenue, Box 36055
San Francisco, California 94102
(415) 436-7200
FAX: (415) 436-7234

FOR IMMEDIATE RELEASE
SEPTEMBER 29, 2009
WWW.USDOJ.GOV/USAO/CAN

CONTACT: Jack Gillund
(415) 436-6599
Jack.Gillund@usdoj.gov

W. SCOTT HARKONEN, FORMER BIOTECH CEO, CONVICTED OF WIRE FRAUD

SAN FRANCISCO – W. Scott Harkonen, M.D., and the former CEO of InterMune, Inc., was convicted of wire fraud for the creation and dissemination of false and misleading information about the efficacy of InterMune's drug Actimmune (Interferon gamma-1b) as a treatment for idiopathic pulmonary fibrosis ("IPF"), the United States Attorney's Office for the Northern District of California and the Civil Division of the United States Department of Justice announced.

The jury, in its third day of deliberations, found the defendant guilty of wire fraud related to a press release issued on Aug. 28, 2002. The defendant was acquitted of a misbranding charge brought under the Federal Food, Drug, and Cosmetic Act. The guilty verdict followed a seven-week jury trial before U.S. District Court Judge Marilyn Hall Patel.

Evidence at trial showed that Harkonen, a medical doctor, was the Chief Executive Officer of InterMune from February 1998 through June 30, 2003, and a member of InterMune's Board of Directors. Under defendant Harkonen's direction, InterMune marketed and sold Actimmune to treat the fatal disease IPF sprdespite the fact that Actimmune was not approved by the Food and Drug Administration ("FDA") as a safe and effective treatment. The cost of Actimmune for one IPF patient for one year was approximately $50,000 and the vast majority of InterMune's sales of Actimmune were for the unapproved, off-label use of treating IPF.

Evidence at trial further showed that the defendant caused InterMune to issue a press release publicly announcing the results of a clinical trial of Actimmune for the treatment of IPF on Aug. 28, 2002. Although the clinical trial in fact failed, Harkonen caused the issuance and distribution of a false and misleading press release to portray that the results of the trial established that Actimmune helped IPF patients live longer. Specifically, the press release's headline falsely stated that, "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," with the subheading "Reduces Mortality by 70% in Patients With Mild to Moderate Disease."

In October 2006, InterMune agreed to enter into a deferred prosecution agreement and to pay nearly $37 million to resolve criminal charges and civil liability in connection with the illegal promotion and marketing of its drug Actimmune. InterMune also entered into a five-year Corporate Integrity Agreement with the Office of Inspector General for the Department of Health and Human Services.

"This conviction of W. Scott Harkonen demonstrates the Department of Justice's commitment to hold accountable those corporate executives who provide false or fraudulent information about pharmaceutical trials," said Ann Ravel, Deputy Assistant Attorney General for the Civil Division. "When corporate executives provide false or fraudulent information about pharmaceutical trials, they jeopardize the public health and welfare. The Department of Justice is committed to ensuring that doctors and patients receive

truthful information about medical products."

“Today’s verdict demonstrates that pharmaceutical executives will not be able to hide behind a corporate shield when they promote drugs using false or fraudulent information,” said Thomas P. Doyle, Special Agen in Charge of FDA’s Office of Criminal Investigations, Metro Washington Field Office. "Pharmaceutical companies do not run themselves, and those who engage in criminal conduct will be held personally accountable."

"Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval," said FBI Special Agent in Charge Stephanie Douglas.

Douglas J. Carver, Special Agent in Charge of the U.S. Department of Veterans Affairs, Office of Inspector General, Western Field Office, stated “today’s verdict, which resulted from a complex and labor-intensive investigation and trial, demonstrates our commitment to work with our law enforcement partners to aggressively pursue all individuals that would jeopardize the integrity and safety of the VA’s health care system. The actions of this defendant served to divert precious financial resources from the VA’s critical mission of providing healthcare to this nation’s military veterans. The VA OIG will continue to aggressively pursue investigations of this type and hold those responsible accountable for their actions.”

The maximum statutory penalty for 18 U.S.C. § 1343 (wire fraud) is 20 years in prison, $250,000 fine, three years supervised release, and $100 mandatory special assessment. However, any sentence following conviction would be imposed by the Court after consideration of the U.S. Sentencing Guidelines and the federal statute governing the imposition of a sentence, 18 U.S.C. § 3553.

This case is being prosecuted by Assistant U.S. Attorney Ioana Petrou of the Northern District of California and Trial Attorney Allan Gordus of the Office of Consumer Litigation in the Civil Division in Washington, D.C., with the assistance of Associate Chief Counsel Anne Walsh of the FDA Office of Chief Counsel, Paralegal Specialists Matthew McCrobie and Matthew Robinson, and Legal Technician Jennifer Hiwa. The prosecution is the result of a multi-year investigation by the Federal Bureau of Investigation; the Food and Drug Administration's Office of Criminal Investigations; the U.S. Department of Veterans Affairs, Office of Inspector General; and the Office of Personnel Management, Office of the Inspector General.

Further Information:

Case #: 08-164 MHP

A copy of this press release may be found on the U.S. Attorney’s Office’s website at www.usdoj.gov/usao/can.

Electronic court filings and further procedural and docket information are available at https://ecf.cand.uscourts.gov/cgi-bin/login.pl.

Judges’ calendars with schedules for upcoming court hearings can be viewed on the court’s website at www.cand.uscourts.gov.

All press inquiries to the U.S. Attorney’s Office should be directed to Jack Gillund at (415) 436-6599 or by email at Jack.Gillund@usdoj.gov.

This site does not contain all press releases or court filings and is not an official record of

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proceedings. Please contact the Clerk of Courts for the United States District Court for official copies of documents and public information.

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Investor contact: Myesha Edwards, InterMune, Inc., 415-466-2242, medwards@intermune.com
Media contact: Jim Weiss, InterMune, Inc., 415-362-5018, weisscomm@earthlink.net

INTERMUNE ANNOUNCES PHASE III DATA DEMONSTRATING SURVIVAL BENEFIT OF ACTIMMUNE IN IPF

- Reduces Mortality by 70% in Patients with Mild to Moderate Disease -

BRISBANE, Calif., August 28, 2002 – InterMune, Inc. (Nasdaq: ITMN) announced today that preliminary data from its Phase III clinical trial of Actimmune® (Interferon gamma-1b) injection for the treatment of idiopathic pulmonary fibrosis (IPF), a debilitating and usually fatal disease for which there are no effective treatment options, demonstrate a significant survival benefit in patients with mild to moderate disease randomly assigned to Actimmune versus control treatment ($p = 0.004$). These data confirm the survival benefit seen in the Phase II trial presented earlier this year at the 98th Annual Conference of the American Thoracic Society. There was also approximately a 10% relative reduction in the rate of progression-free survival associated with Actimmune versus placebo, the trial's primary endpoint, but this was not a statistically significant difference.

The company will hold a conference call at 9:00 a.m. EDT today to discuss these results (details below).

"We are extremely pleased with these results, which indicate Actimmune may extend the lives of patients suffering from this debilitating disease," said W. Scott Harkonen, M.D., President and CEO of InterMune. "Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials. 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."

"The mortality benefit is very compelling and represents a major breakthrough in this difficult disease," said Ganesh Raghu, M.D., Professor of Medicine, University of Washington in Seattle, and the Phase III study's lead principal investigator. "Interferon gamma-1b is the first treatment ever to show any meaningful clinical impact in this disease in rigorous clinical trials, and these results would indicate that Actimmune should be used early in the course of this disease in order to realize the most favorable long-term survival benefit."

Study Details and Results

A total of 330 patients were randomized into this double-blind, placebo-controlled trial conducted at 58 centers around the United States and Europe. Patients received either placebo or 200 micrograms of Actimmune injected subcutaneously three times per week. All patients remained in the trial until the last patient received 48 weeks of therapy. Median treatment duration was 60 weeks. The primary endpoint was progression free survival time defined as either one of the following: (i) a decrease in forced vital capacity (FVC) of >10 percent, (ii) an increase in A-a gradient of 5 mmHg, or (iii) death. While this endpoint did not reach statistical significance, there was a trend in favor of Actimmune-treated patients, representing an approximately 10% relative reduction in the rate of progression-free survival versus placebo.

Importantly, Actimmune also demonstrated a strong positive trend in increased survival in the overall patient population, and a statistically significant survival benefit in patients with mild to moderate IPF. In the overall population, there were 16/162 deaths in the Actimmune-treated group (9.9%) compared to 28/168 deaths in the placebo group (16.7%), representing a 40% decrease in mortality in favor of Actimmune vs. placebo ($p = 0.084$). Further, of the 254 patients with mild to moderate disease (FVC >= 55 percent), there were 6/126 deaths in the Actimmune-treated group (4.8%) and 21/128 deaths in the placebo group (16.4%), representing a 70% decrease in mortality in favor of Actimmune versus placebo ($p = 0.004$).

There were also trends later in the course of the study in favor of Actimmune in terms of improved breathing (i.e., dyspnea) and reduced need for supplemental oxygen. Actimmune treatment was also very well tolerated with the most common side effects reported being flu-like symptoms.

These data appear to confirm long-term follow-up data, reported earlier this year at the ATS meeting, which involved 18 patients from a randomized, controlled, open-label trial of Actimmune, in which 16 patients received one or more doses of Actimmune following study completion. The Kaplan Meier estimate of survival at five years was 77.8% and 16.7% in the Actimmune and control groups, respectively ($p = 0.009$).

Tracking Longer Term Outcomes

InterMune plans to transition all remaining Phase III trial patients in the active and placebo groups into an open-label clinical trial in which all patients receive Actimmune to track longer-term outcomes with Actimmune for a minimum of one year.

"We felt we had an ethical obligation to get this important news out about the survival benefit of Actimmune so physicians can evaluate it when making treatment decisions for their patients," said James E. Pennington, M.D., InterMune's Executive Vice President of Clinical and Medical Affairs. "We now have two well-controlled trials in IPF patients supporting a survival benefit, providing what we believe is compelling rationale for consideration of Actimmune for the treatment of patients with this disease."

About Actimmune

Interferon gamma-1b is a naturally occurring protein that stimulates the immune system. InterMune markets Actimmune for the treatment of life-threatening congenital diseases chronic granulomatous disease and severe, malignant osteopetrosis. InterMune is also conducting a Phase III study of Actimmune in ovarian cancer and a Phase II study of Actimmune for the treatment of severe liver fibrosis, or cirrhosis, caused by hepatitis C virus (HCV).

About Idiopathic Pulmonary Fibrosis

Idiopathic pulmonary fibrosis (IPF) is the most common form of idiopathic interstitial pneumonia. Once symptoms appear, there is a relentless deterioration of pulmonary function and death three to five years after diagnosis. The most common treatment is steroids; however, previously published studies suggest that fewer than 20 percent of patients with IPF respond to steroids. In patients having failed treatment with steroids, cytotoxic drugs such as azathioprine or cyclophosphamide are sometimes added to the steroid treatment. However, a large number of studies have shown little or no benefit from treatments involving steroids and other cytotoxic drugs. There are currently no drugs approved by the FDA for the treatment of IPF.

Conference Call Details

To access the live teleconference, dial 888-799-0528 (U.S.) or 706-634-0154 (international). A replay of the webcast and teleconference will be available approximately three hours after the call for two

business days. To access the replay, please call 1-800-642-1687 (U.S.) or 706-645-9291 (international), and enter the conference ID# 5479918. To access the webcast, please log on to the company's website at www.intermune.com at least 15 minutes prior to the start of the call to ensure adequate time for any software downloads that may be required.

These data will be presented in more detail at the European Respiratory Society meeting in Stockholm at a symposium on Sept. 15, 2002, and later this year at the American College of Chest Physicians meeting in November in San Diego, Calif.

About InterMune

InterMune is a commercially driven biopharmaceutical company focused on the marketing, development and applied research of life-saving therapies for pulmonary disease, infectious disease and cancer. For additional information about InterMune, please visit www.intermune.com.

Except for the historical information contained herein, this press release contains certain forward-looking statements that involve risks and uncertainties, including without limitation the statements indicating that the company believes that these results will: (i) support use of Actimmune for the treatment of IPF, (ii) lead to $400-$500 million in peak Actimmune sales, (iii) enable the company to achieve profitability in 2004, and (iv) provide compelling rationale for consideration of Actimmune for the treatment of patients with IPF. All forward-looking statements and other information included in this press release are based on information available to InterMune as of the date hereof, and InterMune assumes no obligation to update any such forward-looking statements or information. InterMune's actual results could differ materially from those described in InterMune's forward- looking statements. Factors that could cause or contribute to such differences include, but are not limited to those discussed under the heading "Risk Factors" and the risks and factors discussed in InterMune's 10-K report filed with the SEC on March 21, 2002, and other periodic reports (i.e., 10-Q and 8- K) filed with the SEC. The risks and other factors that follow, concerning the forward-looking statements in this press release, should be considered only in connection with the fully discussed risks and other factors discussed in detail in the 10-K report and InterMune's other periodic reports filed with the SEC. The forward-looking statements that the company believes that these results will: (i) support use of Actimmune for the treatment of IPF, (ii) lead to $400-$500 million in peak Actimmune sales, (iii) enable the company to achieve profitability in 2004, and (iv) provide compelling rationale for consideration of Actimmune for the treatment of patients with IPF, are subject to the uncertainties and risks of a continuing increase in sales of Actimmune for IPF, an indication for which Actimmune has not been approved by the FDA; reimbursement risks associated with third-party payors; and regulation by the FDA with respect to InterMune's communications with physicians concerning Actimmune for the treatment of IPF.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA TUESDAY SEPTEMBER 22, 2009 2:00 P.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

NOT WHAT THE GOVERNMENT CHARGED. WHEN WE HAD THE ARGUMENT, IN OUR -- WE LAID OUT IN DETAIL IN OUR BRIEF, WHEN YOU ASKED THE GOVERNMENT ON THE FIRST AMENDMENT MOTION, "WHAT ARE THE FALSE STATEMENTS FOR THE FRAUD"?

AND THAT MOTION WAS DIRECTED TO BOTH MISBRANDING AND WIRE FRAUD. THEY WENT THROUGH A LITANY OF STATEMENTS THAT WERE MADE; NOT HALF-TRUTHS, NOT OMISSIONS.

THE ONLY OMISSION THEY MENTIONED -- WELL, SUBGROUP ANALYSIS; BUT THEY CONCEDED THAT WAS LATER DISCUSSED IN THE PRESS RELEASE.

SO IT'S OUR POSITION, THOUGH THEY MAY IN THE ABSTRACT BE LEGALLY PERMISSIBLE, THEY ARE NOT CHARGED IN THIS INDICTMENT. AND IT WOULD BE A FATAL VARIANCE OF CONSTRUCTIVE AMENDMENT TO ALLOW HALF-TRUTH OR OMISSIONS AT THIS POINT.

THE COURT: WELL, AS I UNDERSTAND IT, FOR THE WIRE FRAUD, WHAT YOU ARE CITING TO AS THE BASIS FOR THE -- FOR THIS FALSE TO FRAUDULENT STATEMENT IS THE PRESS RELEASE?

MS. PETROU: YES, YOUR HONOR.

THE COURT: THAT'S IT? JUST THE PRESS RELEASE?

MS. PETROU: THE SCHEME TO DEFRAUD CERTAINLY GOES BEYOND THE PRESS RELEASE. AS FAR AS WHAT UNDERLIES THAT PARTICULAR COUNT, IT IS THE PRESS RELEASE.

THE COURT: AND ITS STATEMENT IN THE PRESS RELEASE, CORRECT?

MS. PETROU: YES, YOUR HONOR.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-164 MHP SAN FRANCISCO, CALIFORNIA WEDNESDAY MAY 20, 2009 10:00 O'CLOCK A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF:

OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVE.
SAN FRANCISCO, CALIFORNIA 94102
BY: IOANA PETROU, ASSISTANT UNITED STATES ATTORNEY
AND NICHOLAS BAGLEY,
ASSISTANT UNITED STATES ATTORNEY AND

ALLAN GORDUS
OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, DC 20044

FURTHER APPEARANCES ON NEXT PAGE

REPORTED BY: KATHERINE WYATT, CSR 9866, RMR, RPR
OFFICIAL REPORTER - US DISTRICT COURT
COMPUTERIZED TRANSCRIPTION BY ECLIPSE

"I THINK THIS INDICATES OR SUGGESTS" -- THAT WAS THEIR WORD: "SUGGEST" -- WE WOULDN'T BE HERE.

THE THING THAT THEY ARE SAYING MAKES THIS FRAUD IS HE SAID "DEMONSTRATES."

AND WE SAY THAT CANNOT BE. IT CANNOT BE UNDER NOT ONLY THE LONG LINE OF SUPREME COURT CASES THAT DEAL WITH THE DIFFERENCE BETWEEN OPINION AND FACT, WHICH IS FRAUD, AND THE CASES -- AND IT IS UP TO YOU TO MAKE THAT DETERMINATION IN THE FIRST INSTANCE.

THERE IS NO QUESTION THAT AS GATEKEEPER WE HAVE RAISED THIS CONTENTION. THE CONTENTION IS IS THIS PRESS RELEASE, WHICH GIVES THE DETAILED DATA -- I'VE BLOWN UP -- IT'S IN OUR BRIEF, SO YOU HAVE IT.

BUT THIS IS THE DETAILED DATA OF THE STUDY. THERE IS NO CONTENTION THAT THE DETAILED DATA IS NOT THE DETAILED DATA. THE CONTENTION IS IS THAT HARKONEN OVERSTATED OR INTERMUNE OVERSTATED THAT.

AND OUR CONTENTION BACK IS:

"SO WHAT? THAT'S HIS OPINION."

AND WE HAVE ON THE ONE --

THE COURT: WELL, LET'S JOIN THE ISSUE RIGHT NOW.

WHAT IS YOUR POSITION AS TO WHAT STATEMENT OR STATEMENTS IN THIS PRESS RELEASE ARE FALSE OR MISLEADING?

MR. BAGLEY: GREAT. I GUESS WE CAN START WITH THE HEADLINE. THEY PULLED IT DOWN. I'LL JUST REFER TO IT.

THE COURT: NO, I THINK IT'S BEHIND THERE.

MR. TOPEL: IT'S RIGHT BEHIND IT.

THE COURT: IT'S RIGHT BEHIND.

MR. BAGLEY: GREAT.

THE COURT: MR. TOPEL WILL BE KIND ENOUGH TO HOLD THE EXHIBIT FOR YOU.

MR. TOPEL: ALLOW ME TO ASSIST THE GOVERNMENT IN THE ARGUMENT, EVEN THOUGH I FEEL THAT IT'S UTTERLY SPECIOUS.

MR. BAGLEY: "INTERMUNE ANNOUNCES PHASE III DATA DEMONSTRATING SURVIVAL BENEFIT OF ACTIMMUNE IN IPF."

THE STUDY, IN FACT -- AND AS WE'RE PREPARED TO PROVE AT TRIAL -- SHOWED ENTIRELY TO THE CONTRARY.

AND IT GOES ON, ANNOUNCES THE RESULTS OF THE STUDY --

THE COURT: WHAT ABOUT THE SUBHEADLINE THERE?

MR. BAGLEY: "REDUCES MORTALITY BY 70 PERCENT IN PATIENTS."

THE COURT: IS THAT -- DO YOU CONTEND THAT THAT IS INACCURATE?

MR. BAGLEY: THERE'S A MATERIAL OMISSION, WHICH IS TO SAY THAT THAT'S NOT A STATISTICALLY SIGNIFICANT FINDING. THEY DO CLARIFY THAT IN THE BALANCE OF PRESS RELEASE.

WE'RE FOCUSING ON THE STATEMENTS ABOUT THE EFFICACY OF ACTIMMUNE IN TREATING MILD TO MODERATE FORMS OF IPF.

"DEMONSTRATE A SIGNIFICANT SURVIVAL BENEFIT IN

PATIENTS WITH MILD TO MODERATE DISEASE, RANDOMLY ASSIGNED TO ACTIMMUNE VERSUS CONTROLLED TREATMENT."

AND THEY OFFER A P VALUE THERE OF .004, WHICH, AGAIN, IS SORT OF A STATISTICAL SHORTHAND FOR:

"WE'RE NOT MAKING THIS UP. THIS IS A TRUE RESULT. THIS ISN'T JUST RANDOM CHANCE."

NOW, AS A MATTER OF STATISTICS THIS WAS FALSE. WHAT THEY DID WAS THEY TOOK A WHOLE LOT OF DATA. IT WAS A BIG WASH OF DATA THAT SHOWED GENERALLY THAT ACTIMMUNE WAS INEFFECTIVE. AND THEY SLICED AND DICED --

THE COURT: ALL RIGHT. I DON'T WANT YOU TO GO INTO THE BASES FOR YOUR STATEMENT THAT IT'S INACCURATE.

MR. BAGLEY: FAIR ENOUGH.

THE COURT: BUT THE PARTS OF IT THAT YOU CONTEND ARE FALSE OR MISLEADING, OKAY?

MR. BAGLEY: GREAT. I'LL KEEP GOING THROUGH IT, IF YOU LIKE.

THE COURT: AND THEN, I WILL GIVE MR. TOPEL BACK THE FLOOR, SINCE IT'S HIS MOTION.

MR. BAGLEY: SO LET ME PULL MY COPY, BECAUSE IT GOES ON. THERE ARE A COUPLE OF OTHER STATEMENTS I CAN POINT TO.

I SHOULD NOTE THAT THESE STATEMENTS WERE REPEATED, NOT ONLY IN THE PRESS RELEASE, BUT ALSO IN THE FAX BLAST OF 2000 PULMONOLOGISTS. THE CONTENT OF THIS WAS ALSO DISTRIBUTED TO ACTIMMUNE PATIENTS ALL UNDER DEFENDANT'S CONTROL.

THE COURT: WELL, BUT WHAT YOU'RE SAYING IS THAT THESE OTHER -- THESE OTHER TRANSMISSIONS THAT YOU'VE REFERRED TO ESSENTIALLY ARE NO DIFFERENT FROM, YOU KNOW, IN SUBSTANCE FROM THE PRESS RELEASE.

MR. BAGLEY: SURE. THEY SAID THE STUDY WORKED --

THE COURT: THEY SAID THE SAME THING.

MR. BAGLEY: -- WHEN THE STUDY DIDN'T. SURE.

THEY SAID THEY WOULD BELIEVE THESE RESULTS WOULD SUPPORT THE USE OF ACTIMMUNE. THEY SAID THE DATA CONFIRMED THE SURVIVAL BENEFIT SHOWN BY A PREVIOUS STUDY. THAT, AGAIN, WAS FALSE.

THEY HAVE QUOTES FROM EMPLOYEES THAT SAY:

"WE BELIEVE THESE RESULTS INDICATE THAT ACTIMMUNE SHOULD BE USED EARLY IN THE COURSE OF THIS DISEASE IN ORDER TO REALIZE THE MOST FAVORABLE LONG-TERM SURVIVAL BENEFIT."

THEY SAY THAT THERE WAS A STATISTICALLY SIGNIFICANT SURVIVAL BENEFIT IN PATIENTS WITH MILD TO MODERATE IPF.

AGAIN, AS A MATTER OF MATH THERE IS SOMETHING TO THIS. AS A MATTER OF STATISTICAL INFERENCE THIS WAS FALSE. THIS IS A MATERIAL OMISSION OF FACT ABOUT THE WAY YOU SPECIFY SUBGROUPS IN A STUDY. WE'RE PREPARED TO PUT ON EXPERTS AT TRIAL THAT WILL TESTIFY TO THAT EFFECT. I'M SURE THEY HAVE THEIR OWN EXPERTS. BUT THAT'S A --

THE COURT: OKAY. LET'S GET TO THE STATEMENTS

THEMSELVES RATHER THAN JUST THE BACKUP. YOU'LL GET YOUR CHANCE WHEN IT'S YOUR TURN.

