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.)

REPLY BRIEF OF DR. W. SCOTT HARKONEN

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

October 8, 2013

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

CASES

STATUTES AND REGULATIONS

STATUTES AND REGULATIONS

INTRODUCTION

When the Department of Justice disseminated a press release with false information about him, Dr. Harkonen sought correction through the Information Quality Act ("IQA"). DOJ denied Harkonen's requests, saying that its IQA guidelines and those of the Office of Management and Budget ("OMB") exempt DOJ's press releases from accountability under the IQA. Before the district court and this Court, DOJ refuses accountability for the accuracy of its own press releases. DOJ refuses to be accountable even though it considers press releases sufficiently important that it prosecuted Harkonen over the veracity of a press release; even though DOJ itself uses press releases as a principal means to disseminate information and the news media rely upon and repeat statements in DOJ press releases; and even though Congress mandated in plain language that agencies "shall" be accountable to "affected persons" for the truth of the information they have "disseminated." 44 U.S.C. § 3516, note.

The Agencies now urge this Court to hold that federal courts are powerless, notwithstanding the IQA, the Administrative Procedure Act, and Article III, to hold DOJ accountable for disseminating false information. If the Court accepts this argument, DOJ will be free to distribute false press releases and to post them indefinitely on its website while ignoring all requests from the public for

corrections. The IQA's plain language and the presumption of judicial review of final agency action foreclose that extraordinary result.

Congress did delegate responsibility for promulgating implementing guidelines to OMB. But Congress nowhere gave OMB or agencies carte blanche to rewrite the IQA. Congress mandated that OMB's guidelines "shall" apply to "information disseminated by Federal agencies," and "shall" require individual federal 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 the guidelines." *Id.* OMB and DOJ have not followed those requirements. Excluding, from the ambit of guidelines, a principal means by which DOJ publicly disseminates information conflicts with the IQA.

The Agencies have not explained, and cannot persuasively explain, *why* it is desirable to permit our nation's preeminent law enforcement agency to disseminate, with impunity, false information in a press release, or how one could reconcile such an extraordinary exemption with Congress's intent. Under the government's cramped reading of the statute, Congress enacted the IQA merely to put OMB to the task of drafting guidelines. *See* GB 11-13, 16-22. Ordering OMB to create precatory paperwork is an odd interpretation of an amendment to the Paperwork Reduction Act. The government's interpretation of a toothless IQA contravenes both the text and purpose of the statute which, as OMB itself

recognized in a less guarded context, make it "clear that agencies should not disseminate substantive information that does not meet a basic level of quality." 67 Fed. Reg. 8452, 8452 (Feb. 22, 2002). It is also inconsistent with the longstanding "presumption favoring interpretations of statutes [to] allow judicial review of administrative action" and against giving the executive branch the "authority to remove cases from the Judiciary's domain," *Kucana v. Holder*, 558 U.S. 233, 237 (2010) (quotation marks omitted; alterations in original)—a presumption the government's brief does not even acknowledge, much less rebut.

On the merits, the government asks this Court to ignore the actual basis for DOJ's final denials of Harkonen's petitions (which is that DOJ's press release was exempt from the IQA under the OMB and DOJ guidelines). Instead, the government seeks affirmance based on DOJ's preliminary decisions that the challenged statements were accurate—*findings that the agency did not adopt or rely upon* in either of its final decisions. The government cites no authority for this approach, which violates the "fundamental rule of administrative law" that a "reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency." *SEC v. Chenery Corp*., 332 US 194, 196 (1947). And in all events, the challenged statements were and remain manifestly false. Harkonen was not convicted because he "falsif[ied] test

results"—conduct that "damages the foundation of the clinical trial process." ER0056. DOJ acknowledges that Harkonen did *not* falsify any data, but was prosecuted instead for the *conclusions* he drew from the data (ER0186) —conduct that is viewed by scientists, doctors and medical boards as qualitatively different. *See* AOB 13-14. The Court should enforce the IQA, and reverse.