MR. BAGLEY: SURE. I THINK WE'RE PRETTY MUCH THROUGH THE PRESS RELEASE, BUT WE'RE REALLY PUSHING VERY HARD ON THE STATEMENT THAT THE STUDY DEMONSTRATED THE EFFICACY OF A DRUG WHEN, IN FACT, IT DIDN'T.

AND THE P VALUE IS A STATEMENT TO THE SCIENTIFIC COMMUNITY THAT THIS IS A TRUE, VALID STUDY THAT DEMONSTRATED THIS DRUG WORKED.

"WE'RE NOT, AGAIN, MAKING THIS UP."

THE COURT: OKAY. SO WITH THAT UNDERSTANDING.

MR. TOPEL: YES, I'M A LITTLE CONFUSED ABOUT THE P VALUE. THE P VALUE, AS I UNDERSTAND IT -- AND I DON'T UNDERSTAND THE GOVERNMENT IS CONTENDING DIFFERENTLY -- IS THE P VALUE THAT AROSE FROM THE POST HOC SUBGROUP ANALYSIS, NOT FROM THE STUDY AT LARGE, BECAUSE THE PRESS RELEASE VERY CLEARLY SAID THAT THE STUDY DID NOT MEET ITS END POINT AND DID NOT REACH STATISTICAL SIGNIFICANCE.

SO I'M GOING TO ASSUME THAT'S WHAT THE -- I DON'T WANT TO TALK TO HIM, BUT I'M ASSUMING THAT THAT'S WHAT THEY ARE COMPLAINING ABOUT HERE. AND, OF COURSE, THAT P VALUE IS ABSOLUTELY TRUE.

BUT THAT'S NOT THE POINT. THE THRUST OF THEIR --

THE COURT: WELL, THE THRUST OF IT IS NOT, YOU KNOW, THE INTERPRETATION OF THIS TO THE PUBLIC AT LARGE FOR --

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA TUESDAY AUGUST 18, 2009 8:36 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

LIVES, WHEN, IN FACT, THERE WAS NO PROOF THAT THAT WAS TRUE. IT'S A CASE ABOUT WANTING TO MAKE BELIEVE THAT A FAILED CLINICAL TRIAL WAS ACTUALLY A SUCCESS. THIS IS A CASE ABOUT A CEO AND DOCTOR WHO CARED MORE ABOUT THE HEALTH OF HIS COMPANY THAN HE DID ABOUT THE HEALTH OF PATIENTS WITH A FATAL DISEASE. THAT CEO AND DOCTOR IS THE DEFENDANT IN THIS CASE.

W. SCOTT HARKONEN.

THIS IS A SIMPLE CASE. YOU WILL NEED TO LEARN A LITTLE BIT ABOUT STATISTICS. YOU'LL NEED TO LEARN A LITTLE BIT ABOUT CLINICAL-TRIAL DESIGN IN ORDER TO UNDERSTAND WHAT HAPPENED; BUT IT'S NOT A CASE ABOUT STATISTICS, AND IT'S NOT A CASE ABOUT CLINICAL TRIALS OR TRIAL DESIGN. THIS IS REALLY A CASE ABOUT FRAUD, AND IT'S REALLY A CASE ABOUT CHOICES: THE DEFENDANT'S CHOICES.

DR. HARKONEN BUILT HIS COMPANY ON THE SALES OF ONE DRUG: ACTIMMUNE; A DRUG THAT COSTS $50,000 PER YEAR PER PATIENT.

AND IN AUGUST OF 2002 HE RECEIVED THE RESULTS FROM A CLINICAL TRIAL; A TRIAL THAT HAD FAILED. IT WAS VERY CLEAR THAT THE TRIAL HAD FAILED. DR. HARKONEN KNEW IT FAILED. HE WAS TOLD IT FAILED BY PEOPLE IN HIS COMPANY, OUTSIDE OF HIS COMPANY, AND BY F.D.A. -- THE FOOD AND DRUG ADMINISTRATION.

AND DESPITE KNOWING THIS, AND INSTEAD OF PUTTING OUT A TRIAL -- EXCUSE ME -- INSTEAD OF PUTTING OUT A PRESS RELEASE THAT CLEARLY SAID, HEADLINE, "FAILED TRIAL," DR. HARKONEN CHOSE

TO PUT OUT A PRESS RELEASE THAT SAID ACTIMMUNE SAVED LIVES. HE CHOSE TO PUT OUT A PRESS RELEASE WITHOUT LETTING THE PEOPLE IN HIS COMPANY MOST FAMILIAR WITH THE TRIAL SEE IT. AND HE CHOSE TO IGNORE THE F.D.A.

AFTER HE PREPARED A PRESS RELEASE THAT HE KNEW WOULD GO UP ON THE COMPANY'S WEBSITE, AND IT WOULD BE SENT ACROSS THE COUNTRY THROUGH THE WIRE SERVICE, HE CHOSE TO IGNORE COMPLAINTS ABOUT THE FALSE AND MISLEADING STATEMENTS IN THE PRESS RELEASE. HE CHOSE TO IGNORE THE PERSON THAT HE HAD HIRED TO BE IN CHARGE OF SAFEGUARDING THE PATIENTS' INTERESTS IN THE TRIAL. HE CHOSE TO IGNORE AN F.D.A. DOCTOR. HE CHOSE TO IGNORE HIS OWN COMPANY'S CONSULTANT. AND, WHILE CHOOSING TO IGNORE ALL OF THESE PEOPLE, HE CHOSE TO KEEP HIS COMPANY'S BOARD OF DIRECTORS IN THE DARK.

WHY DID HE DO ALL OF THIS?

HE DID THIS TO MAKE MONEY FOR HIS COMPANY, PLAIN AND SIMPLE.

WHO IS DR. HARKONEN? NOW, NATURALLY, MUCH OF THE EVIDENCE IN THIS CASE IS GOING TO FOCUS ON HIM. WHO IS HE?

WHAT DID HE KNOW?

WHAT DID HE DO AND NOT DO?

WHAT DID HE SAY AND NOT SAY?

WHAT DID HE WRITE AND NOT WRITE?

AND, PERHAPS MOST IMPORTANTLY, WHY DID HE DO THESE THINGS?

THE TRIAL, AND WHAT WOULD BE SOME GOOD NEXT STEPS GOING FORWARD.

AND ON AUGUST 27TH OF 2002, LITERALLY HOURS BEFORE DR. HARKONEN SENT OUT THE PRESS RELEASE ABOUT THE TRIAL, THE F.D.A. TOLD DR. HARKONEN THE TRIAL FAILED, AND PROVED NOTHING.

THE F.D.A. ALSO TOLD HIM THAT SOME ANALYSES DR. HARKONEN HAD PROVIDED ABOUT A POSSIBLE MORTALITY BENEFIT -- ABOUT A POSSIBILITY THAT MAYBE THIS DRUG HELPED SOME OF THESE PATIENTS LIVE LONGER -- WERE INTERESTING ANALYSES, BUT THAT INTERMUNE WAS GOING TO HAVE TO DO A SECOND TRIAL, ANOTHER TRIAL, TO SEE WHETHER THESE ANALYSES WERE TRUE.

THEY WERE SAYING, YES, WE SEE SOME DIFFERENCES IN THE NUMBERS, BUT BASED ON THIS KIND OF DATA, WE CAN'T TELL IF THAT'S REAL. IS IT REALLY BECAUSE THESE PATIENTS TOOK THIS DRUG, OR IS IT WHAT WE SEE BY CHANCE, AND NOT REAL?

AND, IN FACT, YOU'LL HEAR THAT WITHIN A FEW WEEKS, INTERMUNE STARTED PLANNING THAT NEXT CLINICAL TRIAL.

SO THE TRIAL RESULTS WERE IN. DR. HARKONEN HAD SPOKEN TO THE F.D.A. AND IT WAS TIME GET THE PRESS RELEASE OUT.

AND YOU'LL HEAR DR. HARKONEN, AS WITH ALL THINGS AT INTERMUNE, WAS COMPLETELY IN CONTROL OF THE PRESS RELEASE. HE WAS IN CONTROL OF WHAT IT SAID, AND HE WAS IN CONTROL OF WHO WAS ALLOWED TO SEE IT BEFORE IT WENT OUT.

AND, DESPITE THE CLEAR RESULTS, DESPITE THE CLEAR

FEEDBACK OF THE F.D.A., AND DESPITE PLENTY OF PEOPLE TELLING DR. HARKONEN WHAT HE ALREADY KNEW -- THAT THE TRIAL FAILED -- THIS IS THE PRESS RELEASE THAT HE CHOSE TO WRITE AND PUT UP ON HIS WEBSITE AND SEND ACROSS THE NATION.

INTERMUNE ANNOUNCES PHASE III DATA
DEMONSTRATING SURVIVAL BENEFIT OF ACTIMMUNE
AND IPF. REDUCES MORTALITY BY 70 PERCENT
IN PATIENTS WITH MILD TO MODERATE DISEASE.

NOW, WHERE DO THOSE HEADLINES COME FROM, WHEN I'VE BEEN STANDING HERE TELLING YOU THAT THIS WAS A FAILED TRIAL?

REMEMBER, I TOLD YOU DR. HARKONEN RECEIVED THE TRIAL RESULTS A COUPLE OF WEEKS BEFORE THIS: AUGUST 16TH OF 2002.

THERE WERE TWO OTHER DOCTORS AT INTERMUNE WHO RECEIVED THE TRIAL RESULTS AS WELL: DR. PENNINGTON, AND DR. CRAGER. YOU'LL LEARN THAT DR. PENNINGTON WAS THE CHIEF MEDICAL OFFICER AT THE COMPANY, AT INTERMUNE; BUT AS YOU'LL ALSO LEARN, HE WAS NOT ONE OF THE DOCTORS MOST FAMILIAR WITH THE TRIAL, AND HE WAS NOT SOMEONE DR. HARKONEN EVER RELIED ON TO UNDERSTAND ANYTHING, LET ALONE THIS CLINICAL TRIAL.

DR. CRAGER WAS THE BIOSTATISTICIAN AT THIS COMPANY. DR. CRAGER, AS A BIOSTATISTICIAN, WAS THE PERSON IN CHARGE OF USING STATISTICS TO ANALYZE THE DATA AND HELP FIGURE OUT: WHAT IS THE DATA; AND, MOST IMPORTANTLY, IS IT REAL? ARE THE NUMBERS WE'RE SEEING REAL, OR DUE TO CHANCE?

IN THE DAYS AFTER GETTING THE RESULTS, IN THE DAYS

AFTER AUGUST 16TH, DR. HARKONEN INSTRUCTED DR. CRAGER TO TAKE THE TRIAL DATA ON MORTALITY -- HOW LONG PEOPLE WERE LIVING -- AND RUN THE NUMBERS DIFFERENT WAYS; RUN THE NUMBERS BY BREAKING UP THE PATIENTS INTO DIFFERENT GROUPS.

NOW, DR. CRAGER, KNOWING IN HIS OWN MIND, AS HE WILL TELL YOU, THAT HE WAS SURE THEY WERE GOING TO HAVE TO DO ANOTHER TRIAL, A TRIAL ABOUT MORTALITY, HE THOUGHT HE WAS DOING THESE ANALYSES IN ORDER TO GET READY FOR THE NEXT TRIAL. HE HAD NO IDEA THERE WAS A PRESS RELEASE COMING.

SO WHEN DR. CRAGER AND OTHERS WERE TALKING TO DR. HARKONEN ABOUT THE DATA ON MORTALITY, THEY MADE IT CLEAR THAT THESE AFTER-THE-FACT ANALYSES -- ANALYSES THAT WERE NOT PART OF THE TRIAL DESIGN, ANALYSES THAT WERE NOT FOCUSED ON WHAT THE TRIAL WAS DESIGNED TO TEST -- COULD NOT BE RELIED ON TO ACTUALLY PROVE ANYTHING; THAT ANOTHER TRIAL WOULD BE NEEDED, WHICH IS, OF COURSE, WHAT THE F.D.A. HAD ALREADY TOLD DR. HARKONEN. THE DATA IS NOT RELIABLE. YOU NEED TO DO ANOTHER TRIAL, AND LET'S SEE IF IT'S REAL.

DR. HARKONEN WAS EXPERIENCED, AND KNEW WHAT THEY KNEW. AND HE KNEW WHAT HE WAS BEING TOLD; THAT YOU CAN'T SLICE AND DICE THE NUMBERS, PICK WHAT LOOKS BEST, GET RID OF THE STUFF THAT DOESN'T LOOK AS GOOD, AND HOLD OUT THE BEST NUMBER TO MAKE BELIEVE SOMETHING HAS BEEN PROVEN. IT'S FINE TO LOOK AT DATA TO DESIGN THE NEXT TRIAL. IT'S FINE TO SHARE ALL OF YOUR INFORMATION WITH OTHER SCIENTISTS AND HAVE A GOOD, ROBUST,

SCIENTIFIC DISCUSSION; BUT DON'T MAKE BELIEVE, BY PICKING A NUMBER OUT OF A HAT, THAT THAT'S WHAT THE TRIAL SHOWED, AND THAT THAT'S WHAT WAS PROVEN.

BUT WHAT DR. HARKONEN DID WAS JUST THAT. HE RAN A BUNCH OF DIFFERENT ANALYSES. HE PICKED THE BEST NUMBER THAT MADE IT LOOK LIKE PATIENTS LIVED LONGER. HE LEFT OUT THE OTHER NUMBERS THAT DIDN'T LOOK ANYWHERE NEAR AS GOOD. AND HE MADE IT SOUND LIKE THE TRIAL PROVED SOMETHING IT DIDN'T ACTUALLY PROVE.

THIS IS THE PRESS RELEASE THAT DR. HARKONEN PUT OUT BASED ON A FAILED TRIAL.

INTERMUNE ANNOUNCES PHASE III DATA DEMONSTRATING SURVIVAL BENEFIT OF ACTIMMUNE IN IPF REDUCES MORTALITY BY 70 PERCENT IN PATIENTS WITH MILD TO MODERATE DISEASE.

AND THIS IS THE VERY FIRST SENTENCE OF THE PRESS RELEASE.

"INTERMUNE, INC. NASDAQ" --

SO THAT'S THE TRADING SYMBOL FOR TRADING STOCK ON THE COMPANY.

INTERMUNE, INC., NASDAQ I.T.M.N., ANNOUNCED TODAY THAT PRELIMINARY DATA FROM ITS PHASE III CLINICAL TRIAL OF ACTIMMUNE INTERFERON GAMMA-1B INJECTION FOR THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS, IPF, A DEBILITATING AND USUALLY FATAL

DISEASE FOR WHICH THERE ARE NO EFFECTIVE TREATMENT OPTIONS, DEMONSTRATES A SIGNIFICANT SURVIVAL BENEFIT IN PATIENTS WITH MILD TO MODERATE DISEASE.

AND THIS IS HOW THE DEFENDANT CHOOSES TO QUOTE HIMSELF, W. SCOTT HARKONEN, M.D., PRESIDENT AND CEO OF INTERMUNE.

ACTIMMUNE IS THE ONLY AVAILABLE TREATMENT DEMONSTRATED TO HAVE CLINICAL BENEFIT IN IPF. WE BELIEVE THESE RESULTS WILL SUPPORT USE OF ACTIMMUNE, AND WE NEED TO KEEP SALES IN THE RANGE OF $400 MILLION TO $500 MILLION PER YEAR.

NOW, YOU'LL ALSO SEE A QUOTE -- BECAUSE, OF COURSE, YOU'LL GET ACCESS TO THE ENTIRE PRESS RELEASE VERY SOON. YOU'LL ALSO SEE A QUOTE IN THE PRESS RELEASE FROM A DOCTOR WHO DIDN'T WORK FOR INTERMUNE: DR. GANESH RAGHU. HE WAS A TRIAL INVESTIGATOR INVOLVED WITH THE TRIAL, BUT DIDN'T WORK FOR INTERMUNE. AND, AS DR. RAGHU WILL COME HERE AND TELL YOU HIMSELF, HE DIDN'T EVEN HAVE THE TRIAL DATA. THE DATA -- THIS PRESS RELEASE CAME OUT. AND THE ONLY INFORMATION HE HAD ABOUT THE TRIAL RESULTS WAS INFORMATION THAT WAS GIVEN TO HIM DIRECTLY AND SOLELY BY W. SCOTT HARKONEN.

SO BY NOW YOU'RE PROBABLY ASKING YOURSELVES: WHERE IN THE PRESS RELEASE DOES IT SAY THAT THE TRIAL HAS FAILED?

BECAUSE IT HAS TO SAY IT SOMEWHERE IN THERE.

AND IF YOU LOOK LONG ENOUGH, YOU GO PAST THE GLOWING HEADLINES, PAST THE FIRST PAGE OF THE PRESS RELEASE, ABOUT FIVE PARAGRAPHS IN, THIS IS WHAT YOU GET. AFTER THE CLEAR HEADLINES UP FRONT ABOUT SUCCESS, HERE IS HOW HE CHOOSES TO SAY THAT THE TRIAL FAILED.

> WHILE THIS ENDPOINT DID NOT REACH STATISTICAL SIGNIFICANCE, THERE WAS A TREND IN FAVOR OF ACTIMMUNE-TREATED PATIENTS REPRESENTING AN APPROXIMATELY 10 PERCENT RELATIVE REDUCTION IN THE RATE OF PROGRESSION-FREE SURVIVAL VERSUS PLACEBO.

THAT'S HOW HE CHOSE TO LET THE WORLD -- IT'S NOT JUST TO SCIENTISTS. THIS IS A PRESS RELEASE TO EVERYONE. THIS IS HOW HE CHOSE TO LET THE WORLD KNOW THAT THE TRIAL HAD FAILED.

AND ON THE SAME DAY AS THE PRESS RELEASE CAME OUT, DR. HARKONEN WAS INTERVIEWED BY C.N.B.C. AND YOU'LL GET TO SEE HIS PART OF THAT INTERVIEW ON VIDEO. AND IN THAT INTERVIEW, HE SAID, "WE'RE IN THE PROCESS" -- ACTUALLY WHAT HE SAID FIRST WAS,

> WE ACTUALLY REDUCED MORTALITY OVER THREEFOLD, BY 70 PERCENT, IN THESE PATIENTS.

AND HE ALSO SAID,

> WE'RE IN THE PROCESS OF SUBMITTING THE

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL, JUDGE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	NO. CR 08-00164 MHP
	)	
W. SCOTT HARKONEN,	)	
	)	
Defendant.	)	
	)	

San Francisco, California
Wednesday, April 13, 2011

TRANSCRIPT OF SENTENCING PROCEEDINGS

APPEARANCES:

For Plaintiff:

MELINDA L. HAAG, ESQ.
United States Attorney
450 Golden Gate Avenue
San Francisco, California 94102

BY: **KYLE WALDINGER**
Assistant United States Attorney

U.S. Department of Justice
Office of Consumer Litigation
450 Fifth Street, N.W.
Suite 6400-South
Washington, D.C. 20001

BY: **ALLAN GORDUS**
Trial Attorney

(Appearances continued on following page.)

Reported By: Leo T. Mankiewicz, CSR 5297, RMR, CRR

press release; and that goes to the government's argument that materiality of the press release in this case was obvious.

This was a fatal disease, uniformly fatal. The defendant distributed this press release to thousands of sites. He wanted to get it to patients. Patients read it, patients wanted Actimmune.

The demonstration of materiality in this case was obvious. Even assuming that not a single doctor would have considered the press release, the defendant's own documents that they're asking the Court to rely upon to find a *Brady* violation demonstrate straight that patients relied upon the press release, and for that reason, I think your Honor can just simply deny this *Brady* motion out of hand.

THE COURT: I will give you a chance to briefly walk through it, okay?

MR. HADDAD: Thank you, your Honor.

THE COURT: But I have my doubts, okay?

MR. HADDAD: All right. I will attempt to dispel them; and let me start, first of all, with the fundamental confusion that the government's first point perpetuates here.

The question is not whether a press release can matter or can have an affect, because the case is not about the press release. The case is about the conclusions that the manufacturer drew in the press release from what the government has repeatedly conceded was accurately stated data.

THE COURT: Okay, and there's no dispute, is there, that the data that's actually referred to in the press release is accurately reflected? Is that correct?

MR. WALDINGER: No dispute. The government says the conclusions were inaccurate, --

THE COURT: It's the interpretation thereof, et cetera.

MR. WALDINGER: -- were false.

THE COURT: It's the interpretation thereof, et cetera. Is that correct? Okay.

MR. HADDAD: And that is the critical overarching point to begin with, because what the question then becomes is, could the conclusions have had an impact on the decision-making of the physicians, who are the ones that have to make the prescription decision.

So even if the patients come in and ask for information, or can I have Actimmune or whatever, because of the press release, they don't get it unless the physician makes the decision. So how does the physician make the decision, and can the conclusions of the manufacturer in a press release affect that? That's the critical question.

And if I can show the Court -- and I will do this expeditiously, what I think are the compelling reasons why the documents matter.

I want to start first, briefly, with a document

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

United States of America, Plaintiff, vs. W. Scott Harkonen, Defendant.	)	NO. CR 08-0164-MHP San Francisco, California Wednesday June 24, 2009 2:35 p.m.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

For Plaintiff: Office of the United States Attorney
450 Golden Gate Avenue, Box 36055
San Francisco, CA 94102
(415) 436-7232
BY: IOANA PETROU

For Plaintiff: Office of Consumer Litigation
United States Department of Justice
Post Office Box 386
Washington, D.C. 20044
BY: ALLAN GORDUS

(Appearances continued on next page)

Reported By: Lydia Zinn, CSR #9223, RPR
Official Reporter - U.S. District Court

THE COURT: Not going forward.

MR. TOPEL: The point, for further clarification, which may or may not be needed, the -- is there is no allegation here in the indictment that the data is under dispute as to what the data was; for instance, how many people died.

THE COURT: In other words, it wasn't transposed or changed in any way.

MR. TOPEL: No. We're not talking about jiggling the data, which would be fraud.

We're talking about how you interpret the data. And we have a fight between biostatisticians and pulmonary interstitial disease pulmonologists.

MS. PETROU: And, your Honor, I think --

THE COURT: Is that correct?

MS. PETROU: Yeah, but what I was about to say is that I feel like I'm about to completely derail this *in limine* discussion. A lot of these issues are going to the expert disclosures and what they're going to say and what role Dr. Fleming's letter is going to play.

And if your Honor wants to hear that, I'm more than happy to address it. If you'd rather stay on track with the *in limine* --

THE COURT: Let's stay on track right now. And we'll get to some of these issues, and what the experts will testify

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL

UNITED STATES OF AMERICA, PLAINTIFF, VS. W. SCOTT HARKONEN, DEFENDANT.	NO. CR 08-0164-MHP SAN FRANCISCO, CALIFORNIA WEDNESDAY SEPTEMBER 23, 2009 8:35 A.M.

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF: OFFICE OF THE UNITED STATES ATTORNEY
450 GOLDEN GATE AVENUE, BOX 36055
SAN FRANCISCO, CA 94102
(415) 436-7232
BY: IOANA PETROU

FOR PLAINTIFF: OFFICE OF CONSUMER LITIGATION
UNITED STATES DEPARTMENT OF JUSTICE
POST OFFICE BOX 386
WASHINGTON, D.C. 20044
BY: ALLAN GORDUS

(APPEARANCES CONTINUED ON NEXT PAGE)

REPORTED BY: LYDIA ZINN, CSR #9223
KATHERINE WYATT, CSR # 9866
OFFICIAL REPORTERS - U.S. DISTRICT COURT

SIMPLE ONE, WHICH IS THAT YOU HAVE TO TELL THE TRUTH. WE DON'T NEED TO LOOK INTO A CFR. WE DON'T NEED TO LOOK INTO THE E9 PRINCIPLES OF STATISTICS.