ARGUMENT

I. The Denials of Harkonen's IQA Petitions Are Subject to Judicial Review Under the APA.

The Agencies principally defend the district court judgment on the ground that there is no judicial review because the denials of Harkonen's IQA petitions are not "final agency action," 5 U.S.C. § 704, and are "committed to agency discretion by law," *id.* § 701(a)(2). Neither argument is correct.

A. DOJ's Denials Of Harkonen's IQA Petitions Are Final Agency Action.

1. The government argues that it is "well established" that agency press releases and reports "are not final agency action subject to APA review because they have no legal consequences." GB15-16 (citing cases). The government attacks a straw man. Harkonen has never claimed that the issuance of the DOJ press release was final agency action reviewable under the APA. Rather, Harkonen challenges DOJ's denial of his *IQA petitions* for correction of false statements in the DOJ press release. *See* AOB12-20. Harkonen filed his petitions pursuant to administrative review mechanisms expressly required by the IQA, 44

U.S.C. § 3516, note. Where a statute or regulation permits a person to petition an agency to take some action, courts repeatedly have held that the denial of such a petition has "legal consequences" and is final agency action subject to review under the APA. This right to judicial review exits even if the agency has discretion to deny the petition and thus to determine on the merits that the petitioner has no "right" to the requested relief. *See* AOB 31-36.

With the exception of a few district court decisions involving the IQA, the government has cited *no* case in which a court has held that the denial of a petition authorized by statute or regulation was not "final agency action" reviewable under the APA. The non-IQA case on which the government principally relies, *Guerrero v. Clinton*, 157 F.3d 1190 (9th Cir. 1998), is wholly inapposite. Unlike in cases Harkonen cites, the underlying statute in *Guerrero* provided no opportunity for private parties to seek agency action; it only required the agency to report annually to Congress. *Id.* at 1191-92. This Court distinguished such a reporting provision "from the prototypical kind of agency action which is subject to the general presumption of reviewability," such as that at issue here in which an agency exercises "authority delegated by Congress akin to rule-making or adjudicatory functions." *Id.* at 1195.

The government tries to distinguish the cases cited in our Opening Brief , but it does so on grounds that do not withstand scrutiny. The government argues

that unlike the IQA, the denial of a petition for a declaratory order has "'legal consequence'" because "a separate provision of the APA, 5 U.S.C. § 554(e), expressly conferred the right to review of such a declaratory order decision." GB 22. The text of § 554(e), however, does not expressly confer a right to judicial review. It simply states that "[t]he agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty." 5 U.S.C. § 554(e). Yet the D.C. Circuit held the denial of a petition for a declaratory order, like the denial of petition to initiate a rulemaking, is final agency action because it has the "legal consequence" of affecting the petitioner's right "to a reasoned agency disposition of its request." *Intercity Transp. Co. v. United States*, 737 F.2d 103, 106-07 & n.6 (D.C. Cir. 1984) (citing *WWHT, Inc. v. FEC*, 656 F.2d 807, 814-16 (D.C. Cir. 1981) (holding the denial of a petition to initiate rulemaking is subject to judicial review under the APA)).

The same principle governs petitions for the correction of military records. That statute likewise confers no express right to judicial review. It states only that the "Secretary of a military department *may correct* any military record of the Secretary's department when the *Secretary considers it necessary* to correct an error or remove an injustice." 10 U.S.C. § 1552(a)(1) (emphasis added). Even though this statutory language is far less susceptible than the IQA to a construction

that it creates a right to a correction or to judicial review, this Court (among others) has long recognized that the Secretary's denial of a request for correction of military records is reviewable under the APA . *See* AOB 34-36 (citing cases).

The government responds that reliance on this Court's decision in *Barber v. Widnall*, 78 F.3d 1419 (9th Cir. 1996), is misplaced because the question of final agency action was not "specifically consider[ed]." GB 22. This Court did find, however, that the case was justiciable, relying on prior circuit precedent holding that the denial of a petition for correction of military records is "reviewable in accordance with the Administrative Procedure Act," *Barber*, 78 F.3d at 1423 (citing *Guerrero v. Stone*, 970 F.2d 626, 628 (9th Cir. 1992). In other cases the government itself has conceded that "the Secretary's denial of an application for correction of naval records is a final agency action subject to review under the standards of the Administrative Procedure Act." *Miller v. Lehaman*, 801 F.2d 492, 496 (D.C. Cir. 1986). Given the greater specificity with which Congress granted individuals an opportunity to seek and obtain corrections under the IQA, it would be irrational to deny judicial review of IQA petitions while allowing judicial review of denials of requests for correction of military records.