THIS PERSON, THE DEFENDANT, W. SCOTT HARKONEN, NEEDED TO TELL THE TRUTH. HE NEEDED TO TELL THE TRUTH TO, AS MR. TOPEL SAID, DYING PATIENTS.

THESE PATIENTS ARE DYING, AND THEY ARE GOING TO TAKE A DRUG BASED ON ANY HOPE AT ALL, INCLUDING BASED ON FALSE HOPE.

DR. RAGHY TOLD YOU HIMSELF, EVEN BEFORE THIS CLINICAL TRIAL TOOK PLACE HE WAS PRESCRIBING IT TO SOME PEOPLE ON A COMPASSIONATE BASIS, BECAUSE THERE'S SIMPLY NOTHING ELSE OUT THERE. AND DYING PATIENTS WILL TAKE A DRUG ON FALSE HOPE, EVEN WHEN IT COSTS THEM $50,000 A YEAR, AND EVEN IF IT COSTS THEM $50,000 A YEAR OUT OF THEIR OWN POCKET.

IT'S NOT COMPLICATED. HE NEEDED TO TELL THEM THE TRUTH. DR. HARKONEN COULD HAVE TOLD THE TRUTH, BECAUSE HE KNEW IT. HE WAS TOLD IT TIME AND AGAIN BEFORE THE PRESS RELEASE CAME OUT, AND AFTER THE PRESS RELEASE CAME OUT.

HE WAS TOLD TIME AND AGAIN THAT THE TRIAL DID NOT DEMONSTRATE A SURVIVAL BENEFIT. I DON'T NEED TO SPEND ANY TIME ON THE NUMBERS IN THERE. WE ALL KNOW THE NUMBERS ARE CORRECT.

DR. FLEMING CAME IN HERE AND TOLD YOU:

"THIS WAS A REALLY, REALLY WELL-RUN TRIAL. IT WAS DONE EXTREMELY WELL. WE COULD RELY ON THE NUMBERS. AND THAT, IN PART, IS WHEN I SAW A .5 ON

SIDLEY AUSTIN LLP
SIDLEY

SIDLEY AUSTIN LLP
555 WEST FIFTH STREET
LOS ANGELES, CA 90013
(213) 896 6000
(213) 896 6600 FAX

mhaddad@sidley.com
(213) 896 6604

February 11, 2010

By Federal Express

The Honorable Joseph P. Russoniello
United States Attorney, Northern District of California
United States Attorney's Office
450 Golden Gate Avenue, 11th Floor
San Francisco, California 94102

Re: *United States v. Harkonen*, No. CR 08-0164 MHP (N.D. Cal.)
Request for Correction under Information Quality Guidelines

Dear Mr. Russoniello:

We represent W. Scott Harkonen, the defendant in the above-referenced matter. On his behalf, we submit this letter as a Request for Correction under the Information Quality Guidelines ("Guidelines"), promulgated by the U.S. Department of Justice pursuant to the Information Quality Act, Pub. L. No. 106-554, Appendix C § 515(a), 114 Stat. 2763A-154 (2000) (codified at 44 U.S.C. § 3516 note). *See* www.justice.gov/iqpr/dojinformationqualityguidelines.htm (setting forth Guidelines).

On September 29, 2009, the U.S. Attorney's Office of the Northern District of California issued a press release titled "W. Scott Harkonen, Former Biotech CEO, Convicted of Wire Fraud." Ex. A, *available at* www.justice.gov/usao/can/press/2009/2009_09_29_harkonen.convicted.press.html. The DOJ press release contains the following statement: "'Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval,' said FBI Special Agent in Charge Stephanie Douglas." *Id.*

We are filing this Request not to dispute the Government's charges against him—we have done that in separate post-trial motions filed with the District Court—but rather to request

SIDLEY AUSTIN LLP
SIDLEY

that the Government correct its *description* of those charges in the statement quoted above. The charges against him did *not* include—in the words of the DOJ press release—that he "falsif[ied] test results." By stating otherwise, the DOJ press release announcing his conviction is itself false. The statement thus violates the Guidelines, which provide in part: "DOJ components will ensure disseminated information, as a matter of substance and presentation, is accurate . . . ."

During Dr. Harkonen's trial, the Government challenged statements from an August 28, 2002 press release ("Press Release") that announced the preliminary results of a Phase III clinical trial of the prescription drug Actimmune (interferon gamma-1b) for treating idiopathic pulmonary fibrosis ("IPF"). *See* Ex. B (2002 press release); Ex. C (RT 9/22/09 at 3457: The Court: "[F]or the wire fraud, what you are citing to as the basis for the—for this false to fraudulent statement is the press release?" Assistant U.S. Attorney Ioana Petrou: "Yes, your honor."). In particular, the Government claimed that certain statements in the 2002 press release were false and misleading: "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF"; Actimmune "Reduces Mortality by 70% in Patients With Mild to Moderate Disease"; and "Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials." Ex. B (press release); Ex. D (RT 5/20/09 at 10-14); Ex. E (RT 8/18/09 at 270-71, 277-82). According to the Government, these statements were false because the Phase III trial's endpoints were not met within FDA's guidelines for statistical significance, and because the Press Release did not state that the subgroup was retrospectively defined. Ex. F (RT 9/23/09 at 3568-69, 3597).

The Government conceded, however, that the Press Release accurately reported the trial data and statistics. For example, during a pretrial conference, Ms. Petrou agreed that the test results were not "transposed or changed in any way." Ex. G (RT 6/24/09 at 28). And during her closing argument, Ms. Petrou stated: "I don't need to spend any time on the numbers in [the Press Release]. We all know the numbers are correct." Ex. H (RT 9/23/09 at 3697).

The Government's witnesses likewise stated that Dr. Harkonen did not falsify the test results. Dr. Marc Walton, an FDA scientist and a chief witness for the Government, testified that he (and FDA) were not aware of any falsifications or distortions in the reporting of the trial results. Ex. I (RT 8/19/09 at 527-28). Dr. Steven Porter, an Intermune scientist, testified that the "actual numbers in the Press Release" were "correct." Ex. J (RT 9/2/09 at 1535–36); *see also* Ex. K (RT 9/1/09 at 1442-43, 1470). Dr. Michael Crager, InterMune's Chief Biostatistician, testified that there were no incorrect "numbers in the press release . . . ." Ex. L (RT 9/10/09 at 2238); *see also* Ex. M (RT 9/10/09 at 2317–18). And James Weiss, who was involved in the drafting of the Press Release, testified that he had no reason "to doubt the absolute correctness and integrity of those results" reflected in the release. Ex. N (RT 9/15/09 at 2661). Defense witnesses also testified that the test results reported in the Press Release were accurate. *See, e.g.*,

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Ex. O (RT 9/18/09 at 3393: Stephen Rosenfield, the then-General Counsel for Intermune, testified that he "never heard that there's a misstatement of any data in this press release.").

Instead, the Government disputed the *conclusions* that Dr. Harkonen derived from the trial results and reported in the Press Release. *See* Ex. P (RT 9/23/09 at 3570: in its closing, the Government argued: "what you can't do is take the p-values that you get from that subgroup analysis, and make conclusions based on those p-values. You can't make definitive conclusions about whether a drug works or not based on those p-values."). Thus, Dr. Harkonen was convicted for drawing a conclusion that the Government claimed the test results did not support; he was not convicted for having falsified the test results themselves.

The Government's assertion in the DOJ press release that Dr. Harkonen "falsif[ied] test results" thus misrepresents what the Government sought to prove in the case and misleads the public as to what the jury actually found, and as to why Dr. Harkonen was convicted. It is also unfair to Dr. Harkonen for the Government to state falsely that he engaged in fraudulent activity beyond what the evidence at trial sought to prove, especially where the Government conceded at trial that such fraudulent activity did not occur. Finally, the Government's false statement will damage Dr. Harkonen's reputation in the medical community, even beyond his conviction. For example, under California law, the falsification of test results can be a separate violation of medical ethical rules apart from a criminal conviction. *See* Cal. Bus. & Prof. Code § 2236(a) (noting that a criminal conviction can "constitute[] unprofessional conduct"); *id.* § 2262 (noting separately that "creating any false medical record, with fraudulent intent, constitutes unprofessional conduct.").

Dr. Harkonen thus requests the following: (1) the Government issue a retraction of the statement in the September 29, 2009 press release that Dr. Harkonen "falsif[ied] test results," and publish that retraction in the same manner that the Government distributed the September 29 press release to the public; and (2) the Government remove the original September 29 press release from all official Government websites. Such an approach is the only reasonable measure by which the Government can mitigate the harm caused by the public dissemination of its false statement.

We look forward to your response within sixty calendar days of receipt of this letter.

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Very truly yours,

Mark E. Haddad /RBM

Coleen Klasmeier /RBM

Mark E. Haddad

Coleen Klasmeier

Enclosures

cc: Gary Grindler, Acting Deputy Attorney General
Lee J. Lofthus, Assistant Attorney General for Administration, Justice Management Division
Ioana Petrou, Assistant United States Attorney
Marcus S. Topel, Kasowitz, Benson, Torres & Friedman LLP

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U.S. Department of Justice

Executive Office for United States Attorneys

Office of the Director

Room 2261, RFK Main Justice Building
950 Pennsylvania Avenue, NW
Washington, DC 20530

(202) 514-2121

MAR 15 2010

Mark E. Haddad, Esquire
Sidley Austin LLP
555 West Fifth Street
Los Angeles, CA 90013

Dear Mr. Haddad:

This responds to your letter dated February 11, 2010, to the United States Attorney for the Northern District of California, a copy of which you provided to the Acting Deputy Attorney General, concerning your Request for Correction pursuant to the Department of Justice's Information Quality Guidelines. You seek a retraction of a statement contained in a press release issued by the United States Attorney's Office for the Northern District of California (USAO) on September 29, 2009, regarding the conviction of your client, W. Scott Harkonen. Because your request falls outside the scope of the Department's guidelines, we are unable to accommodate your request. Moreover, regardless of the guidelines' application, we do not believe a retraction is warranted under the circumstances.

Section 515 of the Treasury and General Appropriations Act for Fiscal Year 2001 required the Office of Management and Budget (OMB) to issue government-wide guidelines for ensuring and maximizing the quality of information disseminated by federal agencies. It also required federal agencies to promulgate their own implementing guidelines consistent with those established by OMB. The OMB guidelines apply only to information that is "disseminated." Under the OMB guidelines, "dissemination" means "agency initiated or sponsored distribution of information to the public," but excludes certain distributions, including press releases. (67 FR 8460.) Similarly, the DOJ guidelines apply to all "DOJ initiated or sponsored dissemination of information," subject to specific exceptions. The exceptions include information disseminated in "press releases[,] fact sheets, press conferences, or similar communications (in any medium) that announce, support or give public notice of information in DOJ." Because the statement of which you complain was disseminated in a press release, the guidelines do not apply.

Even if the guidelines applied, no retraction is necessary because the statement at issue is correct. As you know, Mr. Harkonen was convicted of wire fraud for the creation and dissemination of false and misleading information about the efficacy of a certain drug for the treatment of a fatal disease. Following his trial and conviction, the USAO issued a press release containing the following statement:

> "Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval," said FBI Special Agent in Charge Stephanie Douglas.

You contend this statement is false because Mr. Harkonen did not alter the clinical trial data but instead drew unsupported conclusions from the data. While we agree that Mr. Harkonen did not change the data, he nevertheless used it to support his false and misleading conclusions. Because data alone is meaningless without analysis and conclusions, Mr. Harkonen's false statements regarding the data's meaning were part and parcel of the results. Thus, it was accurate to say that he falsified the results.

Thank you for raising your concerns with the Department.

Sincerely,

H. Marshall Jarrett
Director

cc: Joseph P. Russoniello
United States Attorney
Northern District of California

SIDLEY AUSTIN LLP
SIDLEY

SIDLEY AUSTIN LLP
555 WEST FIFTH STREET
LOS ANGELES, CA 90013
(213) 896 6000
(213) 896 6600 FAX

mhaddad@sidley.com
(213) 896 6604

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FOUNDED 1866

April 20, 2010

By Federal Express

The Honorable Joseph P. Russoniello
United States Attorney, Northern District of California
United States Attorney's Office
450 Golden Gate Avenue, 11th Floor
San Francisco, California 94102

Re: *United States v. Harkonen*, No. CR 08-0164 MHP (N.D. Cal.)
Request for Reconsideration under Information Quality Guidelines

Dear Mr. Russoniello:

On behalf of W. Scott Harkonen, and pursuant to the Information Quality Guidelines promulgated by the U.S. Department of Justice ("DOJ Guidelines")[1] under the Information Quality Act, Pub. L. No. 106-554, Appendix C § 515(a), 114 Stat. 2763A-154 (2000) (codified at 44 U.S.C. § 3516 note) ("the Act"), we submit this letter as a Request for Reconsideration concerning Dr. Harkonen's earlier-filed Request for Correction, dated February 11, 2010. The Department of Justice denied the Request for Correction by letter dated March 15, 2010 ("Response"), a copy of which is attached as Exhibit A. We submit this Request for Reconsideration to you as the "disseminating DOJ component" pursuant to the DOJ Guidelines.

In the Request for Correction, Dr. Harkonen asserted that the following statement, contained in a September 29, 2009 press release issued by the U.S. Attorney's Office of the Northern District of California, is false and thus violates the DOJ Guidelines: "'Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval,' said FBI Special Agent in Charge Stephanie Douglas."[2] In particular, the statement that Dr. Harkonen "falsif[ied] test results" is untrue, because the Government at trial conceded

[1] The DOJ Guidelines are available at www.justice.gov/iqpr/dojinformationqualityguidelines.htm.
[2] The press release is available at www. justice.gov/usao/can/press/2009/2009_09_29harkonen.convicted.press.html.

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that Dr. Harkonen did not falsify any test results. In its Response, the Government again "agree[s] that [Dr.] Harkonen did not change the data."

The Government's false statement in its press release is not merely a semantic error. There is a profound difference between falsifying clinical test results – an allegation never even made let alone proven here – and drawing allegedly unsupported conclusions from clinical test results. The DOJ's statement that Dr. Harkonen falsified test results is causing ongoing and severe injury to Dr. Harkonen's reputation in the medical community and to Dr. Harkonen in his personal and professional life. It should be corrected immediately.

Rather than owning up to its obvious error and taking responsibility for it, DOJ has now offered two excuses for inaction. Each is transparently meritless. It is precisely in a situation such as this that the agency, in the exercise of its statutory duty to review the case independently on rehearing, should step in, assess the situation dispassionately and see it for what it is, and correct the public record.

1. First, the Response argues that DOJ can say anything it wants to say, including false statements, so long as it utters those false statements in the medium of a press release. That DOJ would even advance such an argument in this case – where it seeks to treat an alleged misstatement in a press release as felonious conduct warranting 30 years imprisonment – is astonishing and bitterly ironic. The argument is all the more surprising as it conflicts with the plain language of DOJ's own guidelines.

The DOJ Guidelines expressly cover material disseminated on DOJ's web site, as well as DOJ's press releases. The DOJ "guidelines apply to all information disseminated by DOJ . . . , [including] any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. It includes information that an agency disseminates from a web page . . . ." The guidelines further state that "[t]he information DOJ disseminates includes: Departmental briefs in major cases, regulations, business review letters, memoranda, *press releases*, opinions, research, statistical and special reports, newsletters, and general publications." (emphasis added).

Nevertheless, the Response contends the following exemption in the DOJ Guidelines applies to the press release at issue: "[T]he guidance does not apply to information disseminated in the following contexts: . . . press releases [sic] fact sheets, press conferences or similar communications (in any medium) that announce, support or give public notice *of information in DOJ*." DOJ Guidelines, note 1 *supra* (emphasis added). That exemption has no application to information posted on web pages, and applies only to those press releases that "announce, support or give public notice of information in DOJ." *Id.* In contrast, the press release at issue here announced the verdict of a criminal trial in federal court; the press release thus did not give

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"public notice of information in DOJ." The exemption is thus inapplicable by its terms, and the Response's assertion to the contrary is incorrect and arbitrary.

The Response also cites to the OMB Guidelines. The OMB guidelines, however, require federal agencies (including DOJ) to "issue their own implementing guidelines" consistent with the objectives of the Act. 67 Fed. Reg. 8452, 8452 (Feb. 22, 2002) (attached as Exhibit B). The OMB guidelines thus do not and cannot supplant, but instead only reinforce, the applicability of DOJ's own guidelines.

Nonetheless, the Response cites to a provision of the OMB guidelines that purports to exclude "dissemination" by "press release." *See id.* at 8460 ("'Dissemination' means agency initiated or sponsored distribution of information to the public. Dissemination . . . does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." (internal citation omitted)). This exemption does not apply here.

First, the OMB's guidelines merely provide guidance for federal agencies generally to use in developing their own guidelines. Where, as here, an agency has promulgated its own guidelines, and those guidelines specifically address an issue that is treated only more generally in the OMB guidelines, the agency's own, more specific guidelines control.

Second, the OMB guidelines on their face do not exempt the DOJ press release at issue, because the purported exemption is for "distribution limited to . . . press releases," and the distribution here was not so "limited." DOJ not only sent out the press release in September 2009, but posted this press release on its web site, where it remains to this day, more than six months after the trial, readily accessible to the public via an internet search, and continuing to mislead all who see it on an issue of public importance. The distinction between a press release and information on a web site is material, because DOJ's own guidelines recognize and separately address the fact that information "disseminate[d] from a web page" is covered by the IQA.

Third, the OMB Guidelines are designed "to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate (meaning to share with, or give access to, the public). It is crucial that information Federal agencies disseminate meet these guidelines." 67 Fed. Reg. at 8452. Here, that calls for applying the IQA to the DOJ's press releases, because unlike other federal agencies that communicate primarily with the public through other means, such as rulemaking processes, "[t]he use of a press release . . . is the usual method to release public information to the media by Department of Justice components and investigative agencies." U.S. Attorneys' Manual 1-7.401(A) (2003) (attached as Exhibit C). Because of the importance of press releases to DOJ's public mission, it was

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appropriate for the DOJ Guidelines to limit any exemption for press releases only to those that "announce, support or give public notice of information in DOJ." DOJ Guidelines, note 1 *supra*. As explained above, that exemption does not apply to the press release at issue, and the DOJ Guidelines thus apply in full force here.

It is inconsistent with DOJ's public mission for DOJ to insulate itself from any responsibility for disseminating false or misleading statements about the results of criminal trial through press releases. It particularly undermines public faith and trust in DOJ's integrity for DOJ to do so here, where the same DOJ seeks to imprison Dr. Harkonen for his alleged false statement in a press release. The DOJ's double standard is arbitrary and unreasonable, and we urge you to reject it.

2. Second, the Response attempts, in the alternative, to defend the merits of the challenged statement. Although the Response "agree[s] that [Dr.] Harkonen did not change the data," the Response argues that Dr. Harkonen used the data "to support his false and misleading conclusions. Because data alone is meaningless without analysis and conclusions, [Dr.] Harkonen's false statements regarding the data's meaning were part and parcel of the results. Thus, it was accurate to say that he falsified the results." Response at 2.

This explanation, upon examination, is sleight-of-hand. It arbitrarily ignores the well-recognized distinction between scientific *data* and scientific *analysis*. Data are separate from, and precede, analysis. *See, e.g.*, Webster's II New College Dictionary 293 (3d ed. 2005) ("Data" is defined as "information organized for analysis or used as the basis for making a decision."). If data are falsified, the integrity of any subsequent analysis is immediately compromised for that reason alone. The falsification of results is thus easily distinguishable from a dispute over the meaning of accurately reported data.

The distinction between data and analysis is readily apparent in both science and the law. Scientific articles separate the reporting of test results from the analysis of those results, as review of a respected medical journal like the *New England Journal of Medicine* reveals. *See, e.g.*, Supachai Rerks-Ngarm, M.D., et al., *Vaccination with ALVAC and AIDSVAX to Prevent HIV-1 Infection in Thailand*, N. Engl. J. Med. 2009, at 4–8 (Nov. 9, 2009) (attached as Exhibit D) (setting forth test "Results"); *id.* at 8–10 (setting forth "Discussion" and analysis). And the same is true in the law, where judicial opinions commonly distinguish between the facts of the case, and the analysis of the law as applied to those facts. Even the OMB Guidelines recognize that scientific data are separate from analysis: "In a scientific . . . context, the original and supporting data shall be generated, *and* the analytic results shall be developed, using sound statistical and research methods." 67 Fed. Reg. at 8459 (emphasis added).

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Thus, the Response's conclusion that the "false statements regarding the data's meaning were part and parcel of the results" (Response at 2) is nonsensical. A summary of a clinical study can set forth accurate results; interpretation and analysis of those results may vary. Similarly, a legal opinion may accurately recite the facts of a case, yet prompt one or more dissenting opinions interpreting and analyzing the law in light of those same facts.[3] The Government's theory of prosecution here was never about falsifying test data or results; instead, the Government disputed the analysis and conclusions that Dr. Harkonen drew from those results.

The clinical results, accurately reported in the InterMune press release, included the facts that, of those treated with Actimmune in the Phase III trial, 40% fewer patients died than of those given placebo. In human terms, 16 patients died on Actimmune, but 28 died while being treated with placebo. The chances of this benefit occurring independently of Actimmune were 8% (p-value .084). Additional subgroup analyses showed an even stronger benefit (and at a lower p-value of .004) for those whose disease was not too far advanced. The Government never disputed the accuracy of those data.

Instead, the Government argued at trial that Dr. Harkonen drew a false conclusion from that data by claiming the trial data "demonstrate[ed a] survival benefit of Actimmune in IPF," even though the Government admitted before trial that the data "suggested" a survival benefit. In post-trial motions, we explain why the Government's attempt to draw a line between what the Government conceded was a permissible conclusion (that the data "suggested" a survival benefit) and what it claims was a felonious conclusion (that the data "demonstrated" a survival benefit) lacks any merit whatsoever.

This Request, however, does not require the Government to address the validity of the conclusion that Dr. Harkonen drew from the clinical results. That is for the District Court. This Request raises a separate dispute over the Government's description in *its* press release of the charges it proved against Dr. Harkonen is false. Those charges never included claims that he "falsif[ied] test results," and this point has now been conceded by the Government in the Response. As a result, the statement in the Government's press release that Dr. Harkonen was guilty of falsifying test results is, itself, a false statement. Under the IQA, the Government has a legal duty to correct that statement.

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[3] For example, as the government is aware, the only remaining issues in dispute in Dr. Harkonen's criminal case relate to the reporting of clinical trials to the public. Nonetheless, the government's press release suggests by "falsifying test results," Dr. Harkonen "undermine[d] public trust in our system for drug approval." And yet the jury acquitted Dr. Harkonen of the misbranding charge alleging that he unlawfully marketed a drug. Thus, even assuming the basis of the argument was true (*i.e.*, that Dr. Harkonen falsified test results), which it is not, the government's conclusion that the falsified test results "undermined public trust in our system for drug approval" is false, separate, and independent from the truth or falsity of the basis of the argument.

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We urge DOJ to correct the public record now. As we noted in the Request for Correction, "the falsification of test results can be a separate violation of medical ethical rules apart from a criminal conviction." *See* Request for Correction at 3 (citing California law). Although scientists regularly differ over the conclusions to be drawn from data, no one condones the falsification of the data itself. The latter is widely understood to involve serious wrongdoing. Indeed, since the issuance of the press release, Dr. Harkonen has lost professional employment and research opportunities attributable to the Government's claim that he falsified test results. Given that the Government "agree[s] that [Dr.] Harkonen did not change the data" (Response at 2), these injuries are unnecessary, unfair, and must be remedied.

For these reasons, and those set for in our initial Request, the Government should withdraw its earlier Response and correct the press release as set forth in the Request for Correction.

We look forward to your response within forty-five calendar days of receipt of this letter.

Very truly yours,

Mark E. Haddad

Coleen Klasmeier

Enclosures

cc: H. Marshall Jarrett, Director, Executive Office for United States Attorneys
Ioana Petrou, Assistant United States Attorney
Marcus S. Topel, Kasowitz, Benson, Torres & Friedman LLP

U.S. Department of Justice

Executive Office for United States Attorneys

Office of the Director

Room 2261, RFK Main Justice Building
950 Pennsylvania Avenue, NW
Washington, DC 20530

(202) 514-2121

JUL - 2 2010

Mark E. Haddad, Esq.
Sidley Austin LLP
555 West Fifth Street
Los Angeles, CA 90013

Dear Mr. Haddad:

This responds to your letter dated April 20, 2010, to the United States Attorney for the Northern District of California, concerning your client's Request for Reconsideration under the Department of Justice's Information Quality Guidelines.

As set forth in my letter dated March 15, 2010, the guidelines do not apply because the statement of which you complain was disseminated in a press release. While the guidelines acknowledge that DOJ disseminates information through various sources, including press releases, the guidelines explicitly state that "[n]ot all of this information falls within these guidelines." The exceptions to the guidelines include "press releases ... that announce, support or give public notice of information in DOJ." Your claim that the press release at issue does not fall within this exception because it does not give notice of public information in DOJ is not a reasonable interpretation of such language. One of the primary functions of the Department of Justice is to prosecute violations of federal law. Accordingly, a press release that announces a successful prosecution is clearly public information in the Department of Justice.

Similarly, your argument that the guidelines do not apply because the disputed statement was not limited to a press release, but was disseminated on the Department's website, is also unavailing. The method by which the Department issued the press release is irrelevant. The guidelines make no distinction between a press release that is posted on the Internet and one that is issued any other way (e.g., fax or mail). Rather, it is the very fact that the information is contained in a press release that exempts it from the guidelines.

Because the guidelines do not apply to press releases, the Department was not required to respond substantively to your initial request for a retraction. The guidelines provide that "[t]he Department need not respond substantively ... to requests [for correction] that concern information not covered by the guidelines." As your request for reconsideration relies on the guidelines, your request is misplaced and cannot be accommodated.

Thank you for raising your concerns with the Department.

Sincerely,

H. Marshall Jarrett
Director

cc: Brian Stretch
Acting United States Attorney
Northern District of California

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL, JUDGE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	NO. CR 08-00164 MHP
	)	
W. SCOTT HARKONEN,	)	
	)	
Defendant.	)	
	)	

San Francisco, California
Wednesday, April 13, 2011

TRANSCRIPT OF SENTENCING PROCEEDINGS

APPEARANCES:

For Plaintiff:

MELINDA L. HAAG, ESQ.
United States Attorney
450 Golden Gate Avenue
San Francisco, California 94102

BY: **KYLE WALDINGER**
Assistant United States Attorney

U.S. Department of Justice
Office of Consumer Litigation
450 Fifth Street, N.W.
Suite 6400-South
Washington, D.C. 20001

BY: **ALLAN GORDUS**
Trial Attorney

(Appearances continued on following page.)

Reported By: Leo T. Mankiewicz, CSR 5297, RMR, CRR

then they need to look and see if they have exculpatory documents about the impact of the press release on prescriptions and decision-making of doctors on Actimmune in the Veterans Administration.

THE COURT: Now, who's going to be heard on this from the government's side?

MR. WALDINGER: I will, your Honor.

THE COURT: Mr. Waldinger, do you agree with what he has said so far, in terms of the obligation; was this an investigating agency in connection with this case, and what the obligation is with respect to an investigating agency, without regard to the rest of the argument?

MR. WALDINGER: The Veterans Administration Office of Inspector General was one of the investigating agencies. In fact, an agent from that agency sitting at counsel table today, that's Special Agent Paul Lori.

I disagree that the obligation is to find the information regarding how the press release impacted, I think was the word that Mr. Haddad used. There is an obligation to find information that would tend to show that the press release was not material, but exactly what Mr. Haddad said is what the government did not have to provide, which was reliance evidence.

MR. HADDAD: Then, your Honor, may I qualify? They had to look for evidence that it was capable of influencing

BRIAN J. STRETCH (CABN 163973)
Attorney for the United States, Acting
Under Authority Conferred by 28 U.S.C. § 515

KYLE F. WALDINGER (ILBN 6238304)
Assistant United States Attorney

450 Golden Gate Avenue, Box 36055
San Francisco, California 94102
Telephone: (415) 436-6830
Facsimile: (415) 436-7234
kyle.waldinger@usdoj.gov

ALLAN GORDUS (MOBN 48210)
Trial Attorney

DOJ Office of Consumer Litigation
Liberty Square Building
450 5th Street, NW, Sixth Floor South
Washington, DC 20001
Telephone: (202) 307-1862
Facsimile: (202) 514-8742
allan.gordus@usdoj.gov

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. W. SCOTT HARKONEN, Defendant.	No. CR 08-164 MHP UNITED STATES' OPPOSITION TO DEFENDANT'S MOTION FOR NEW TRIAL DUE TO *BRADY* VIOLATION Hrg. Date: March 14, 2011 Hrg. Time: 11:00 a.m. Courtroom: Hon. Marilyn Hall Patel

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FEDERAL CASES

INTRODUCTION

After a month-long trial involving 19 witnesses and pre-trial discovery from the government of 2.5 million electronic images, the Defendant W. Scott Harkonen now claims that he is entitled to a new trial because the government recently provided 67 pages of documents from the Veterans Administration ("VA"). The Defendant argues that these 67 pages are critical evidence on the materiality of the press release at issue in this case, and that the government's failure to produce these documents before trial is a violation of *Brady v. Maryland*, 373 U.S. 83 (1963), and entitles him to a new trial. The Defendant makes this argument despite the fact that 22 pages of the 67 pages are essentially or completely blank due to redactions of material irrelevant to this case and only 1 page out of the 67 even mentions the press release.

The Defendant's motion is meritless for the following reasons:

- The VA documents have no bearing on the materiality of the press release to doctors. *See* Argument, Section I, *infra*.
- At best, the VA documents constitute irrelevant reliance evidence and would have been inadmissible at the Defendant's trial. *See* Argument, Section II, *infra*.
- The information in the VA documents is duplicative of information found in documents produced to the Defendant before trial and information otherwise available to the Defendant before trial. *See* Argument, Section III, *infra*.
- There was overwhelming evidence of the materiality of the press release at trial, and therefore, there is no reasonable probability that the result of the trial would have been different even if the VA documents had been produced before trial. *See* Argument, Section IV, *infra*.

For all of the above-stated reasons, the Defendant's motion for new trial based on alleged *Brady* violations should be denied.

THE VA DOCUMENTS

The Defendant argues that the VA documents show his press release was not material, that is, that it was not capable of influencing doctors in any way to prescribe Actimmune for idiopathic pulmonary fibrosis ("IPF"). A simple inspection of the VA documents shows that

they have no bearing on the materiality of the press release to doctors.

In his motion, the Defendant divides the 67 pages of VA documents into four categories. The government will discuss the documents according to those same four categories. The VA documents were filed under seal as Exhibits B and C to the defendant's *Brady* motion. *See* Declaration of Robert B. Martin, III, Docket Entry No. 307. The Defendant concedes in his motion that the VA documents numbered VA-000052 to VA-000067, which are Exhibit C to his motion, are irrelevant to his motion. *See* Motion for New Trial Due to *Brady* Violation, Docket Entry No. 306, at 10 (numbered page 5), & footnote 5.

I. THE THREE LETTERS FROM VISN-22 (VA-000002, 000003, 000004).

The VA medical system is divided into 23 separate regions or Veterans Integrated Service Networks ("VISNs") across the United States. Each VISN makes its own decision on the off-label use of a drug, including the off-label use of Actimmune as a treatment for IPF. The VA documents show that some VISNs approved the use of Actimmune as a treatment for IPF, while others did not. VISN 22, which included the VA Healthcare System in Long Beach, California, did not allow the use of Actimmune as a treatment for IPF.

The documents numbered VA-000003 and VA-000004 are two nearly identical VA letters from the VA Healthcare System in Long Beach which respond to inquiries from members of Congress asking why a constituent was not able to receive Actimmune as a treatment for IPF at the VA in Long Beach. The letters are both dated June 27, 2003. Both of these letters state that Actimmune is not available for the treatment of IPF at the VA in Long Beach because VISN-22 has "extensively reviewed" the use of Actimmune for IPF, and found that "current data does not support the use of [Actimmune] outside of clinical trials." This is the sum total of the discussion in these two letters of the use of Actimmune as a treatment for IPF. Neither letter mentions the press release.

The third letter (VA-000002) is the only VA document to that even arguably mentions the Defendant's press release. This letter is another from the VA in Long Beach responding to a request for Actimmune as a treatment for IPF. The letter is dated September 13, 2002. The request appears to be from a VA IPF patient's son who specifically cited the Defendant's press

release in his request. The VA letter denies the request for Actimmune as a treatment for IPF by stating that "the current evidence is insufficient to warrant the use of [Actimmune] outside the setting of a clinical research study." In referencing what appears to be the Defendant's press release, the letter states:

> [T]he press release you quote from Intermune, the pharmaceutical company, is not believed to be sufficient scientific evidence that [Actimmune] is both safe and effective. [The VA] further believe[s] that the results of this trial have not undergone any rigorous scientific evaluation for either safety or efficacy.

Def. Ex. B at VA-000002, Docket Entry No. 307.[1] Even though this letter is the only VA document to mention a press release, it is unclear if the press release referred to in this letter is in fact the Defendant's August 28, 2002 press release.

II. OCTOBER 17, 2002 MEMORANDUM FROM VISN-22 (VA-000015-16).

This memorandum sets forth the decision of VISN-22 to prohibit the use of Actimmune as a treatment for IPF. The memorandum makes the following conclusion: "It is the collective opinion of the individuals involved in this review that the current evidence is insufficient to warrant the use of [Actimmune] outside the setting of a clinical research study." Def. Ex. B at VA-000015, ¶ 1. In making this decision, the memorandum discusses the Ziesche Study and notes its numerous shortcomings. *Id.*, ¶ 3. The memorandum also discusses InterMune's September 18, 2002 press release that contains information on InterMune's recently concluded GIPF-001 clinical trial of Actimmune as a treatment for IPF as presented at the European Respiratory Society meeting in Stockholm, Sweden. The memorandum goes on to state that InterMune's September 18, 2002 press release "was the first public release of information" about the GIPF-001 trial. Def. Ex. B at VA-000015, ¶ 4; InterMune's September 18, 2002 press

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[1] The Defendant's *Brady* motion fails to analyze the fact that the indictment alleged and the government proved at trial that the Defendant's press release was material to IPF patients, not just the doctors who treat IPF patients. Even if a doctor prescribed Actimmune for an IPF patient, the patient also must want to take the drug. These VA letters, and the September 11, 2002 minutes from VISN-22 discussed below, show the materiality of the Defendant's press release to patients, because they show patients actively seeking the drug.

release attached as Exhibit K. The memorandum does not mention the Defendant's August 28, 2002 press release, apparently unaware that it exists.

III. USE CRITERIA FOR ACTIMMUNE FROM VISNs 9 & 21 (VA-000006 TO VA-000014).

These documents consist of two sets of criteria for the use of Actimmune, one for VISN-9, and the other for VISN-21. The VISN-9 criteria apparently date from before the end of the GIPF-001 clinical trial, and therefore, before the Defendant's press release, which first reported the results of InterMune's GIPF-001 clinical trial. This appears to be the case because the criteria state: "A randomized, double-blind, placebo-controlled, Phase III clinical trial evaluating the efficacy and safety of [Actimmune] in 330 patients with IPF is underway. The release of findings is targeted for late 2002." Def. Ex. B at VA-000007. Accordingly, these criteria nowhere mention the Defendant's press release. The criteria allow for the use of Actimmune to treat IPF under certain circumstances, but do not explain that decision. The rest of the criteria list dosing of Actimmune, storage and handling of Actimmune, Actimmune's interactions with other drugs, and other similar information related to the use of Actimmune.

The VISN-21 criteria for the use of Actimmune date from August 2008. These criteria do not mention the Defendant's press release, which occured 6 years before these criteria. These criteria prohibit the use of Actimmune to treat IPF apparently because InterMune's GIPF-007 clinical trial "showed that patients with IPF did not benefit from Actimmune." Def. Ex. B at VA-000010. Finally, these criteria contain similar information on the dosing, storage and handling, drug interactions, etc., of Actimmune.

IV. FORMULARY COMMITTEE MEETING MINUTES FOR VISNs 9 & 22 (VA-000019 TO VA-000051).

The VA documents numbered VA-000019 to VA-000051 are cryptic minutes from the meetings of the formulary committees or "PBMAGs" (which stands for "Pharmacology Benefits Medical Advisory Groups") for VISN-9 and VISN-22. Def. Ex. B at VA-000019 to VA-000051. The PBMAGs for each VISN decide how a particular drug can be prescribed by VA doctors within that VISN.

There is actually very little information in these minutes because the minutes discussing drugs other than Actimmune, which is nearly all of the minutes, are redacted. Accordingly, 21 of these 33 pages are blank or essentially blank. Even those pages with text have very little written on them. The unredacted minutes for the PBMAGs for VISN-9 and VISN-22 show their decisions on the use of Actimmune for IPF with little or no explanation for the decisions. Finally, there is no mention of the Defendant's press release, or any press release, or any information about the effectiveness of Actimmune in treating IPF, in any of these minutes.

The minutes from VISN-22 date from September 11, 2002, October 9, 2002, and November 13, 2002. The September 11, 2002 minutes discuss increasing instances of VA patients who are denied a drug at one VA facility, and then go to other VA facilities to try to get the drug, and the specific case of an IPF patient doing this in an effort to get what appears to be Actimmune ("a highly investigational interferon for IPF"). The minutes go on to state that "[t]he VISN[-22 PBMAG] committee concu[r]red with the San Diego Pulmonology group that this agent should be considered experimental" without any further explanation. Def. Ex. B at VA-000022.

The unredacted minutes for VISN-22's October 9, 2002 PBMAG meeting state:

> The use of Interferon Gamma for IPF in an individual patient was discussed at the last meeting, but clarification of the status of the drug VISN wide for this Indication is needed. Since safety and efficacy data is not available, providers should be referred to IRB if interested in using drug for this indication. Forward copy of VISN letter addressed addressing [sic] this issue to Dr. Morreale[.] Dr. Morreale will draft a response that all sites may use to respond to requests for Interferon Gamma for IPF and provide to CPC [Clinical Practice Council].

Def. Ex. B at VA-000025.

The unredacted minutes for VISN-22's November 13, 2002 PBMAG meeting state:

> Interferon Gamma 1b for Idiopathic Pulmonary Fibrosis – the CPC supports/approves the PBM recommendation that this agent should not be offered, at this time, as treatment to any VA patient with IPF. I will forward copies of the CPC minutes as soon as available.

Def. Ex. B at VA-000048.

The minutes from PBMAG in VISN-9 date from July 16, 2003, and May 16, 2007. The July 16, 2003 minutes show that the PBMAG for VISN-9 allowed the use of Actimmune for VA

patients with IPF. The July 16, 2003 minutes reflect this decision and state:

> The PBMAG members shared the feedback from their respective pulmonology staff with the exception of Louisville and Huntington. The issue of whether the drug will be made available in light of the fact that there is no clinical evidence to support its use in IPF was discussed. However, there are no other treatment alternatives. . . .
>
> The PBMAG is not promoting the use of Actimmune to treat idiopathic pulmonary fibrosis (IPF) and passed a motion to leave actimmune as a non-formulary item. However, if the patient has exhausted all other treatment modalities, the provider can request actimmune on a non-formulary basis. . . .

Def. Ex. B at VA-000030.

The May 16, 2007 minutes reverse the decision to allow Actimmune as a treatment for IPF, apparently because of the results from InterMune's GIPF-007 clinical trial, which were announced on March 5, 2007, showing that Actimmune did not benefit IPF patients. (For the meaning of the results of InterMune's GIPF-007 clinical trial, *see* United States' Sentencing Memorandum on Fraud Loss, Docket Entry No. 304, at 35-36 (numbered 30-31), Exhibits D and E to that memorandum, and Exhibit E to this opposition.) These minutes state: "Recent evidence suggests that interferon gamma-1b should not be used in the treatment of idiopathic pulmonary fibrosis." Def. Ex. B at VA-000042.

PROCEDURAL BACKGROUND

I. THE GOVERNMENT'S PRE-TRIAL DISCOVERY.

Before trial, the government provided to the Defendant approximately 2.5 million electronic images. This discovery exceeded the government's obligations under *Brady*.

The Defendant claims that the VA documents were favorable to him because these documents show that the VA was not persuaded by his press release to prescribe Actimmune for IPF. Even if that were true, and it is not, the government provided to the Defendant before trial numerous documents showing the same thing.

The government provided the Defendant with numerous surveys of doctors asking for their reactions to the Defendant's press release. InterMune asked a market research firm to find out the reaction of doctors to the press release. The market research firm surveyed 12 doctors immediately after the press release and provided InterMune with a report entitled "Actimmune

for IPF Press Release Response Study." Attached as Exhibit A. This report contains responses from doctors who "reacted cautiously stating that they were reacting to a press release rather than a peer-reviewed published journal article." Ex. A at INR528-7667. The report contains other doctor comments critical of the results announced in the press release.

Investment banks also surveyed doctors for their reactions to the Defendant's press release to see how the press release might affect InterMune's sales of Actimmune. These survey results contain comments from doctors that are critical of the press release and the information in it. For example, one doctor stated that he discounted the information in the press release because it was in a press release and not a peer-reviewed medical journal article. *See* Defendant's Trial Exhibit 205, attached as Exhibit B, at INR502-5186. Doctors also stated that they did not find the survival benefit touted in the Defendant's press release compelling because it did not reach statistical significance and was the product of subgroup analysis. Ex. B at INR502-5183 to INR502-5184. There are also statements from doctors that the press release did not make them more likely to prescribe Actimmune for IPF. Ex. A at INR528-7661 and Ex. B at INR502-5186.

II. THE DEFENDANT'S PRE-TRIAL DISCOVERY.

Before trial, the Defendant filed his notice of expert testimony on May 26, 2009. Docket Entry No. 117. The Defendant's notice identifies two pulmonologists, Drs. Roger Maxfield and Joseph Zibrak, as experts who could testify at trial on his behalf. The notice also states that Drs. Maxfield and Zibrak would each testify at trial that "physicians do not make treatment decisions solely on the basis of a press release." Docket Entry No. 117 at 4, 8. The Defendant's notice of expert testimony shows that the Defendant was prepared to offer evidence on the immateriality of the press release to doctors' decisions to prescribe Actimmune for IPF.

III. TRIAL.

At trial, the government produced overwhelming evidence of the materiality of the Defendant's press release. For example, InterMune's general counsel testified that the Defendant's press release was the most important in the history of the company. InterMune, through its sales force and through the pharmacy Priority Healthcare, distributed the press release to IPF patients and pulmonologists who treated IPF patients for the specific purpose of

influencing them to use Actimmune. The press release announced a survival benefit for a fatal disease. The materiality of the press release was not only supported by extensive evidence, it was obvious. Indeed, the Defendant did not contest the materiality of the press release, but instead contested the government's evidence that the press release was false and fraudulent.

LEGAL STANDARD

In order to establish a violation of the rule set out in *Brady v. Maryland*, 373 U.S. 83 (1963), a defendant must prove that the evidence in question was "(1) favorable to the accused because it is either exculpatory or impeachment material; (2) suppressed by the government, either willfully or inadvertently; and (3) material or prejudicial." *United States v. Blanco*, 392 F.3d 382, 387 (9th Cir. 2004); *see also United States v. Antonakeas*, 255 F.3d 714, 725 (9th Cir. 2001) (defendant must show that "(1) the evidence was exculpatory or impeaching; (2) it should have been, but was not produced; and (3) the suppressed evidence was material to [the defendant's] guilt or innocence") (quotation omitted). "Evidence is material under *Brady* only if there is a reasonable probability that the result of the proceeding would have been different had it been disclosed to the defense." *Antonakeas*, 255 F.3d at 725. A "reasonable probability" is a "'probability that, had the evidence been disclosed to the defense, the result of the proceeding would have been different.'" *Strickler v. Greene*, 527 U.S. 263, 280 (1999) (quoting *United States v. Bagley*, 473 U.S. 667, 682 (1985)); *see also Bagley*, 473 U.S. at 678 (evidence is material under *Brady* when "its suppression undermines confidence in the outcome of the trial").

The Ninth Circuit has held that *Brady* material consists of admissible evidence, as well as *in*admissible evidence that could have been used to impeach a government witness. *See Paradis v. Arave*, 240 F.3d 1169, 1178–79 (9th Cir. 2001); *see also United States v. Price*, 566 F.3d 900, 912 (9th Cir. 2009) (noting that it was an open question as to whether "inadmissible evidence is material under *Brady* if its disclosure could have led the defendant to discover favorable *admissible* evidence") (emphasis added); *Smith v. Baldwin*, 510 F.3d 1127, 1148 (9th Cir. 2007) ("Because they are *inadmissible* in Oregon courts, the results of Edmonds's polygraph examination do not qualify as 'evidence' for *Brady* purposes, let alone 'material evidence.'") (emphasis added); *Cooper v. Brown*, 510 F.3d 870 (9th Cir. 2007) ("in order to be material

information within the meaning of *Brady*, the undisclosed information or evidence acquired through that information must be *admissible*") (emphasis added).

As set forth below, Harkonen has not made the required showings to support a finding of a *Brady* violation.

ARGUMENT

I. THE VA DOCUMENTS HAVE NO RELEVANCE TO THE MATERIALITY OF THE DEFENDANT'S PRESS RELEASE TO DOCTORS.

A. The VA Documents that Do Not Mention the Press Release.

With the exception of one page, none of the VA documents mention the Defendant's press release, or even show an awareness that his press release exists. Documents that do not mention or even show any indication of the existence of the Defendant's press release have no relevance to the materiality of the press release to doctors.

The Defendant tries to overcome this obvious conclusion by arguing that the absence of the press release from these documents shows that the VA did not consider the press release important to its decisions on whether to prescribe Actimmune for IPF, and therefore, these documents show that the press release was not material. A simple review of the documents shows that the Defendant's argument is entirely without merit.

The August 2008 criteria for use of Actimmune from VISN-21 post-date the Defendant's press release by 6 years. Def. Ex. B at VA-000010 to VA-000014. These documents would have been inadmissible at the Defendant's trial because of their much later date compared to the events at issue in the Defendant's trial. The Defendant's argument that these criteria show that the VA would never consider a press release in deciding how to prescribe Actimmune is not supported by the criteria. There is nothing in the criteria that indicates that the VA would not consider a press release. On the contrary, the criteria appear to indicate that the VA *did* review two press releases from InterMune's website in formulating these criteria. *See* Def. Ex. B at VA-000010-11, endnotes 10 & 14 at VA-000014; InterMune's February 2, 2006 press release entitled "InterMune Discontinues Ovarian Cancer Trial" attached as Exhibit C; InterMune's May 13, 2004 press release entitled "InterMune Initiates Phase II Clinical Trial of Daily Infergen Plus

Actimmune for the Treatment of Hepatitis C Nonresponders" attached as Exhibit D. This would indicate that to the extent these criteria are relevant to the materiality of the press release, they would tend to support the materiality of the press release, not its immateriality as the Defendant argues.

The May 16, 2007 minutes from the PBMAG in VISN-9 are also irrelevant because they post-date the Defendant's press release by a significant period of time, four-and-a-half years. Def. Ex. B at VA-000037. Additionally, there is nothing in these very minimal minutes that would indicate whether the VA would consider a press release in making a decision about the use of Actimmune. The Defendant has pointed to nothing in these notes that indicates that the VA would not consider information from a press release.[2]

The rest of the PBMAG minutes from VISN-9 and VISN-22 have no bearing on the materiality of the Defendant's press release to doctors for the same reason. Def. Ex. B at VA-000019 to VA-000051. While there is no mention of any press release in these minutes, there is nothing indicating that the VA would *not* consider information in a press release or the information in the Defendant's press release in making decisions on how to use Actimmune. These minutes are so minimal that they shed no light on what the VA considers when making decisions on how to use Actimmune or any other drug.