The government's only other argument is that the denial of a request for correction of military records "*can* have significant legal consequences" because any correction awarded by the Secretary is final and may give rise to back pay or

other benefits. GB 22 (emphasis added). But that does not explain either this Court's decision in *Barber v. Widnall*, or the D.C. Circuit's decision in *Miller v. Lehman*, both of which involved requests for correction of records by service members who suffered no loss of pay or benefits. *See* AOB 34-35. Nor does it address the significant harm to individuals and the public of allowing DOJ to spread misinformation and falsehoods without any possibility of judicial accountability. *See, e.g.*, Pavlo, *Prosecutors Spoon Feed Journalists Stories*, Forbes, Oct. 7, 2013, http://www.forbes.com/sites/walterpavlo/2013/10/07/prosecutors-spoon-feed-journalists-stories/ (noting that journalists feel free to publish assertions about individuals that might be libelous because they are "just parroting what a federal prosecutor said" in a DOJ press release and that a federal judge "ridiculed" a recent DOJ press release's account of the charges against a defendant); 66 Fed. Reg. 34489, 34490 (June 28, 2001) (OMB acknowledging the "harm that can result from dissemination of information that does not meet OMB and agency information quality standards").

2. The government also argues that the denial of Harkonen's IQA petitions are not final agency action because "the IQA 'does not create a legal right to access to information or to correctness.'" GB 18 (emphasis omitted) (quoting *Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006)). The government misreads *Salt Institute* and errs in arguing that the IQA confers no legally enforceable rights.

As discussed in our Opening Brief (at 28-29) and the amicus brief of the Center for Regulatory Effectiveness (at 12-17), the Fourth Circuit held that the *Salt Institute* plaintiffs lacked standing to challenge an agency's denial of their request for disclosure of the data underlying a government-funded study with which plaintiffs disagreed. The government claims that we "incorrectly assert[ed]" that "*Salt Institute* involved only disclosure, not correction, of information." GB 17. The Opening Brief and amicus brief are correct. Although the petition at issue in *Salt Institute* was styled as a petition under the IQA for "'correction of information disseminated by [the agency]'", it specifically stated that plaintiffs did "'*not* at this time request or recommend that the challenged information be removed from the public view.'" *Salt Inst. v. Thompson*, 345 F. Supp. 2d 589, 596 (E.D. Va. 2004) (quoting petition; emphasis added), *aff'd sub nom. Salt Inst. v. Leavitt*, 440 F.3d 156 (4th Cir. 2006). Instead, plaintiffs "limited their request for relief to the disclosure of [the study data]," *id.*, so they could "test" the validity of the study's conclusions "for different groups of individuals." 440 F.3d at 157 (citing petition and noting that plaintiffs' "lone request was that information be made public.").

Because neither the IQA nor the OMB or agency guidelines at issue in *Salt Institute* say anything about disclosure of information, it is not surprising that the Fourth Circuit affirmed the denial of the IQA petitions on the ground that the plaintiffs lacked standing because the IQA gave them no "legal right to access to

information or to correctness." *Id.* at 158-59. But given the limited nature of the relief requested, the Fourth Circuit's suggestion that the IQA confers no right to "correctness" is dicta that cannot be read as holding that the denial of an IQA petition can never be final agency action subject to judicial review under the APA. The Fourth Circuit was not confronted with that issue—a point the government emphasized in the *Salt Institute* oral argument (*see* Amicus Br. of Center for Regulatory Effectiveness 12-13). The Fourth Circuit simply had the equivalent of a Freedom of Information Act request in the guise of an IQA petition.

Here, by contrast, this Court must confront the IQA head-on. "Given the administrative mechanisms required by [the IQA] 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." 67 Fed. Reg. at 8452. If, as here, an agency fails to meet that level of quality and declines a request for correction under the administrative review mechanisms required by the IQA, its final decision is subject to judicial review under the APA.