The undated criteria for use of Actimmune from VISN-9 appear to pre-date the Defendant's press release as they discuss what appears to be InterMune's GIPF-001 clinical trial as being still underway. Def. Ex. B at VA-000007. Since these criteria pre-date the Defendant's press release, it is no surprise that they do not mention the press release. Additionally, these criteria contain information about the use of Actimmune, but there is no indication of the source

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[2] In deciding to stop using Actimmune for IPF, these minutes simply state: "Recent evidence suggests that interferon gamma-1b should not be used in the treatment of idiopathic pulmonary fibrosis." Def. Ex. B at VA-000042. Considering the date of these minutes, this information may in fact have come from InterMune's March 5, 2007 press release announcing the early termination of InterMune's GIPF-007 clinical trial testing Actimmune for IPF because Actimmune failed to show any benefit. *See* InterMune's March 5, 2007 press release entitled "InterMune Discontinues Phase 3 INSPIRE Trial of Actimmune in Idiopathic Pulmonary Fibrosis" is attached as Exhibit E.

of this information. Consequently, there is no way to draw any conclusion about what sources of information the VA would or would not consider in deciding how to use Actimmune or about whether the VA would consider information in a press release. It is entirely possible that some of the information in these criteria came from one or more press releases, as appears to be the case with the August 2008 criteria from VISN-21.

The two June 27, 2003 VA letters responding to inquiries from members of Congress also fail to provide any insight into what sources of information the VA would consider in deciding how to use Actimmune. Def. Ex. B at VA-000003, VA-000004. The total discussion of the VA's decision making on the use of Actimmune for IPF in these basically identical letters is: "[Actimmune] and its use for [the] condition (Idiopathic Pulmonary Fibrosis), has been extensively reviewed by the VISN Formulary Committee. It has been the VISN Formulary Committee's position that current data does not support the use of this agent outside of clinical trials." *Id.* This language in no way indicates that the VA would not consider information in a press release or the Defendant's press release in deciding whether to prescribe Actimmune for IPF. Like the other VA documents discussed, this bare bones language simply has no bearing on the materiality of the Defendant's press release to doctors.

The final VA document that does not mention the Defendant's press release is the October 17, 2002 memorandum from VISN-22 that explains the VISN-22's decision to prohibit the use of Actimmune as a treatment for IPF. Def. Ex. B at VA-000015-16. Contrary to the Defendant's argument, this memorandum, if it shows anything, tends to show that his press release was material.

This memorandum's explanation includes a discussion of the GIPF-001 clinical trial results, and uses as its source for those results InterMune's September 18, 2002 press release. Def. Ex. B at VA-000015, ¶4. This press release came after the Defendant's press release and discussed the results of the GIPF-001 trial as presented at the European Respiratory Society meeting. The memorandum's discussion of the GIPF-001 results as presented in this press release indicates that the VA would consider information in a press release, including the Defendant's press release, in making decisions on the use of Actimmune for IPF.

The memorandum also indicates that the PBMAG or formulary committee for VISN-22 did not consider the Defendant's press release because it was unaware of the Defendant's press release. In referring to InterMune's September 18, 2002 press release, the memorandum states that this press release "was the first public release of information" on the GIPF-001 clinical trial results. In fact, that is not true. The Defendant's press release was the first public release of information on that clinical trial. Presumably, if the PBMAG for VISN-22 had known about the Defendant's press release, it would have considered the Defendant's press release, just as it considered the September 18 press release. Consequently, if this memorandum is at all relevant to the materiality of the Defendant's press release, it supports the materiality of the press release.

B. The One VA Document that Mentions the Press Release.

The one page out of the VA documents that possibly mentions the Defendant's press release (and it is not certain that this page is referring to the Defendant's press release) is the September 13, 2002 letter from the VA in Long Beach, California, responding to a request for Actimmune to treat a VA patient's IPF. Def. Ex. B at VA-000002. The letter simply states that the press release "is not believed to be sufficient scientific evidence that [Actimmune] is both safe and effective." This short statement is evidence that the VA in Long Beach was not persuaded by the Defendant's press release and is simply inadmissible reliance evidence. But this statement does not prove or even tend to prove that the Defendant's press release had no capacity to influence doctors to prescribe Actimmune for IPF. Rather, it simply shows that it did not persuade the VA in Long Beach to do so. For this letter to have any bearing on the materiality of the Defendant's press release to doctors, there would have to be some explanation as to why the Long Beach VA thought the press release was insufficient evidence. There is no explanation, only the bare conclusion that the press release was insufficient evidence, meaning this letter is inadmissible reliance evidence and nothing more.

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II. THE VA INFORMATION IS NEITHER EXCULPATORY NOR IMPEACHING; EVIDENCE THAT SOME DOCTORS MAY NOT HAVE BEEN DECEIVED BY THE DEFENDANT'S FRAUDULENT STATEMENTS IN THE PRESS RELEASE — OR THAT SOME DOCTORS CHOSE NOT TO PRESCRIBE ACTIMMUNE BASED SOLELY ON THOSE STATEMENTS — WOULD HAVE BEEN IRRELEVANT AND *IN*ADMISSIBLE AT TRIAL.

The alleged *Brady* material relied upon by the Defendant would not have been admissible at trial, nor could it have been used to impeach any government witness. Simply put, evidence that VA doctors may not have relied upon, or been deceived by, the Defendant's false statements in the press release would have been inadmissible because such evidence relates not to materiality, but rather to the success or failure of the fraudulent scheme. Under well-established law interpreting the federal anti-fraud statutes, the government was not required to prove at trial that any doctors, patients, or other individuals or entities *actually relied* on the Defendant's false statements. This is because such evidence is irrelevant under those statutes.

As set forth in detail in Section II.A, *infra*, because evidence of the success or failure of the Defendant's scheme was irrelevant, any lack of reliance by VA doctors' on the press release would have been irrelevant and inadmissible, too. As set forth in Section II.B, *infra*, the conclusion that the VA information would have been irrelevant and inadmissible at trial is buttressed by other well-established case law holding that it is no defense to a federal fraud charge that only *negligent* individuals or entities could have relied on a defendant's statements.

A. Because the Government Need Not Show that Any Entity or Individual Relied on the Defendant's False Statements, Any Lack of Reliance by VA Doctors on the Press Release Would Have Been Inadmissible at Trial.

Controlling case law makes clear that whether any entities or individuals were actually deceived by, or actually relied upon, the Defendant's statements would have been irrelevant at trial. This is so because the success of a defendant's scheme to defraud is irrelevant under federal anti-fraud statutes. *See United States v. Rude*, 88 F.3d 1538, 1547 (9th Cir. 1996) (upholding jury instruction that stated "[a]n unsuccessful scheme to defraud is as illegal as a scheme or plan that is ultimately successful"). To establish the Defendant's guilt of wire fraud, the government here was not required to prove that any entity or individual actually relied on the false and misleading statements made by the Defendant in the press release. What matters is

whether there existed a scheme to defraud, whether the Defendant had the intent to defraud, and whether materially false or misleading statements or omissions were made in furtherance of the scheme.

The Supreme Court addressed this issue in *Neder v. United States*, 527 U.S. 1 (1999), which resolved the question of whether materiality was an essential element of the mail fraud, wire fraud, and bank fraud statutes. In holding that materiality was an essential element of those statutes, the Court also clearly stated that "the government does not have to prove actual reliance upon the defendant's misrepresentations." *Id.* at 24 (quotation omitted). The Court went on to explain that the federal criminal fraud statutes "did not incorporate *all* the elements of common-law fraud. The common-law requirements of 'justifiable reliance' and 'damages,' for example, plainly have no place in the federal fraud statutes. . . . By prohibiting the 'scheme to defraud,' rather than the completed fraud, the elements of reliance and damage would clearly be inconsistent with the statutes Congress enacted." *Id.* at 24–25 (emphasis in original). In this regard, the proof required to establish criminal fraud under the wire fraud statute is entirely different than proving fraud in a civil case. *See id.*

Both before and since *Neder*, Courts of Appeals have affirmed district court rulings precluding testimony related to the question of whether the defendant's fraudulent statements actually misled the intended victim. *See United States v. Biesiadecki*, 933 F.2d 539, 544 (7th Cir. 1991) (affirming district court's decision precluding testimony from customers who were not misled by defendant's statements; holding that the "excluded testimony of the other . . . customers would have improperly shifted the jury's attention away from the knowledge and intent of [the defendant] and focused instead on the beliefs of the victims of the alleged scheme to defraud"); *see also United States v. Blixt*, 548 F.3d 882, 889 (9th Cir. 2008) ("the government need not prove reliance to establish materiality"); *United States v. Rosby*, 454 F.3d 670, 674 (7th Cir. 2006) ("Once the Supreme Court excludes reliance as a separate element of the mail-fraud offense, it will not do for appellate judges to roll reliance into materiality; that would add through the back door an element barred from the front."); *United States v. Yeager*, 331 F.3d 1216, 1222 (11th Cir. 2003) ("We have clearly held, however, that *actual* reliance has no place in a

prosecution for federal mail fraud.") (emphasis in original); *United States v. Daniel*, 329 F.3d 480, 487 (6th Cir. 2003) ("Actual reliance is thus 'plainly' not required in order for the government to establish that a misrepresentation was material."). *But see Yeager*, 331 F.3d at 1221 (noting "analytical[] overlap" between "reasonable reliance" and "materiality").

Indeed, in *United States v. Jenkins*, — F.3d —, 2011 WL 208357 (9th Cir. Jan. 25, 2011) (attached as Exhibit L), the Ninth Circuit recently rejected an argument similar to that put forward by the Defendant here. *Jenkins* related to a "pump and dump" stock scheme in which the two defendants (Jenkins and Gentry) conspired to secretly acquire millions of shares of UniDyn Corporation stock and to then artificially inflate its value by making false statements about the company's prospects in SEC filings, internet message boards, and press releases. *Id.* at *1–2; *see also id.* at *3 (noting that, after [h]aving 'pumped' the value of UniDyn stock," defendants then "proceeded to 'dump' their holdings"). The defendants were convicted of conspiracy, securities fraud, and wire fraud, among other offenses. *Id.* at *4.

On appeal, the defendants raised the argument foreclosed by the Supreme Court's holding in *Neder*. 527 U.S. at 24 (government need not "prove actual reliance upon the defendant's misrepresentations"). Specifically, the defendants in *Jenkins* contended that there was insufficient evidence that the false statements at issue were "*material*" under either the securities or wire fraud statutes, arguing that "the government failed to prove that their misrepresentations had any effect on UniDyn's stock prices or the behavior of independent investors" or that "any investors were influenced by false press releases to purchase UniDyn stock." *Jenkins*, 2011 WL 208357, at *10 & n.3. The Ninth Circuit rejected this argument.

With respect to materiality under the securities fraud statute, the Ninth Circuit first held that "[m]ateriality in securities fraud does not depend on demonstration of a market reaction to the misstatements," because "[i]nformation regarding a company's financial condition is material to investment." *Id.* at *10 (citations and quotation omitted). Like Harkonen's argument here that statements in a mere press release could never be material to doctors' decisions, one of the defendants in *Jenkins* argued that "'vague' posts on an internet message board would not be important to a reasonable investor," and that such posts, "regardless of their content, can never be

important to a reasonable investor." *Id.* The Ninth Circuit rejected this argument. In finding that the message board posts *were* material, the court noted that the government had introduced evidence at trial showing that one defendant had "closely monitored" the message board posts and had instructed employees "to post positive comments and counteract negative ones." *Id.* Further, the court noted that the trial evidence had shown that at least one board member and shareholder of UniDyn read the message board to keep apprised of information about the company.[3] *Id.* The *Jenkins* court held that this evidence "was sufficient to allow the jury to conclude that the [] posts were material." *Id.*

In a footnote, the *Jenkins* court also rejected the defendants' non-materiality arguments regarding their wire fraud convictions. The court noted that a statement is material under that statute "if it has the 'natural tendency to influence or be capable of influencing [the person to whom] it was addressed.'" *Id.* at *10 n.3 (quoting *United States v. Gaudin*, 515 U.S. 506, 509 (1995)). In disposing of the defendants' argument that the government had failed to establish materiality of *press releases* because it had not proven that "any investors were influenced by false press releases to purchase UniDyn stock," the *Jenkins* court stated that "[t]here is no requirement that the statements actually influence those to whom they are addressed." *Id.*

Jenkins is directly applicable to this case. Like the defendant in *Jenkins* (who "closely monitored" message board posts and instructed employees to "to post positive comments and counteract negative ones" on the message board), "Harkonen was the controlling force behind the content of the press release." Docket Entry No. 268, at 13:17–18 (Court's Memorandum and Order Re: Defendant's Post-Trial Motion); *see also id.* at 14:20 (describing "*Harkonen*'s choice of words in the press release") (emphasis added). Before the issuance of the release, the Defendant had learned that the GIPF-001 had missed its primary endpoint (*i.e.*, progression-free survival time), in addition to all secondary endpoints, including survival time. *See* TT at 605:6–9, 684:6–686:7, 1364:3–1365:13, 1367:24–1368:18, 1522:9–17, and 2204. Moreover, the

[3] Similarly, in this case, there was undisputed evidence at trial that doctors and IPF patients saw the Defendant's press release.

Defendant also knew at the time that the press release was issued that it was "impossible" to know whether the observations in the data regarding the survival benefit "were real or not." TT at 1365:18–1366:4; *see also* TT at 1364:22–23 ("impossible to tell whether they [*i.e.*, 'the observations on survival'] were chance or real"). In light of the facts that the Defendant knew that the GIPF-001 was not a proven success and that this press release was the most important press release in Intermune's history, TT at 3270:3–5, 3285:21–3286:6, 3366:19–21, the Defendant's efforts to control the drafting of the press release and to prevent others from reviewing the press release before its dissemination, *see, e.g.*, TT at 2562–81, 2584, 2588, go to establishing the materiality of the statements in the press release, regardless of whether it can be shown that any doctor or other individual later actually relied on those statements.

* * *

This Court has previously held that "there was sufficient evidence for the jury to conclude beyond a reasonable doubt that multiple statements contained in the press release were false or fraudulent," as those terms were defined in the Court's instructions to the jury. Docket Entry No. 268, at 14:9–11. Moreover, the Court found that Harkonen *omitted* "critical information" from the press release, Docket Entry No. 268, at 15:7–23, and held that "the jury could have found beyond a reasonable doubt that the sampling context—the use of multiple endpoints and post-hoc, subgroup analysis—was a material fact that was omitted from the press release, and thus, that the press release was false or fraudulent." Docket Entry No. 268, at 15:20–23.

The Defendant's argument that the VA information represents *Brady* material pertaining to the materiality of his false statements in the press release is simply the same argument rejected in *Jenkins* and other cases. However, *Neder* and its progeny make it clear that the jury would not have been called upon to determine whether any entities or individuals were *actually* deceived by the false and misleading information in the press release. This is so because actual reliance was not an element of the offenses charged and because the materiality standard under the wire fraud statute is an objective one: the question is whether the false and misleading statements and omissions were *capable* of causing a reasonable person to part with money or property, not whether the individuals in question *actually* did so.

In any event, and as noted in Section I, *supra*, there is nothing in the VA materials produced by the United States in November 2010 that leads to the conclusion that the press release was *incapable* of *influencing* doctors' or others' decisions. Moreover, as set forth above in this Section and in more detail in Section IV, *infra*, the United States produced overwhelming evidence at trial demonstrating that the Defendant's statements in the press release met this minimal standard of materiality.

B. Case Law Regarding "Gullible" Victims Supports the Conclusion that Evidence Regarding VA Doctors' Lack of Reliance on the Defendant's False Statements Would Have Been Inadmissible at Trial.

By arguing that the recently produced documents show that VA doctors considered the statements made by the Defendant in his press release, but declined to base prescription decisions solely on those statements, the Defendant is essentially arguing that only "gullible" doctors would have been deceived by his statements and that, therefore, his statements were not material. Such an argument, however, flies in the face of well-established Ninth Circuit law.

The Ninth Circuit has specifically held that "[i]t is immaterial whether only the most gullible would have been deceived" by a defendant's scheme. *United States v. Ciccone*, 219 F.3d 1078, 1083 (9th Cir. 2000) (quotation omitted). The *Ciccone* holding followed the Ninth Circuit's earlier holding in *Lemon v. United States*, 278 F.2d 369 (9th Cir. 1960), in which the defendants argued they were not guilty of their crime because their scheme could only have deceived the "gullible" and not those of ordinary prudence and comprehension. The *Lemon* court held that "the wire fraud statute 'protects the naive as well as the worldly-wise, and the former are more in need of protection than the latter. As a matter of fact . . . the lack of guile on the part of those solicited may itself point with persuasion to the fraudulent character of the artifice." *Id.* at 373; *see also United States v. Hanley*, 190 F.3d 1017, 1023 (9th Cir. 1999) (quoting *Lemon*).

Other Circuits to address this issue have concurred with the Ninth Circuit. For example, in *United States v. Thomas*, 377 F.3d 232 (2d Cir. 2004), the Second Circuit addressed a fraud case in which defense counsel attempted to cross-examine a representative of the victim entity about his purported lack of caution and diligence in dealing with the defendant. The district court foreclosed this line of questioning, noting that it was no defense to fraud that the victim

was foolish or made insufficient inquiries. *Id.* at 240–41. The Second Circuit held the ruling to be an appropriate exercise of the district court's discretion.

The Second Circuit also upheld the district court's mid-trial instruction to the effect that, if the jury found fraud to be proved, it would be no defense that the victim might have discovered the fraud had it probed further. *See id.* at 241–42. The *Thomas* court made clear that federal anti-fraud statutes, *see id.* at 241 n.5, prohibit schemes to defraud and that to establish a scheme to defraud, there is no requirement that the victim act as a person of ordinary prudence would. The *Thomas* court emphatically "refuse[d] to accept the notion that the legality of a defendant's conduct would depend on his fortuitous choice of a gullible victim." *Id.* at 243 (quotation omitted); *see also id.* at 243–44 ("Most circuits that apply the ordinary prudence and comprehension standard have already rejected some form of the 'unreasonable victim' argument."); *United States v. Coyle*, 63 F.3d 1239, 1243–44 (3d Cir. 1995) (holding that although fraudulent scheme must be reasonably calculated to deceive persons of ordinary prudence and comprehension, the "negligence of the victim in failing to discover a fraudulent scheme is not a defense to criminal conduct").

The Seventh Circuit's decision in *United States v. Coffman*, 94 F.3d 330 (7th Cir. 1996), is to like effect. In *Coffman*, the defendants executed a scheme to defraud by calling a brokerage firm (Smith Barney) and attempting to get a large loan by pledging worthless securities and making extravagant misrepresentations about the borrowers' net worth. The defendants argued that they were not guilty of wire fraud, because "their misrepresentations, which primarily involved grossly exaggerating their wealth, could not have influenced Smith Barney in deciding whether to lend them the $300,000." *Id.* at 333; *see also id.* (summarizing defendant's argument as follows: "Smith Barney is a sophisticated business, and no sophisticated business would be taken in by the defendants' preposterous misrepresentations"). The court rejected this argument, holding that if the defendants "intended to obtain money by lying about their financial status and prospects, it is not a defense that the intended victim was too smart to be taken in." *Id.* The court continued, "even if the prospects for success were as poor as the defendants argue — even if they were quite negligible — the defendants would not be off the hook." *Id.* Indeed, because

the wire fraud statute punishes the scheme, rather than the completed fraud, "[a]ttempts are punished even when the chance of success is dim — even when the facts are such that, unbeknownst to the defendant, the attempt could not possibly succeed." *Id.*

C. Conclusion.

Whether any doctors were persuaded by the press release to prescribe Actimmune is classic success-or-failure evidence that would have been inadmissible at trial. Such evidence is irrelevant under the wire fraud statute.

III. THE DEFENDANT WAS AWARE THAT DOCTORS MIGHT CHOOSE NOT TO PRESCRIBE ACTIMMUNE BASED ON THE PRESS RELEASE ALONE.

Although it is true that the United States did not produce the VA materials until after trial in this case, the Defendant was well aware before trial that at least some doctors might choose not to prescribe Actimmune, or any drug for that matter, based solely on a company's press release.

Where the defendant has the means of obtaining exculpatory information, no *Brady* violation has occurred. *See United States v. Aichele*, 941 F.2d 761, 764 (9th Cir. 1991) ("When, as here, a defendant has enough information to be able to ascertain the supposed *Brady* material on his own, there is no suppression by the government.")[4]; *accord United States v. Torres*, 129 F.3d 710, 717 (2d Cir. 1997) ("[E]vidence is not considered to have been suppressed within the meaning of the *Brady* doctrine if the defendant or his attorney either knew, or should have known of the essential facts permitting him to take advantage of that evidence.") (internal punctuation and citation omitted).

In this case, the Defendant was aware of (1) surveys of doctors, (2) investor reports, and (3) *opinions of his own retained experts* that some doctors might not have relied on the false statements in the press release. Accordingly, there can be no finding of a *Brady* violation.

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[4] Although the Ninth Circuit has labeled this language in *Aichele* as "dictum," *see Benn v. Lambert*, 283 F.3d 1040, 1061 (9th Cir. 2002), it has also nevertheless recognized it as binding law. *See United States v. Bond*, 552 F.3d 1092, 1095–96 (9th Cir. 2009).

A. Surveys of Doctors.

Well before the trial in this matter, the Defendant was aware that at least some doctors may not have been fully persuaded by the press release to prescribe Actimmune for their patients. Accordingly, the Defendant's argument that VA doctors may not have prescribed Actimmune based solely on the press release comes as no news to the Defendant.

1. JZM Survey.

At the time that the Defendant was still its CEO, InterMune retained the firm of Johnston, Zabor, McManus, Inc. ("JZM") to perform an "Actimmune for IPF Press Release Response Study" in order "to assess pulmonologists' reactions to the press release and potential effect on IPF treatment algorithms." Ex. A, at INR528-7659. As part of that study, JZM conducted telephone interviews of 12 "high-prescribing pulmonologists." *Id.* at INR528-7660. Although the pulmonologists reportedly considered the data presented in the press release to be "positive," JZM found that a few of the doctors were only "cautiously optimistic, pointing out that they were responding to data in a press release rather than in a peer-reviewed article." *Id.*; *see also id.*, INR528-7667 ("Some, however, reacted cautiously stating that they were reacting to a press release rather than a peer-reviewed published journal article. One respondent described his reaction as 'guarded optimism.'"). Further, JZM concluded that "[t]he lack of statistically significant results . . . was reason for a few respondents to be less impressed." *Id.* at INR528-7660; *see id.* at INR528-7667 (noting that several respondents found alleged "'strong positive trends' in the clinical markers of pulmonary function" to be "less relevant" because they were "not statistically significant"). Indeed, 25% of the doctors interviewed by JZM did "not expect to use the drug in their mild cases." *Id.* at INR528-7661; *see also id.* at INR528-7669.[5]

In addition to the study results that showed that some doctors were not persuaded to prescribe Actimmune for their patients with "mild" IPF based on the press release, the JZM study

[5] In light of the fact that the press release touted a 70% reduction in mortality for mild to moderate patients, the fact that 25% of the survey participants stated that they *would not* prescribe Actimmune for their patients with "mild" IPF should clearly have given the Defendant reason to believe that at least some doctors may not have been deceived by his press release.

also put the defense on notice that the press release left questions unanswered, and that doctors might seek additional information from other sources before deciding to prescribe Actimmune. For example, JZM reported that survey "[r]espondents also asked about the criteria used in the study to determine mild, moderate, and severe cases," and had questions regarding "whether the data would be enough to convince third-party payers to cover or supplement the cost." *Id.*

It will be uncontested at sentencing that these materials were produced to the Defendant in discovery. Indeed, at trial, counsel for the Defendant asked a series of questions to one witness that indicated the defense's awareness of the JZM study. TT at 1139:7–16.

2. Gerson Lehman Group Survey.

Prior to trial, the Defendant placed a "survey of practicing pulmonologists with IPF expertise regarding preliminary results of the Phase III Actimmune trial" on his exhibit list (Exhibit 205). *See* Ex. B. The survey was a poll of 20 doctors conducted by the Gerson Lehman Group. The doctors appear to have read a half-page summary of the GIPF-001 results as announced by InterMune on August 28, 2002, and then provided yes/no answers and a sentence-long explanation of each yes/no answer. *See* Ex. B, at 8–9 (summary of GIPF-001 results). The survey indicates that it was conducted in the days immediately following the issuance of the press release, specifically, between August 30, 2002, and September 3, 2002.

A number of the responses clearly put the Defendant on notice that at least some doctors might not be swayed by a drug company's announcement of preliminary study results. For example, when asked whether they found "the mortality benefit in the overall population (40%, p=0.084) to be compelling," 25% of the doctors answered "no." *See* Ex. B, at 9. Ten percent of the respondents indicated that they did not find "the mortality benefit in the subset of mild/moderate patients (70%) to be compelling." *See, e.g.*, *id.* at 10 (Physician #4: "this was a subgroup analysis, with all its attendant problems/biases"). Moreover, even among the doctors who found this mortality benefit to be "compelling," one doctor noted that she "need[ed] more of the original data to properly assess." *Id.* at 11 (Physician #10). In response to another question, some of the doctors stressed the importance of further analysis before making any decisions regarding using Actimmune to treat IPF patients. *See id.* at 12 (Physician #4: "I will probably

make no final decision until I see the article published in [its] entirety in a peer-reviewed journal. After this, I will make a decision about when and if to use it [*i.e.*, Actimmune].") & 13 (Physician #10: "I will not change my therapy presently until I see more of the data."; Physician #18: "I think i would but again i would like to see how it compares to other immunosuppressives already in use"). Finally, when asked about their overall opinion of Interferon gamma-1b (Actimmune) for the treatment of IPF, several doctors' responses indicated their reticence in relying on a company's announcement of preliminary test results. *See id.* at 13 (Physician #7: "We need to await the independent data review."), 14 (Physician #9: "I want to see all of the data presented in a scientific forum . . . ."; Physician #10: ". . . need to see all the data"); *see also id.* at 16 (Physician #4: "The bottom line is that there was no statistical significance in the endpoints that were chosen apriori. It will be hard to convince either the FDA or physicians who practice evidence-based medicine to use this product. Only potentially saving grace . . . we really don't have a good treatment for IPF. . . .").

B. Investor Reports.

In addition to the fact that InterMune's own commissioned survey revealed that not all doctors intended to rely on the press release to prescribe Actimmune, the defense was also aware of investor reports that took a "neutral-to-negative" view of the GIPF-001 results as announced in the press release. For example, on August 29, 2002 (the day after the press release was issued), the investment bank SunTrust Robinson Humphrey Capital Markets ("SunTrust") issued an investor report regarding InterMune. The authors of the report appear to have been Martin Auster, M.D., and Kelly Stoehs. The authors noted that the results of the study were "mixed" and that they were "underwhelmed" by the trial data. They noted that their investment advice of "Buy" was "NOT [driven by] 'good' data." Ex. F, at INR017-1800. Specifically, the authors noted as follows:

> Our initial read of this data was neutral-to-negative and it remains unclear to us how a near-significant (p-value of 0.004) survival benefit could be seen without supportive data showing significant improvement in disease benefit. However, there is a difference between a pure scientific data analysis and how patients and physicians interpret and use the data. Feedback from doctors since the announcement yesterday has been uniformly positive with regards to the likelihood of increased future ACTIMMUNE sales. Even physicians who shared

> our skepticism over Phase III data conceded that at the end of the day, keeping patients alive was the most crucial goal of treatment and indicated an increased expected use of ACTIMMUNE.

Ex. F, at INR017-1801 (Defendant's Trial Exhibit 105); *see also* Ex. G, at INR017-1822 ("Our initial take on this data was skeptical, and it remains unclear to us how a significant (p-value of 0.004) survival benefit could be seen without supportive data showing significant improvement in disease progression.") (Defendant's Trial Exhibit 106).

The Defendant placed these investor reports on his exhibit list. Although the United States moved to exclude these documents and although they were not introduced at trial, they certainly put the Defendant on notice that some doctors may not have relied on the press release because of initial skepticism about the data announced therein. Indeed, the United States moved to exclude the reports based in part on the argument that "[a] jury could interpret these exhibits to mean the *physicians did not rely on the press release*, and the Defendant may intend to offer them for that purpose." Docket Entry No. 175, at 7 (emphasis added).

C. The Defendant's Experts.

Finally, the Defendant's argument that the VA materials were the first indication that he received that statements made in a press release could never be material to a doctor's decision as to whether to prescribe a drug are belied by the Defendant's prior filings. For example, in his post-trial motion, the Defendant argued that "a public press release, which all know will be followed by full data disclosure and intense scrutiny from skeptical market analysts and sophisticated international scientific experts, is not a plausible vehicle for intentional deception." Def's Post-Trial Mtn., at 26:10–12.

Moreover, *before trial*, the Defendant filed his Notice of Expert Testimony. *See* Docket Entry No. 117 (pages 1 through 10 attached hereto as Exhibit H). In that filing, the Defendant disclosed at least two experts who he said would render opinions about doctors' reliance on press releases. Specifically, the Defendant announced that Roger Maxfield, M.D., would "opine that *physicians do not make treatment decisions solely on the basis of a press release*." Ex. H, at 4:18–19. The Defendant also announced that Joseph Zibrak, M.D. (one of the doctors that he continues to retain and consult in this case), also would "opine that *physicians do not make*

treatment decisions solely on the basis of a press release." *Id.* at 8:16–17.

D. Conclusion.

As set out above, the Defendant was aware before trial of evidence or opinions that might support the conclusion that doctors would not have been swayed by the false statements that he placed in the press release. There is no reason to believe that production of the VA materials would have altered the Defendant's trial strategy, and he cannot obtain relief now because he wishes he had investigated and presented his case differently.

IV. EVEN IF THE EVIDENCE HAD BEEN DISCLOSED PRIOR TO TRIAL, THERE IS NO REASONABLE PROBABILITY THAT THE RESULT OF THE TRIAL WOULD HAVE BEEN DIFFERENT.

Finally, there was overwhelming evidence of the materiality of the false statements in the press release. Because of this overwhelming evidence of materiality, the VA materials would not have changed the result of the trial, even if they were admissible and even if they showed what the Defendant claims they show.

To be material, a false statement need only have a "'natural tendency to influence or be capable of influencing [the person to whom] it was addressed.'" *Jenkins*, 2011 WL 208357, at *10 n.3 (quoting *Gaudin*, 515 U.S. at 509); *accord Daniel*, 329 F.3d at 487 (misrepresentations are material if they "would have affected a reasonable person's actions in the situation"). Put another way, a false representation is "material if 'it is made to induce action or reliance by another.'" *United States v. LeVeque*, 283 F.3d 1098, 1103–04 (9th Cir. 2002) (quoting *United States v. Halbert*, 712 F.2d 388, 390 (9th Cir. 1983)). In *Blixt*, the court noted that "[w]hat is important is the intent of the person making the statement that it be in furtherance of some fraudulent purpose." *Blixt*, 548 F.3d at 889 (quoting *United States v. Halbert*, 640 F.2d 1000, 1009 (9th Cir. 1981)).

At least one court has held that a drug company's public statements about the efficacy of its drugs are material, at least in the securities fraud context. *See In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 967 (D. Md.1995) (holding that a drug company's statements that "[t]he results of treatment with [its product] were highly statistically significant along all of the efficacy parameters," and "[t]he data are overwhelmingly good" were material).

Here, the clinical trial at issue failed, and no mortality benefit was proven for either the trial population or any subgroup. However, the Defendant issued a press release — when no other information was publicly available about the results of the clinical trial — that falsely stated in its subheading that Actimmune "Reduces Mortality by 70% in Patients with Mild to Moderate Disease" and that conveyed the false impression that Actimmune was an effective treatment for IPF. In addition to containing those false statements, the press release omitted "critical information," Docket Entry No. 268, at 15:7–23, regarding the sampling context that would have shed light on the significance of the results announced in the press release.

The false statements and "critical omissions" in the press release were clearly material. In closing argument, the defense conceded as much when counsel stated that the press release "accurately depicts the information for people suffering from a horrific fatal disease who needed to know about this *immediately*, *as soon as possible*." TT at 3623:8–10 (emphasis added). Indeed, defense counsel stressed the importance of the press release several times during closing, arguing that the Defendant was justified in getting the information out to people who were dying of IPF. *See also* TT at 3623:17–18 (arguing that the press release was "all about getting information to people who are dying of a fatal disease"); TT at 3646:7–15 ("... here we have for all these people that are dying of this hideous disease . . . . You don't think that the people who are drowning in their own bodily fluids want to know, in general, if there's a 40 percent reduction? And that they shouldn't know?"); TT 3648:10–12 ("How can the existence of something important going on be denied, especially to people out in the world who are dying?"); TT at 293:5–6 ("The information in the press release was true and it was accurate.") (opening statement).

Moreover, the materiality of the press release is obvious. The press release was the first information provided to the general public and the medical community about the results of a trial concerning the efficacy of a drug for the treatment of a fatal disease with no known cure. *See* TT at 688:12–689:6 (Fleming testimony). Thomas Fleming, Ph.D., the chair of the data monitoring committee for GIPF-001, testified at trial that he and the other members of the data monitoring committee felt that the GIPF-001 results "reflected a negative trial." TT at 687:3. Yet, when

Professor Fleming saw the press release several days after it had been issued (on September 4, 2002), he was "stunned" and felt that the press release was "a serious misrepresentation of the truth." TT at 690:9–10. Professor Fleming was so upset by the misrepresentations in the press release that he could not sleep. TT at 690:12. He sent a letter dated September 5, 2002, to InterMune, which was received by the Defendant. Professor Fleming's letter underscores the materiality of the press release. In it, he noted that he "was stunned by the misrepresentations in the News Release of the results from the clinical trial and of other issues related to the trial." Ex. I, at 4 (INR544-9767) (USA's Trial Ex. 3). He stated that "[t]he News Release provides a serious misrepresentation of results obtained from exploratory data subgroup analyses," *id.*, and that "[t]he claims for established survival benefit in the mild to moderate disease subgroup . . . are so fallacious that they would provide a humorous illustration of an absurd misrepresentation of exploratory statistical analyses *if not for the serious consequences to patients, caregivers, and the investment community who might be misled in their therapeutic or financial decision-making processes*," *id.* at 6 (INR544-9769). Witnesses from InterMune also recognized that disseminating information similar to that which was in the press release was "inappropriate" and "misleading." *See* TT at 1408:8–9 (Porter testimony regarding Priority Healthcare "fax blast" to doctors, USA's Trial Ex. 6); *see also* TT at 2238:2–3 (Crager testimony noting that he "kind of winced" when seeing the opening line of the press release); TT at 1860:12–14 (Armstrong testimony: "I felt that it was false and misleading to patients stating to the world that we had found a drug that was effective in preventing patients from dying with IPF.")

Materiality was also proven by the testimony at trial of InterMune's general counsel, Stephen Rosenfield. Rosenfield testified that the August 28, 2002, press release was the most important press release that InterMune had issued. TT at 3270:3–5, 3285:21–3286:6, 3366:19–21. Simply put, if the statements in the press release did *not* have the "natural tendency" to affect use of Actimmune, then why was it so important?

Further, the press release itself contained statements vouching for the materiality of the statements it contained. Specifically, the press release quoted James E. Pennington, M.D., InterMune's Executive Vice President of Clinical and Medical Affairs, who stated that "[w]e felt

we had an ethical obligation to get this important news out about the survival benefit of Actimmune so physicians can evaluate it when making treatment decisions for their patients." Ex. J, at 3 (INR501-3071) (USA's Trial Ex. 1).

The materiality of the press release was also shown by the considerable evidence of InterMune's efforts to get the press release to doctors and IPF patients. Not only did InterMune's sales force give the press release to doctors, but InterMune worked with Priority Healthcare, the pharmacy that filled most Actimmune prescriptions, to get the press release to doctors and IPF patients taking Actimmune. *See* United States' Sentencing Memorandum on Fraud Loss, Docket Entry No. 304, at 21–23 (numbered 16–18). InterMune's extensive efforts to get the press release to doctors and patients shows that the press release had the capacity to influence doctors to prescribe and patients to take Actimmune for IPF.

CONCLUSION

Before trial, the Defendant filed a notice of expert testimony informing the government and the Court that two of his witnesses would opine that "physicians do not make treatment decisions solely on the basis of a press release." Moreover, the defendant was prepared to offer an exhibit (Defense Trial Exhibit 205) that indicated that at least some doctors were unwilling to rely on the study results announced in the Defendant's press release.

The Defendant's protestations now about being recently provided formulary decisions made by a single government agency (the VA) ring hollow in light of these facts. Simply put, the Defendant was well aware of a possible defense pertaining to the non-materiality of the press release, but he chose to not pursue that defense, arguing instead that his statements in the press release were true.

Setting aside this fact that the information in the VA documents is duplicative of other information available to the defendant before trial, the VA documents have no bearing on the materiality of the press release to doctors, and, further, constitute irrelevant and inadmissible evidence of the success or failure of the fraudulent scheme. Finally, there was overwhelming evidence of materiality; even had the VA documents been disclosed, and even if they were admissible, there is no reasonable probability that the result of the trial would have been

different.

For all of these reasons, the defendant's Motion for New Trial Due to *Brady* Violation should be denied.

DATED: February 22, 2011

Respectfully submitted,

BRIAN J. STRETCH
Acting United States Attorney

/S/
KYLE F. WALDINGER
Assistant United States Attorney

ALLAN GORDUS
Trial Attorney

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL, JUDGE

UNITED STATES OF AMERICA, Plaintiff, vs. W. SCOTT HARKONEN, Defendant.	No. CR-08-0164 MHP San Francisco, California Monday, November 15, 2010

TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

FOR PLAINTIFF:

OFFICE OF CONSUMER LITIGATION
U.S. DEPARTMENT OF JUSTICE
450 5TH STREET, NW,
6TH FLOOR SOUTH
WASHINGTON D.C., 20001

BY: Allan Gordus, Attorney at Law

UNITED STATES ATTORNEY'S OFFICE
450 GOLDEN GATE AVE., 11TH FLOOR
SAN FRANCISCO, CALIFORNIA 94102

BY: Kyle Waldinger, Attorney at Law

(FURTHER APPEARANCES ON NEXT PAGE.)

REPORTED BY: SARAH L. GOEKLER, CSR NO. 13446
Computerized Technology By Eclipse

is lawful to give -- to respond to doctor inquiries about a medicine.

Dr. Zibrak's declaration illustrates how doctors were coming to the company, reading the article and then reviewing the journal. They didn't know where to get the medicine. They had to make phone calls to try to find it. The company was not set up to manufacture it in the quantities that were becoming demanded. There were lots of questions; it's lawful to answer questions.

If the Government wanted to have someone go to jail or to be criminally punished in this way for falsely promoting -- or promoting off brand during this pre-period before the press release, that's something they could have charged. That's something they could have tried. They didn't do either, and so to come in now and say, oh, we're going to justify our actual loss calculation or our intended loss calculation based on irrelevant facts that are entirely separate from the charge conduct is impermissible.

THE COURT: But I am going to give them some time to come up with some methodology and hard numbers, and I want to see it described. Don't just dump a lot of exhibits on me and expect that I'm going to read through columns and columns of names and figures and everything else and come up with my own answer. That's not my job.

It's up to you to come up with the answer, the

methodology and both for actual loss and intended loss. And I want to see some real data. Because I have to sentence the defendants, and it has to be based on reality and not speculation. I have to have a reasonable basis for it.

Now, with respect to some of these enhancements, we can take them up. You're not proceeding on sophisticated means, as I understand it?

MR. GORDUS: Correct, Your Honor.

THE COURT: And you've also pulled back on the role in the offense as well --

MR. GORDUS: Correct, Your Honor.

THE COURT: -- right?

Mass marketing. Why would this not come within, quote, mass marketing?

MR. HADDAD: Your Honor, it's not marketing. That is the crux of it. It's not marketing because to be marketing, there needs to be a solicitation component, and this is not a solicitation. This is a press release. This is information. It's going out -- it's the use of the internet. We acknowledge it's the use of the internet but not for purposes of solicitation.

THE COURT: That's part of the overall scheme and the scheme involved also hustling to sell the drug.

MR. HADDAD: But Dr. Harkonen was acquitted of the conduct that involved the use of the press release in directly

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE MARILYN HALL PATEL, JUDGE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	NO. CR 08-00164 MHP
	)	
W. SCOTT HARKONEN,	)	
	)	
Defendant.	)	
	)	

San Francisco, California
Wednesday, April 13, 2011

TRANSCRIPT OF SENTENCING PROCEEDINGS

APPEARANCES:

For Plaintiff:

MELINDA L. HAAG, ESQ.
United States Attorney
450 Golden Gate Avenue
San Francisco, California 94102

BY: **KYLE WALDINGER**
Assistant United States Attorney

U.S. Department of Justice
Office of Consumer Litigation
450 Fifth Street, N.W.
Suite 6400-South
Washington, D.C. 20001

BY: **ALLAN GORDUS**
Trial Attorney

(Appearances continued on following page.)

Reported By: Leo T. Mankiewicz, CSR 5297, RMR, CRR

MR. HADDAD: Yes.

THE COURT: Okay. Anything further, then?

MR. HADDAD: Nothing further on paragraph 60, your Honor.

THE COURT: Okay. So those changes will be made, and then with respect -- and the government says there are no objections to any of the findings of fact contained in the presentence report. And of course, we know there is much dispute regarding the guideline calculations. I don't know if there's anything else that needs to be said or not.

My conclusion is this: There's no dispute that the base offense level for this offense, which of Dr. Harkonen was convicted is a level 6.

The Court finds, based upon what I've said before, that whichever burden of proof the Court would use, that it is unable to determine with a sufficient degree of accuracy that, you know, there is a loss as a result of the conduct reflected in the wire fraud count.

I know that there are those calculations that talk about -- it sometimes is imprecise, and I guess it's sort of rough justice, you know, approximation, but there has to be some basis for it, and I just think that there just isn't enough evidence in the record under either burden of proof to satisfy the Court that there is a loss as a result of the press release.

Yes, you know, there were changes and undoubtedly, you know, some people were influenced by it, but it's just, you know, speculation. Some degree of common sense, but I think that that is not a basis for determining an amount of loss to enhance a sentence.

With respect to the other enhancements that the probation officer found, having reviewed the mass marketing and its definition, I conclude that that is an appropriate enhancement, because there was -- the press release was posted and distributed through various wire applications, and whether it be on the internet or was made available through phone calls and so forth, and it is the press release that forms the basis for the offense, and therefore, an enhancement of two levels is appropriate for the mass marketing.

With respect to the victim-related adjustment having to do with vulnerable victim, actually, the guidelines define a victim as someone who suffered an actual loss. So the Court concludes that without a victim, you can't have a vulnerable victim, and that there's no basis for enhancement there.

The government has agreed not to enhance for an organizer or leader, or ask for a enhancement on that basis, and so no enhancement is made.

Now, Ms. Black had recommended a level 4. If I were going to find any such level of enhancement, it certainly wouldn't be a level 4, it would only be a level 2, but I think

EXHIBIT 10

U.S. Department of Justice

Executive Office for United States Attorneys

Office of the Director

Room 2261, RFK Main Justice Building
950 Pennsylvania Avenue, NW
Washington, DC 20530

(202) 252-1000

AUG - 4 2011

Mark E. Haddad, Esquire
Sidley Austin LLP
555 West Fifth Street
Los Angeles, CA 90013

Dear Mr. Haddad:

This responds to your letter dated June 8, 2011, to the Acting United States Attorney for the Northern District of California, a copy of which you provided to the Director of the Executive Office for United States Attorneys, concerning your Request for Correction pursuant to the Department of Justice's Information Quality Guidelines. You seek a retraction of a statement contained in a press release issued by the United States Attorney's Office for the Northern District of California (USAO) on September 29, 2009, regarding the conviction of your client, W. Scott Harkonen. Specifically, you contend that the following statement by Douglas J. Carver, Special Agent in Charge of the U.S. Department of Veterans Affairs, Office of Inspector General, was not accurate: "The actions of [Dr. Harkonen] served to divert precious financial resources from the VA's critical mission of providing health care to this nation's military veterans." Because your request is outside the scope of the Department's guidelines and is not warranted under the facts, your request is hereby denied.

Section 515 of the Treasury and General Appropriations Act for Fiscal Year 2001 required the Office of Management and Budget (OMB) to issue government-wide guidelines for ensuring and maximizing the quality of information disseminated by federal agencies. It also required federal agencies to promulgate their own implementing guidelines consistent with those established by OMB. The OMB guidelines apply only to information that is "disseminated." Under the OMB guidelines, "dissemination" means "agency initiated or sponsored distribution of information to the public," but excludes certain distributions, including press releases. (67 FR 8460.) Similarly, the DOJ guidelines apply to all "DOJ initiated or sponsored dissemination of information," subject to specific exceptions. The exceptions include information disseminated in "press releases[,] fact sheets, press conferences, or similar communications (in any medium) that announce, support or give public notice of information in DOJ." Because the statement of which you complain was disseminated in a press release and served to inform the public of a successful prosecution by the Department of Justice, the guidelines do not apply.

We are aware of your contention that the press release at issue does not fall within the above exception because it does not give "public notice of information in DOJ." We have reviewed your position, as set forth in your request for reconsideration dated April 20, 2010, but

find your arguments without merit. One of the primary goals of the Department of Justice is to enforce our nation's federal criminal laws. Accordingly, statements contained in a press release regarding the outcome of such efforts clearly constitute "information in DOJ" and are exempt from the guidelines.

Even if the guidelines applied, no retraction is necessary because the statement accurately described the government's position. As you know, the government has consistently maintained that Dr. Harkonen's false and misleading press release fraudulently caused patients to seek and doctors to prescribe Actimmune as a treatment for idiopathic pulmonary fibrosis, thereby leading to increased sales of Actimmune. Although the district court found that the government did not meet its burden of proving actual loss for purposes of Dr. Harkonen's sentencing, this does not mean the press release did not have any effect on Actimmune's sales. The district court simply held that it was not possible to determine with the degree of certainty necessary for Dr. Harkonen's sentencing, the role the press release played in the increased sales of Actimmune that followed after the press release over eight years ago.

Moreover, the statement that Dr. Harkonen's actions "served to divert precious financial resources from the VA's critical mission of providing health care to this nation's military veterans" can reasonably be interpreted to mean that Dr. Harkonen's wrongdoing necessitated an investigation into the matter by the Veterans Administration. As the investigation into this matter was comprehensive, it was accurate to say that it diverted precious financial resources from the VA's primary mission.

Thank you for raising your concerns with the Department of Justice.

Sincerely,

H. Marshall Jarrett

H. Marshall Jarrett
Director

cc: Mr. Brian Stretch
First Assistant United States Attorney
Northern District of California

EXHIBIT 11

SIDLEY AUSTIN LLP
SIDLEY

SIDLEY AUSTIN LLP
555 WEST FIFTH STREET
LOS ANGELES, CA 90013
(213) 896 6000
(213) 896 6600 FAX

mhaddad@sidley.com
(213) 896 6604

August 22, 2011

By Hand Delivery

Brian J. Stretch
First Assistant United States Attorney, Northern District of California
United States Attorney's Office
450 Golden Gate Avenue, 11th Floor
San Francisco, California 94102

Re: *United States v. Harkonen*, No. CR 08-0164 MHP (N.D. Cal.)
Request for Reconsideration Under Information Quality Guidelines

Dear Mr. Stretch:

On behalf of W. Scott Harkonen, M.D., and pursuant to the Information Quality Guidelines promulgated by the U.S. Department of Justice ("DOJ Guidelines")[1] under the Information Quality Act, Pub. L. No. 106-554, Appendix C § 515(a), 114 Stat. 2763A-154 (2000) (codified at 44 U.S.C. § 3516 note) ("the Act" or "IQA"), we submit this letter as a Request for Reconsideration, sent to us by H. Marshall Jarrett, Director, Executive Office for United States Attorneys, concerning Dr. Harkonen's earlier-filed Request for Correction, dated June 8, 2011, a copy of which is attached as Exhibit A. The Department of Justice denied the Request for Correction by letter dated August 4, 2011 ("Response"), a copy of which is attached as Exhibit B. We submit this Request for Reconsideration to you as the "disseminating DOJ component" pursuant to the DOJ Guidelines, and we request that the Department observe its own guidelines for reconsideration and assign an official other than Mr. Jarrett to review this request; in this regard, we note that DOJ's Guidelines state that "the official conducting the second level review [will] not [be] the same official that responded to the initial request." DOJ Guidelines *supra* note 1.

In the Request for Correction, Dr. Harkonen asserted that the following statement, contained in a September 29, 2009 press release issued by the United States Attorney's Office of the Northern District of California, is false and thus violates the DOJ Guidelines: "Douglas J. Carver, Special Agent in Charge of the U.S. Department of Veterans Affairs, Office of Inspector

[1] The DOJ Guidelines are available at http://www.justice.gov/iqpr/iqpr.html.

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General, Western Field Office, stated 'today's verdict, which resulted from a complex and labor-intensive investigation and trial, demonstrates our commitment to work with our law enforcement partners to aggressively pursue all individuals that would jeopardize the integrity and safety of the VA's health care system. The actions of this defendant served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans. The VA OIG will continue to aggressively pursue investigations of this type and hold those responsible accountable for their actions.'"[2] In particular, the statement that "[t]he actions of this defendant served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans" is untrue, because the District Court, at sentencing, found that the Government had failed to prove, by even a preponderance of the evidence, that the August 28, 2002 press release had caused any financial loss either to the VA or to any other alleged victim.

DOJ's false statement in its own September 29, 2009 press release, and its ongoing publication of that press release on its website, have caused, and continue to cause, severe injury to Dr. Harkonen's reputation in the medical and business communities and to Dr. Harkonen in his personal and professional life.[3] It should be corrected immediately.

Rather than acknowledging its error and correcting it, DOJ has now offered two justifications for its inaction: (1) DOJ Guidelines permit DOJ to make false statements in press releases, no matter their subject matter or how they are maintained, and (2) DOJ can make statements that are untrue in their obvious and intended meaning, so long as DOJ's lawyers can think up an after-the-fact rationalization to try to make the statement true in some other sense. Each justification is unavailing. It is precisely in a situation such as this that DOJ, in the exercise of its statutory duty to review the request independently on rehearing, should correct the public record.

1. The Response argues that, according to DOJ Guidelines, DOJ is free to make false statements in any of its press releases. Once again, we ask DOJ to reconsider its reliance on this double standard, one that puts DOJ's press releases above the law even while DOJ seeks to punish an individual criminally for his statements in a press release. DOJ's arguments conflict with the plain language of the Guidelines as well as with the Department's obligation to uphold the rule of law throughout the United States, including within its own walls.

The DOJ Guidelines expressly "apply to all information disseminated by DOJ . . . , [including] any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual

[2] The press release is still available online at www.justice.gov/usao/can/press/2009/2009_09_29harkonen.convicted.press.html.
[3] Although it has been nearly two years since its issuance, the DOJ's false press release is one of the top search results generated by conducting an internet search of "Scott Harkonen" using Google, Bing, or Yahoo! as of August 22, 2011.

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forms. It includes information that an agency disseminates from a web page . . . ." The Guidelines further state that "[t]he information DOJ disseminates includes: Departmental briefs in major cases, regulations, business review letters, memoranda, *press releases*, opinions, research, statistical and special reports, newsletters, and general publications." (emphasis added).

Nevertheless, the Response contends that certain DOJ-initiated or -sponsored disseminations of information are subject to specific exceptions, including "information disseminated in 'press releases[,] fact sheets, press conferences, or similar communications (in any medium) that announce, support or give public notice of information in DOJ." Resp. at 1. (alteration in Response). That exception has no application here, however, because it does not exempt information that is posted – as the 2009 Press Release has been and still is — on DOJ web pages, including those of the United States Attorneys' Offices.

Furthermore, the exception on which DOJ relies is limited only to those press releases that "announce, support or give public notice of information in DOJ." DOJ Guidelines *supra* note 1. Press releases that address other topics remain covered. The 2009 Press Release did not "announce, support, or give public notice of information in DOJ"; rather, it purported to report on the results of a criminal trial held in an Article III court and on the impact that the defendant's conduct had on financial resources that allegedly would otherwise have been allocated to veterans by the Department of Veterans' Affairs. None of this is "information in DOJ." Indeed, much of the evidence that emerged at sentencing and that showed that the 2002 Press Release caused no financial loss to the nation's veterans was evidence that DOJ lawyers claimed they received from the VA only in 2010 — and thus was subject to a motion under *Brady v. Maryland*. If these VA documents were, in fact, "information in DOJ" in 2009, that is an admission that the United States immediately should bring to the defendant's and the Courts' attention, as it would directly contradict the representation of the DOJ attorneys handling this matter that they were *not* aware of these VA documents prior to turning them over to Dr. Harkonen's counsel in 2010. DOJ cannot have it both ways — either the IQA exception DOJ invokes here is inapplicable, or DOJ must advise the Court and defendant that DOJ's prior representation that DOJ did not have the VA documents within DOJ prior to November, 2010, was false.

The Response also asserts that "[o]ne of the primary goals of the Department of Justice is to enforce our nation's federal criminal laws. Accordingly, statements contained in a press release regarding the *outcome* of such efforts clearly constitute 'information in DOJ' and are exempt from the guidelines." Resp. at 1 (emphasis added). This response is inapposite. Dr. Harkonen contests DOJ's false characterization of those legal proceedings, which did not prove that Dr. Harkonen's conduct led to any diversion of the VA's resources. As stated in the Request for Retraction, dated June 8, 2011, the Government was unable, despite multiple opportunities, to prove that Dr. Harkonen caused any loss to the VA (*i.e.*, "diver[sion]" of "precious financial resources"). At the request of the Government, the District Court agreed that the jury would not address the issue of whether the conclusions in the 2002 Press Release caused any loss. Not one

of the 67 pages of belatedly produced VA documents showed any loss or harm to the VA resulting from the conclusions in the Press Release, and the District Court criticized the Government for failing to provide the court with any "real data" to supports its allegation of loss. Further, the Government conceded, and the court concluded, that the Government had "no basis for determining restitution" (4/13/11 RT 118); such restitution (if proved) could have recompensed the VA for any "previous financial resources" allegedly diverted by Dr. Harkonen's actions. *United States v. Phillips*, 367 F.3d 846, 863 (9th Cir. 2004) ("the Government can be a victim for restitution purposes" under the U.S. Sentencing Guidelines).

The Response acknowledges that "the government did not meet its burden of proving actual loss for purposes of Dr. Harkonen's sentencing." Resp. at 2. It is thus immaterial that "the government has consistently maintained" that Dr. Harkonen caused actual loss to the government. DOJ tried, and failed, to prove that this assertion is true. The Government's belief — when the Government tries, but is found, by a court, to be unable to prove that belief true — is not an "outcome" of law enforcement efforts. For all these reasons, DOJ's characterization of Dr. Harkonen's trial as showing that his actions "served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans" does not constitute "information in DOJ" and thus are not exempt from the DOJ Guidelines.

The Response also cites the OMB guidelines. The OMB guidelines, however, require federal agencies (including DOJ) to "issue their own implementing guidelines" consistent with the objectives of the Act. 67 Fed. Reg. 8452, 8452 (Jan. 3, 2002) (attached as Exhibit B to the Request for Correction). The OMB guidelines thus do not and cannot supplant, but instead only reinforce, the applicability of DOJ's own guidelines.

Nonetheless, the Response cites a provision of the OMB guidelines that purports to exclude "dissemination" by "press release." *See id.* at 8460 ("'Dissemination' means agency initiated or sponsored distribution of information to the public. Dissemination . . . does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." (internal citation omitted)). This exemption does not apply here.

First, the OMB's guidelines merely provide guidance for federal agencies generally to use in developing their own guidelines. Where, as here, an agency has promulgated its own guidelines, and those guidelines specifically address an issue that is treated only more generally in the OMB guidelines, the agency's own, more specific guidelines control.

Second, the OMB guidelines on their face do not exempt the DOJ press release at issue, because the purported exemption is for "distribution limited to . . . press releases," and the distribution here was not so "limited." DOJ not only sent out the press release in September 2009, but also posted this press release on its web site, where it remains to this day, nearly two years after the trial, readily accessible to the public via an internet search, and continuing to

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mislead all who see it on an issue of public importance. The distinction between a press release and information on a web site is material, because DOJ's own guidelines recognize and separately address the fact that information "disseminate[d] from a web page" is covered by the IQA.

Third, the OMB guidelines are designed "to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate (meaning to share with, or give access to, the public). It is crucial that information Federal agencies disseminate meet these guidelines." 67 Fed. Reg. at 8452. Here, that calls for applying the IQA to the DOJ's press releases, because unlike other federal agencies that communicate primarily with the public through other means, such as rulemaking processes, "[t]he use of a press release . . . is the usual method to release public information to the media by Department of Justice components and investigative agencies." U.S. Attorneys' Manual 1-7.401(A) (2003) (attached as Exhibit C to the Request for Correction). Because of the importance of press releases to DOJ's public mission, it was appropriate for the DOJ Guidelines to limit any exemption for press releases only to those that "announce, support or give public notice of information in DOJ." DOJ Guidelines, note 1 *supra*. As explained above, that exemption does not apply to the press release at issue, and the DOJ Guidelines thus apply in full force here.

It is inconsistent with DOJ's public mission for DOJ to insulate itself from any responsibility for disseminating false or misleading statements in its press releases about the criminal prosecutions it brings. It particularly undermines public faith and trust in DOJ's integrity for DOJ to do so here, where the same DOJ sought to imprison Dr. Harkonen for his alleged false statement in a press release. We urge you to reject this double standard.

2. The Response also attempts to defend the merits of the challenged statement, but succeeds only in highlighting that the statement is misleading. As at sentencing, the Government is unable in its Response to point to any evidence to support the statement that Dr. Harkonen's conduct diverted health care resources from this nation's military veterans. The Response is mistaken in asserting that the court "simply held that it was not possible to determine with the degree of certainty necessary for Dr. Harkonen's sentencing, the role the press release played in the increased sales of Actimmune that followed after the press release over eight years ago." Resp. at 2. In fact, the court found that the government had not adduced sufficient evidence to prove that the allegedly false conclusions in the press release had played a role in generating *any* sales of Actimmune. *See, e.g.*, 4/13/11 RT 116-17 (the court noted that "it is unable to determine with a sufficient degree of accuracy that . . . there is a loss as a result of the conduct reflected in the wire fraud count," and that "there just isn't enough evidence . . . to satisfy the Court that there is a loss as a result of the press release,"); *id.* 4/13/11 RT 77 (there is no "basis for determining an amount of loss to enhance a sentence."). The District Court's finding that the Government could not prove, by even a preponderance of the evidence, that the challenged conclusions in the 2002 Press Release caused any financial loss to any individual or federal agency thus require a retraction and correction.

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In tacit recognition that the Special Agent's statement lacks any factual support, the Response now invents a new interpretation that could not conceivably be what the agent intended or the public understood. The Response now asserts that the statement that Dr. Harkonen's actions "'served to divert precious financial resources from VA's critical mission of providing health care resources from the VA's critical mission of providing health care to this nation's military veterans'" "can reasonably be interpreted to mean that Dr. Harkonen's wrongdoing necessitated an investigation into the matter by the Veterans Administration. As the investigation into this matter was comprehensive, it was accurate to say that it diverted precious financial resources from the VA's primary mission." Resp. at 2.

This is specious. No reasonable reader would assume that the statement means that the VA "diverted" funds that the VA had originally allocated to providing health care for veterans, to the investigation of this case. Rather, a reasonable reader would assume that the VA chose to allocate funds that *already were designated* for the investigation of potential health care fraud to the investigation of this case. Indeed, the VA's own 2010 Organizational Briefing Book makes clear that the VA maintains a staff of lawyers and investigators in their Office of Inspector General ("OIG"); OIG is "independent" from the VA and is considered "a separate Federal agency with annual budgetary submission requirements." *See* Briefing Book at 42 (available at http://www.va.gov/ofcadmin/docs/vaorgbb.pdf. Here, OIG chose to direct some of its investigatory funds to support this prosecution without ever (1) looking at the VA's own Actimmune-related documents, which would show the VA that the underlying conduct had caused its program no financial loss, or (2) developing any other evidence sufficient to prove a financial loss. Thus, the fact that OIG chose to devote some of its investigative funds to this case to conduct a "comprehensive" investigation does not support the VA's statement that Dr. Harkonen's conduct diverted any resources that otherwise would have gone to the provision of "health care" to this nation's veterans. In fact, the resources used by OIG in its investigation would likely have come from OIG's budget, rather than the VA's budget from which DOJ claimed a diversion of "precious financial resources." Resp. at 2.

Furthermore, the expenses that OIG might have incurred incident to its investigation were not facts even raised — let alone proven — at trial or sentencing. DOJ's *ex post* attempt to justify the statement of Special Agent Carver is tortured. In so reasoning, the Response underscores the fact that the statement, in its natural and direct meaning, is false.

We urge DOJ to correct the public record now, particularly because, nearly two years after its initial issuance, the press release continues to be widely disseminated on the internet and continues to cause substantial harm to Dr. Harkonen. DOJ would need to undertake very minimal effort in order to correct its press release so that it contains truthful and non-misleading information. Part of DOJ's mission is "to ensure fair and impartial administration of justice for all Americans." *See* http://www.justice.gov/02organizations. Regardless of how DOJ may interpret its Guidelines, it is not clear why DOJ, in service of its mission, would refuse to correct

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what it now knows is a factually incorrect and misleading press release about the outcome of one of its proceedings.

For these reasons, and those set forth in our initial Request, the Government should withdraw its earlier Response and correct the press release as set forth in the Request for Correction.

We look forward to your response within forty-five calendar days of receipt of this letter.

Very truly yours,

Mark E. Haddad SAGA

Coleen Klasmeier SAGA

Enclosures

cc: H. Marshall Jarrett, Director, Executive Office for United States Attorneys
Kyle Waldinger, Assistant United States Attorney

EXHIBIT 12

U.S. Department of Justice

Executive Office for United States Attorneys

Office of the Director

Room 2261, RFK Main Justice Building
950 Pennsylvania Avenue, NW
Washington, DC 20530

(202) 252-1000

OCT - 7 2011

Coleen Klasmeier, Esquire
Sidley Austin LLP
555 West Fifth Street
Los Angeles, CA 90013

Dear Ms. Klasmeier:

This responds to your letter dated August 22, 2011, to the First Assistant United States Attorney for the Northern District of California, a copy of which you provided to the Director of the Executive Office for United States Attorneys, concerning your Request for Reconsideration under the Department of Justice's Information Quality Guidelines (Guidelines). You are again requesting that the government retract statements made in a September 29, 2009 press release concerning *United States v. Harkonen,* No. CR 08-164 (N.D. Cal.). As we have previously explained, the Guidelines do not apply to press releases. Moreover, because the Guidelines do not apply to press releases, the Department was not required to respond substantively to your June 8, 2011 request for a retraction and, similarly, is not required to respond substantively to your most recent request for reconsideration. The Guidelines provide that "[t]he Department need not respond substantively... to repetitive requests for correction.... [nor to] requests that concern information not covered by the guidelines." Accordingly, your request for reconsideration will not be accommodated.

Thank you for raising your concerns with the Department of Justice.

Sincerely,

H. Marshall Jarrett
Director

cc: Mr. Brian Stretch
First Assistant United States Attorney
Northern District of California

STUART F. DELERY
Acting Assistant Attorney General
JOHN R. TYLER
Assistant Branch Director
TAMARA ULRICH
Senior Counsel
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue, NW
Washington, D.C. 20530
Telephone: (202) 305-1432
Fax: (202) 616-8470
Email: Tamara.Ulrich@usdoj.gov

Counsel for the Defendants

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

W. SCOTT HARKONEN, M.D., Plaintiff, v. UNITED STATES DEPARTMENT OF JUSTICE and UNITED STATES OFFICE OF MANAGEMENT AND BUDGET, Defendants.	Case No. 4:12-cv-00629 DMR **DEFENDANTS' NOTICE OF MOTION AND MOTION TO DISMISS** Date: July 26, 2012 Time: 11:00 a.m. Judge: Donna M. Ryu

Notice of Motion and Motion to Dismiss Plaintiff's Complaint, set for hearing on July 26, 2012 at 11:00 a.m. or as soon thereafter as counsel may be heard.

Defendants hereby move the Court to dismiss plaintiff's Complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), for the reasons more fully set forth in defendants' accompanying memorandum of points and authorities.

Dated: April 9, 2012

Respectfully submitted,

STUART F. DELERY
Acting Assistant Attorney General

JOHN R. TYLER
Assistant Branch Director

/s/ Tamara Ulrich
TAMARA ULRICH

Senior Counsel
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue, NW
Washington, D.C. 20530
Tel: (202) 305-1432
Fax: (202) 616-8470
Email: Tamara.Ulrich@usdoj.gov

Counsel for Defendant

STUART F. DELERY
Acting Assistant Attorney General
JOHN R. TYLER
Assistant Branch Director
TAMARA ULRICH
Senior Counsel
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue, NW
Washington, D.C. 20530
Telephone: (202) 305-1432
Fax: (202) 616-8470
Email: Tamara.Ulrich@usdoj.gov

Counsel for the Defendants

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

W. SCOTT HARKONEN, M.D., Plaintiff, v. UNITED STATES DEPARTMENT OF JUSTICE and UNITED STATES OFFICE OF MANAGEMENT AND BUDGET, Defendants.	Case No. 4:12-cv-00629 DMR **MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS** Date: July 26, 2012 Time: 11:00 a.m. Judge: Donna M. Ryu

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INTRODUCTION

The Plaintiff in this action is an individual who, in September 2009, was criminally convicted of wire fraud relating to the dissemination of false and misleading information about the results of a clinical trial of his company's drug. The U.S. Attorney's Office, which handled the prosecution, issued a press release about the conviction. Plaintiff disagreed with certain statements in the press release for allegedly being inaccurate, and, following the procedures set forth in the Information Quality Act ("IQA"), contacted the Department of Justice ("DOJ") to seek correction of what he believed to be misstatements in the press release. DOJ reviewed and denied these requests, because press releases do not fall within the scope of the IQA and because the statements in the press release were correct (they accurately described the government's position). In dismissing these requests, as falling outside the scope of the IQA Act, DOJ was following the government-wide guidelines issued in 2002 by the Office of Management and Budget ("OMB"), which Congress entrusted with implementing the IQA, as well as DOJ's own IQA guidelines, issued later in 2002, both of which expressly state that press releases - and other specified matters - do not fall within the scope of the IQA. Now, Plaintiff is asking this Court to overturn the OMB and DOJ guidelines with respect to press releases, to issue a ruling that press releases are subject to the IQA, and to overturn DOJ's decision to dismiss the plaintiff's correction requests.

This case should be dismissed. Courts have uniformly rejected claims of private individuals seeking to enforce rights under the IQA. Established law requires the same result here. As the courts have held, the IQA does not establish a private right of action. In addition, as other courts have held, in dismissing IQA lawsuits, agency statements of the type at issue here do not involve "final agency action" that is reviewable under the Administrative Procedure Act ("APA"). Also, DOJ in dismissing the plaintiff's requests acted in accordance with the governing guidelines issued in 2002 by OMB and DOJ; these guidelines make clear that press releases do not fall within the scope of the IQA. In issuing these guidelines, OMB and DOJ properly exercised the discretion that Congress had given them under the IQA.

BACKGROUND

A. The Information Quality Act

The Information Quality Act (also known as the "Data Quality Act"), resides in section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 and directs the OMB to issue "guidelines" that provide "policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of the . . . Paperwork Reduction Act." Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515(a)], 114 Stat. 2763, 2763A-153, 2763A-154 (Dec. 21, 2000), codified at 44 U.S.C. § 3516 note. The IQA also directs OMB to include three specific requirements in its guidelines: (1) that federal agencies develop their own information quality guidelines within one year of the issuance of OMB's guidelines; (2) that federal agencies establish administrative mechanisms allowing affected persons to seek and obtain correction of information that does not comply with OMB guidelines; and (3) that federal agencies report periodically to OMB on the number and nature of complaints that they receive regarding the accuracy of the information they disseminate. See id. at 515(b)(2). Notably, the Act does not provide a mechanism for judicial review of the quality of information or any avenue for judicial relief.[1]

1. OMB Guidelines

OMB issued proposed guidelines implementing the IQA on June 28, 2001, 66 Fed. Reg. 34489 (June 28, 2001), then, after a period for public comment, published revised guidelines on September 28, 2001, 66 Fed. Reg. 49718 (Sept. 28, 2001). Following another period for

[1] Certainly nothing in the Act's legislative history suggests judicial review. Indeed, the only legislative history regarding the IQA is found in a single sentence in the Conference Report and Committee Report accompanying the omnibus appropriations bill. The Conference Report states: "The conferees include a new provision requiring OMB to develop guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies as proposed by the House." H.R. Conf. Rep. No. 106-1033, at 396 (2000); see also H.R. Rep. No. 106-756, at 83 (2000) (committee report providing nearly identical language).

additional comment, OMB published final guidelines on February 22, 2002. See 67 Fed. Reg. 8452 (Feb. 22, 2002). In its final guidelines, OMB provides guidance to federal agencies for ensuring and maximizing the quality of the information they disseminate to the public. Generally, the guidelines require federal agencies to undertake four principal responsibilities: (1) to "adopt specific standards of quality that are appropriate for the various categories of information they disseminate"; (2) to "develop a process for reviewing the quality . . . of information before it is disseminated"; (3) to "establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines"; and (4) to provide OMB with reports regarding the agencies' information quality guidelines and any information quality complaints they receive. 67 Fed. Reg. at 8458-59.

The consistent theme throughout the guidelines is that "agencies must apply these standards flexibly," "in a common-sense and workable manner," and that the "guidelines . . . [do] not impose unnecessary administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and other technologies to disseminate information that can be of great benefit and value to the public." 67 Fed. Reg. at 8453. For example, the OMB guidelines provide that federal agencies are to "adopt a basic standard of quality . . . as a performance goal," and "[q]uality is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated." Id. at 8458. Recognizing that the guidelines "cannot be implemented by each agency in the same way," OMB directs agencies to "incorporate [quality standards] into their existing agency information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes." Id. at 8453. Agencies thus maintain substantial discretion in determining how best to ensure the quality of the information they disseminate.

By their terms, the OMB guidelines apply only to "information" that is "disseminated" by a federal agency. 67 Fed. Reg. at 8458. The term "information" includes "any communication or representation of knowledge such as facts or data," but "does not include opinions, where the

agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views." Id. at 8460. The term "dissemination" means "agency initiated or sponsored distribution of information to the public," but "does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." Id. (emphasis added)

With respect to the administrative correction mechanisms, the OMB guidelines require agencies to "specify appropriate time periods for agency decisions on whether and how to correct the information" and to "establish an administrative appeal process to review the agency's initial decision." 67 Fed. Reg. at 8459. OMB makes clear, however, that agencies should correct information only "where appropriate," and that "[t]hese administrative mechanisms shall be flexible" and "appropriate to the nature and timeliness of the disseminated information." Id. As explained in the preamble to the OMB guidelines:

> Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB.

Id. at 8458.

2. DOJ Guidelines

On October 1, 2002, pursuant to the IQA and the OMB guidelines, the Department of Justice issued its own Information Quality Guidelines. See 67 Fed. Reg. 62266 (Oct. 4, 2002) (announcing DOJ's guidelines on its website); http://www.justice.gov/iqpr/iqpr.html ("DOJ Guidelines"). The guidelines adhere to the basic standards cited in the final OMB guidelines, and focuses on three areas: (1) the basic standard of quality of information; (2) the process for reviewing the quality of information; and (3) and the process for citizen complaints. See DOJ Guidelines. The DOJ guidelines specifically state that they "provide[] guidance to component staff and inform[] the public of the agency's policies and procedures. These guidelines are not a regulation. They are not legally enforceable and do not create any legal rights or impose any legally binding requirements or obligations on the agency or the public." Id.

The DOJ guidelines apply to all information disseminated by DOJ except for the categories of information that are specifically exempted from coverage. See DOJ Guidelines. In accordance with the OMB guidelines upon which they are based, among the categories of information exempted from the DOJ guidelines are "press releases, fact sheets, press conferences or similar communications (in any medium) that announce, support, or give public notice of information in DOJ." Id.

B. Factual Background

Plaintiff in this action is a medical doctor who was formerly the Chief Executive Officer of InterMune. Compl. ¶ 9. He was criminally prosecuted in the Northern District of California and convicted for wire fraud relating to the dissemination of false and misleading information about the efficacy of InterMune's drug, Actimmune as a treatment for idiopathic pulmonary fibrosis. Compl. Ex. 1.

Plaintiff's complaint focuses on a press release issued by the United States Attorney's Office on September 29, 2009 announcing the jury verdict in the criminal trial. See Compl. Ex. 1.[2] Plaintiff takes issue with two of the statements contained in the press release: (1) that Dr. Harkonen "lied to the public about the results of a clinical trial" by "falsifying test results,"[3] and (2) that Dr. Harkonen's actions "served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans." Compl. ¶ 3 & Ex. 1. Plaintiff alleges that these statements are not true. Id.

On February 11, 2010, Dr. Harkonen sent a letter to DOJ entitled "Request for Correction under Information Quality Guidelines" seeking correction of the statement in the press release that Plaintiff falsified test results. Compl. ¶ 29-31. Dr. Harkonen contended that the government

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[2] This press release is no longer available on the Department of Justice website.

[3] This quote states, in full, "'Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease. Manipulating scientific research and falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval,' said FBI Special Agent in Charge Stephanie Douglas." Compl. Ex. 1 at 2.

conceded at trial that the test result data were accurate, but that Dr. Harkonen interpreted the clinical trial data in a false manner. Id. On March 15, 2010, DOJ denied Dr. Harkonen's request on two grounds. First, because his request fell outside the scope of OMB and DOJ guidelines for the IQA and, second, because the statement at issue was correct, even if the guidelines applied. Compl. ¶ 33 & Ex. 4. On April 20, 2010, Dr. Harkonen filed a request for reconsideration. Id. ¶ 34 & Ex. 5. This reconsideration request was denied in July, 2010 because press releases are exempt from the IQA guidelines. Id. ¶ 36 & Ex. 6.

On June 8, 2011, Dr. Harkonen sent a second letter to DOJ entitled "Request for Correction Under Information Quality Guidelines." Compl. ¶ 38 & Ex. 9. In this request. Dr. Harkonen asserted that the statement that his actions "served to divert precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans" was not true. Id. On August 4, 2011, DOJ denied this request for two reasons. First, because press releases are not covered under the IQA. Compl. ¶ 40 & Ex. 10. Second, DOJ stated that, even if the press release fell within the IQA, the statements therein accurately described the government's position. Id. Dr. Harkonen sought reconsideration on August 22, 2011, which was denied by DOJ on October 7, 2011. Compl. ¶¶ 41-42 & Exs. 11 & 12.

On February 8, 2012, Plaintiff filed this lawsuit, raising three APA claims; two against DOJ and one against OMB. The first count alleges that DOJ's denials of Plaintiff's two requests for correction were arbitrary and capricious an abuse of discretion, and contrary to law. Compl. ¶¶ 46-48. The second count alleges that the exclusion of press releases from DOJ's information quality guidelines is arbitrary and capricious, an abuse of discretion, and contrary to law. Id. ¶¶ 49-51. The third count alleges that the exclusion of press releases from the OMB information quality guidelines is arbitrary and capricious, an abuse of discretion, and contrary to law. Id. ¶¶ 52-54.

STANDARD OF REVIEW

Under Rule 12(b)(6), a pleading may be dismissed when it fails to "state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Dismissal for failure to state a claim "can

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

W. SCOTT HARKONEN, M.D.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF JUSTICE; and UNITED STATES OFFICE OF MANAGEMENT AND BUDGET,

Defendants.

_____/

No. C 12-629 CW

AMENDED JUDGMENT

For the reasons set forth in this Court's Order Granting Defendants Motion to Dismiss and Denying Plaintiff's Motion for Summary Judgment,

IT IS ORDERED AND ADJUDGED

That Plaintiff W. Scott Harkonen, M.D. take nothing, and that Defendants United States Department of Justice and United States Office of Management and Budget recover from Plaintiff W. Scott Harkonen, M.D. their costs of action.

Dated at Oakland, California, this 3rd day of December, 2012.

RICHARD W. WIEKING
Clerk of Court

By: _____
Deputy Clerk

Mark E. Haddad (SBN 205945)
mhaddad@sidley.com
SIDLEY AUSTIN LLP
555 West Fifth Street, Suite 4000
Los Angeles, California 90013
Telephone: (213) 896-6000
Facsimile: (213) 896-6600

Kathleen M. Mueller (*admitted pro hac vice)*
kmueller@sidley.com
SIDLEY AUSTIN LLP
1501 K St. NW
Washington, DC 20005
Telephone: (202) 736-8987
Facsimile: (202) 736-8711

Robert B. Martin III (SBN 235489)
rbmartin@sidley.com
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, California 94104
Telephone: (415) 772-1200
Facsimile: (415) 772-7400

Attorneys for W. SCOTT HARKONEN, M.D.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

W. SCOTT HARKONEN, M.D., Plaintiff, v. UNITED STATES DEPARTMENT OF JUSTICE and UNITED STATES OFFICE OF MANAGEMENT AND BUDGET, Defendants.	Case No. 4:12-cv-00629-CW **NOTICE OF APPEAL**

NOTICE OF APPEAL

Notice is hereby given that plaintiff W. Scott Harkonen hereby appeals to the U.S. Court of Appeals for the Ninth Circuit from this Court's Order Granting Defendants' Motion to Dismiss and Denying Plaintiff's Motion for Summary Judgment and from the final Judgment for defendants, which were entered on December 3, 2012.

Dated: January 31, 2013

Respectfully submitted,

SIDLEY AUSTIN LLP

By: /s/ Mark E. Haddad
Mark E. Haddad

Attorneys for Plaintiff
W. SCOTT HARKONEN, M.D.

ADRMOP,APPEAL,CLOSED

U.S. District Court
California Northern District (Oakland)
CIVIL DOCKET FOR CASE #: 4:12−cv−00629−CW

Harkonen v. United States Department of Justice et al
Assigned to: Hon. Claudia Wilken
Case in other court: Ninth Circuit Court of Appeals, 13−15197
Cause: 05:702 Administrative Procedure Act

Date Filed: 02/08/2012
Date Terminated: 12/03/2012
Jury Demand: None
Nature of Suit: 899 Other Statutes: Administrative Procedures Act/Review or Appeal of Agency Decision
Jurisdiction: Federal Question

Plaintiff

M.D. W. Scott Harkonen represented by **Mark E. Haddad**
Sidley Austin Brown &Wood
555 West Fifth Street, Suite 4000
Los Angeles, CA 90013−1010
213−896−6000
Email: mhaddad@sidley.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Sheila Anil Gogate Armbrust
Sidley Austin LLP
555 California St
Suite 2000
SF, CA 94104
415−772−7434
Fax: 415−772−7400
Email: sarmbrust@sidley.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Kathleen M. Mueller
Sidley Austin LLP
150 K St NW
Washington, DC 20005
202−736−8987
Fax: 202−736−8711
PRO HAC VICE
ATTORNEY TO BE NOTICED

Robert Brooks Martin , III
Sidley Austin LLP
555 California St.
Suite 2000
San Francisco, CA 94104−1715
415−772−1200
Fax: 415−772−7400
Email: rbmartin@sidley.com
ATTORNEY TO BE NOTICED

V.

Defendant

United States Department of Justice represented by **Michael Andrew Zee**
U.S. Department of Justice, Civil Division
Federal Programs Branch
20 Massachusetts Avenue NW
Room 7225
Washington, DC 20530

202−305−8648
Email: m.andrew.zee@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Tamara Ulrich
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Ave. Room 7202
P.O. Box 883
Washington, DC 20044
202−305−1432
Email: tamara.ulrich@usdoj.gov
TERMINATED: 07/25/2012

Defendant

United States Office of Management and Budget

represented by **Michael Andrew Zee**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Tamara Ulrich
(See above for address)
TERMINATED: 07/25/2012

Date Filed	#	Docket Text
02/08/2012	1	COMPLAINT against United States Department of Justice, United States Office of Management and Budget (Filing fee $350, receipt number 34611070358). Filed byW. Scott Harkonen. (cjl, COURT STAFF) (Filed on 2/8/2012) (Additional attachment(s) added on 3/7/2012: # 1 Exhibit, # 2 Civil Cover Sheet) (vlk, COURT STAFF). (Entered: 02/10/2012)
02/08/2012	2	Certificate of Interested Entities by W. Scott Harkonen. (cjl, COURT STAFF) (Filed on 2/8/2012) (Entered: 02/10/2012)
02/08/2012	3	Summons Issued as to United States Department of Justice, United States Office of Management and Budget, U.S. Attorney and U.S. Attorney General. (cjl, COURT STAFF) (Filed on 2/8/2012) (Entered: 02/10/2012)
02/08/2012	4	ADR SCHEDULING ORDER: Case Management Statement due by 5/16/2012. Case Management Conference set for 5/23/2012 01:30 PM in Courtroom 4, 3rd Floor, Oakland. (Attachments: # 1 Standing Order)(cjl, COURT STAFF) (Filed on 2/8/2012) (Entered: 02/10/2012)
02/23/2012	5	CERTIFICATE OF SERVICE by W. Scott Harkonen re 3 Summons Issued as to USA, 2 Certificate of Interested Entities, 1 Complaint, 4 ADR Scheduling Order (Armbrust, Sheila) (Filed on 2/23/2012) (Entered: 02/23/2012)
02/23/2012	6	CERTIFICATE OF SERVICE by W. Scott Harkonen re 3 Summons Issued as to USA, 2 Certificate of Interested Entities, 1 Complaint, 4 ADR Scheduling Order (Armbrust, Sheila) (Filed on 2/23/2012) (Entered: 02/23/2012)
02/29/2012	7	CLERKS NOTICE re: Failure to E−File. (vlk, COURT STAFF) (Filed on 2/29/2012) (Entered: 02/29/2012)
04/09/2012	8	MOTION to Dismiss filed by United States Department of Justice, United States Office of Management and Budget. Motion Hearing set for 7/26/2012 11:00 AM in Courtroom 4, 3rd Floor, Oakland before Magistrate Judge Donna M. Ryu. Responses due by 7/5/2012. Replies due by 7/12/2012. (Ulrich, Tamara) (Filed on 4/9/2012) (Entered: 04/09/2012)
04/11/2012	9	CLERKS NOTICE RE CONSENT TO PROCEED BEFORE MAGISTRATE (lrcS, COURT STAFF) (Filed on 4/11/2012) (Entered: 04/11/2012)

04/11/2012	10	AMENDED CLERK'S NOTICE TO PARTIES Re: Consent or Declination to Proceed before a Magistrate Judge with deadline set. (ig, COURT STAFF) (Filed on 4/11/2012) (Entered: 04/12/2012)
04/12/2012	11	Declination to Proceed Before a U.S. Magistrate Judge by United States Department of Justice, United States Office of Management and Budget . (Ulrich, Tamara) (Filed on 4/12/2012) (Entered: 04/12/2012)
04/13/2012	12	CLERK'S NOTICE of Impending Reassignment to U.S. District Judge (ig, COURT STAFF) (Filed on 4/13/2012) (Entered: 04/16/2012)
04/17/2012	13	ORDER REASSIGNING CASE. Case reassigned to Judge Hon. Claudia Wilken for all further proceedings. Magistrate Judge Donna M. Ryu no longer assigned to the case. Signed by the Executive Committee on April 17, 2012. (cjl, COURT STAFF) (Filed on 4/17/2012) (Entered: 04/17/2012)
04/17/2012	14	CASE MANAGEMENT SCHEDULING ORDER FOR REASSIGNED CIVIL CASE: Case Management Statement due by 5/16/2012. Case Management Conference set for 5/23/2012 02:00 PM. Signed by Judge Claudia Wilken on 4/17/2012. (Attachments: #1 Standing Order)(ndr, COURT STAFF) (Filed on 4/17/2012) (Entered: 04/17/2012)
04/17/2012		CLERKS NOTICE. Notice is hereby given that counsel must re−notice the 8 motion to dismiss before Judge Wilken on an available Thursday at 2 p.m. The previous briefing schedule remains in effect. **(This is a text only docket entry, there is no document associated with this notice.)** (ndr, COURT STAFF) (Filed on 4/17/2012) (Entered: 04/17/2012)
04/17/2012	15	ORDER REGARDING FILING DEADLINE FOR RESPONSE AND REPLY TO DEFENDANTS' MOTION TO DISMISS. Signed by Judge Claudia Wilken on April 17, 2012. (cwlc2, COURT STAFF) (Filed on 4/17/2012) (Entered: 04/17/2012)
04/19/2012	16	STIPULATION WITH PROPOSED ORDER *Setting Briefing Schedule for Plaintiff's Opposition To Defendants' Motion to Dismiss, and Plaintiff's Motion for Summary Judgment* filed by W. Scott Harkonen, United States office of Management and Budget, United States Department of Justice. (Attachments: #1 Declaration)(Haddad, Mark) (Filed on 4/19/2012) Modified on 4/20/2012 (cp, COURT STAFF). (Entered: 04/19/2012)
04/21/2012	17	Order granting 16 Stipulation entered by Hon. Claudia Wilken. (This is a text−only entry generated by the court. There is no document associated with this entry.) (Entered: 04/21/2012)
04/23/2012		Set/Reset Deadlines as to 8 MOTION to Dismiss. Set Deadlines/Hearings: Motions due by 6/29/2012. Responses due by 6/29/2012. Replies due by 8/3/2012. Replies due by 8/24/2012. Motion Hearing set for 9/13/2012 02:00 PM before Hon. Claudia Wilken. **See Text Order, Docket No. 17** (ndr, COURT STAFF) (Filed on 4/23/2012) (Entered: 04/23/2012)
06/26/2012	18	STIPULATION WITH PROPOSED ORDER *Setting Page Limits on Plaintiff's Opposition to Defendants' Motion to Dismiss, Plaintiff's Motion for Summary Judgment, and Defendants' Response* filed by W. Scott Harkonen, United States Office of Management and Budget, United States Department of Justice. (Haddad, Mark) (Filed on 6/26/2012) Modified on 6/27/2012 (cpS, COURT STAFF). (Entered: 06/26/2012)
06/27/2012	19	Order granting 18 Stipulation entered by Hon. Claudia Wilken. (This is a text−only entry generated by the court. There is no document associated with this entry.) (Entered: 06/27/2012)
06/27/2012	20	MOTION for leave to appear in Pro Hac Vice as to Kathleen M. Mueller (Filing fee $ 305, receipt number 44611009029.) Filing fee previously paid on 6/27/2012 filed by W. Scott Harkonen. (Attachments: #1 Proposed Order)(cp, COURT STAFF) (Filed on 6/27/2012) (Entered: 07/02/2012)

07/02/2012	21	MOTION for Summary Judgment *and Response to Defendants' Motion to Dismiss* filed by W. Scott Harkonen. Motion Hearing set for 9/13/2012 02:00 PM in Courtroom 2, 4th Floor, Oakland before Hon. Claudia Wilken. Responses due by 7/16/2012. Replies due by 7/23/2012. (Attachments: # 1 Declaration Declaration of Mark E. Haddad in Support of Plaintiff's Motion for Summary Judgment and Response to Defendants' Motion to Dismiss, # 2 Proposed Order Proposed Order Granting Motion for Summary Judgment)(Haddad, Mark) (Filed on 7/2/2012) Modified on 7/3/2012 (cpS, COURT STAFF). (Entered: 07/02/2012)
07/02/2012	22	Declaration of Robert B. Martin III in Support of 21 MOTION for Summary Judgment *and Response to Defendants' Motion to Dismiss* filed byW. Scott Harkonen. (Related document(s) 21) (Martin, Robert) (Filed on 7/2/2012) Modified on 7/3/2012 (cpS, COURT STAFF). (Entered: 07/02/2012)
07/05/2012	23	Order granting 20 Motion for Pro Hac Vice entered by Hon. Claudia Wilken. (This is a text−only entry generated by the court. There is no document associated with this entry.) (Entered: 07/05/2012)
07/25/2012	24	NOTICE of Substitution of Counsel by Michael Andrew Zee (Zee, Michael) (Filed on 7/25/2012) (Entered: 07/25/2012)
07/27/2012	25	STIPULATION WITH PROPOSED ORDER *RESETTING BRIEFING SCHEDULE FOR, AND HEARING DATE ON, DEFENDANTS MOTION TO DISMISS, AND PLAINTIFFS MOTION FOR SUMMARY JUDGMENT* filed by W. Scott Harkonen, United States Department of Justice, United States Office of Management and Budget. (Attachments: # 1 Declaration of M. Andrew Zee)(Zee, Michael) (Filed on 7/27/2012) (Entered: 07/27/2012)
07/31/2012	26	Order granting 25 Stipulation entered by Hon. Claudia Wilken. (This is a text−only entry generated by the court. There is no document associated with this entry.) (Entered: 07/31/2012)
08/01/2012		Reset Deadlines as to 8 MOTION to Dismiss . Replies due by 9/14/2012. Motion Hearing set for 11/15/2012 02:00 PM before Hon. Claudia Wilken. See Docket No. 26. (ndr, COURT STAFF) (Filed on 8/1/2012) (Entered: 08/01/2012)
08/01/2012		Reset Deadlines as to 21 MOTION for Summary Judgment. Responses due by 9/14/2012. Replies due by 10/5/2012. Motion Hearing set for 11/15/2012 02:00 PM before Hon. Claudia Wilken. See Docket No. 26. (ndr, COURT STAFF) (Filed on 8/1/2012) (Entered: 08/01/2012)
09/11/2012	27	STIPULATION WITH PROPOSED ORDER *RESETTING BRIEFING SCHEDULE FOR DEFENDANTS' MOTION TO DISMISS, AND PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT* filed by W. Scott Harkonen, United States Department of Justice, United States Office of Management and Budget. (Attachments: # 1 Declaration of M. Andrew Zee)(Zee, Michael) (Filed on 9/11/2012) (Entered: 09/11/2012)
09/12/2012	28	Order granting 27 Stipulation entered by Hon. Claudia Wilken. (This is a text−only entry generated by the court. There is no document associated with this entry.) (Entered: 09/12/2012)
09/13/2012		Reset Deadlines as to 8 MOTION to Dismiss . Replies due by 9/21/2012. See Docket No. 28. (ndr, COURT STAFF) (Filed on 9/13/2012) (Entered: 09/13/2012)
09/13/2012		Reset Deadlines as to 21 MOTION for Summary Judgment. Responses due by 9/21/2012. Replies due by 10/12/2012. See Docket No. 28. (ndr, COURT STAFF) (Filed on 9/13/2012) (Entered: 09/13/2012)
09/21/2012	29	REPLY (re 8 MOTION to Dismiss) *AND OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT* filed byUnited States Department of Justice, United States Office of Management and Budget. (Zee, Michael) (Filed on 9/21/2012) (Entered: 09/21/2012)
10/12/2012	30	REPLY in support of (re 21 MOTION for Summary Judgment) filed byW. Scott Harkonen. (Haddad, Mark) (Filed on 10/12/2012) Modified on 10/15/2012 (cpS, COURT STAFF). (Entered: 10/12/2012)

11/15/2012	31	Minute Entry: Motion Hearing held on 11/15/2012 before Claudia Wilken (Date Filed: 11/15/2012). (Court Reporter Diane Skillman.) (ndr, COURT STAFF) (Date Filed: 11/15/2012) (Entered: 11/19/2012)
12/03/2012	32	ORDER GRANTING DEFENDANTS 8 MOTION TO DISMISS AND DENYING PLAINTIFFS 21 MOTION FOR SUMMARY JUDGMENT. Signed by Judge Claudia Wilken on 12/3/2012. (ndr, COURT STAFF) (Filed on 12/3/2012) (Entered: 12/03/2012)
12/03/2012	33	CLERK'S JUDGMENT in favor of United States Department of Justice, United States Office of Management and Budget against W. Scott Harkonen. (ndr, COURT STAFF) (Filed on 12/3/2012) (Entered: 12/03/2012)
12/03/2012	34	AMENDED CLERK'S JUDGMENT in favor of United States Department of Justice, United States Office of Management and Budget against W. Scott Harkonen. (ndr, COURT STAFF) (Filed on 12/3/2012) (Entered: 12/04/2012)
01/31/2013	35	NOTICE OF APPEAL to the 9th CCA W. Scott Harkonen. Appeal of Order, Terminated Case 32 , Clerk's Judgment 34 (Appeal fee of $455 receipt number 0971−7450010 paid.) (Haddad, Mark) (Filed on 1/31/2013) (Entered: 01/31/2013)
01/31/2013	36	USCA Case Number 13−15197 Ninth Circuit Court of Appeals for 35 Notice of Appeal filed by W. Scott Harkonen. (kk, COURT STAFF) (Filed on 1/31/2013) (Entered: 02/01/2013)
02/25/2013	37	TRANSCRIPT DESIGNATION by W. Scott Harkonen for proceedings held on 11/15/2012 before Judge Claudia Wilken.. (Haddad, Mark) (Filed on 2/25/2013) (Entered: 02/25/2013)
04/01/2013	38	Transcript of Proceedings held on November 15, 2012, before Judge Claudia Wilken. Court Reporter Diane E. Skillman, Telephone number 510−451−2930, Diane_Skillman@cand.uscourts.gov. Per General Order No. 59 and Judicial Conference policy, this transcript may be viewed only at the Clerks Office public terminal or may be purchased through the Court Reporter until the deadline for the Release of Transcript Restriction.After that date it may be obtained through PACER. Any Notice of Intent to Request Redaction, if required, is due no later than 5 business days from date of this filing. Release of Transcript Restriction set for 7/1/2013. (Skillman, Diane) (Filed on 4/1/2013) (Entered: 04/01/2013)

CERTIFICATE OF SERVICE

I hereby certify that 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 on May 31, 2013.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

Dated: May 31, 2013

s/ Mark E. Haddad
Mark E. Haddad (CABN 205945)
SIDLEY AUSTIN LLP
555 West Fifth Street, Suite 4000
Los Angeles, California 90013
Telephone: (213) 896-6000
Facsimile: (213) 896-6600