B. DOJ's Denials Of Harkonen's Petitions Are Not "Committed to Agency Discretion by Law"

The government also invokes the exception to judicial review for action that is "committed to agency discretion by law." This narrow exception admittedly applies only when the relevant statute and regulations provide "no meaningful standard against which to judge the agency's exercise of discretion." GB 23

(quotations omitted). The government invokes it here only by ignoring important sections of the IQA and binding precedent.

1. As our Opening Brief explained (at 36-41), the IQA's text—which requires that the OMB guidelines "shall" apply to "information disseminated by Federal agencies," 44 U.S.C. § 3516, note—provides a meaningful standard against which to judge the exemption for DOJ press releases. That is clear from the fact that the D.C. Circuit was able to resolve, on the merits, a challenge to an agency's refusal to correct information that fell within another exemption to the OMB guidelines. *See Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010) (holding that OMB reasonably exempted documents distributed in adjudicative proceedings). The government does not dispute any of this. The government thus effectively concedes that the denials of Harkonen's petitions are *not* committed to agency discretion by law to the extent they are based on the exemption of press releases from the OMB and DOJ guidelines.

2. The government relies instead on the assertion that DOJ found that the press release was "accurate," and claims that decision is committed to agency discretion by law because neither the IQA nor the OMB guidelines establish a meaningful standard for evaluating the "'quality'" of information disseminated by an agency. *See* GB 22-25. The government ignores, however, that the DOJ guidelines state that "DOJ components will ensure disseminated information, as a

matter of substance and presentation is accurate, reliable, and unbiased."[1] As explained in our Opening Brief (at 40-41), these guidelines are more specific than a regulation authorizing the reopening of an administrative adjudication in "exceptional circumstances," or a statute authorizing the agency to make exceptions "in the public interest," each of which this Court has held to provide a meaningful standard for judicial review. *See Socop-Gonzalez v. INS*, 208 F.3d 838, 844-45 (9th Cir. 2000), *aff'd en banc*, 272 F.3d 1176 (9th Cir. 2001); *Keating v. FAA*, 610 F.2d 611, 612 (9th Cir. 1980); *see also, e.g., Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402. 405 n.2, 411-12 (1971) (statute prohibiting construction of highway through a park unless "there is no feasible and prudent alternative" provides meaningful standard for review), *abrogated on other grounds, Califano v. Sanders*, 430 U.S. 99 (1977).

Again, the government does not respond to the holdings of these cases. Instead, it cites language from the preamble to the OMB guidelines (which the government erroneously attributes to the guidelines themselves, *see* GB at 23) stating that agencies need only make corrections that they deem appropriate, and

---

[1] AOB Attachment E at 4 (drawing on the definitions from the OMB guidelines); *cf.* 67 Fed. Reg. at 8459 (OMB guidelines stating that the "'quality'" of information depends on various factors, including its "'objectivity,'" which includes "whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner" and is the information itself is "accurate, reliable, and unbiased").

should weigh the costs and benefits in determining the "'level of quality to which the information disseminated will be held.'" *Id.* at 24 (quoting 67 Fed. Reg. at 8,452-53). This language, even if it were expressly incorporated into the OMB and DOJ guidelines, is not sufficient to overcome the APA's strong presumption of judicial review. Agencies often have discretion to implement statutes and must weigh the costs and benefits before making a decision. Although that discretion is relevant to the level of scrutiny that a court will apply, it does *not* deprive the court of all authority to review the agency's decision. That fundamental legal principle is clear from decisions like *Socop-Gonzalez*, *Keating*, and *Citizens to Preserve Overton Park*. Each case was cited in our Opening Brief (at 40-41), and each is ignored by the government.

The government thus has no viable escape route. It must stand judicially accountable under the APA for its final decisions to deny Harkonen's IQA petitions.

II. DOJ Wrongfully Denied Harkonen's Requests for Correction

Turning to the merits, the government argues that this Court need not address Harkonen's claim that the exclusion of press releases from the OMB and DOJ guidelines violates the IQA. That question, the government claims, "has no practical significance in this case because DOJ reviewed the U.S. Attorney's press

release and determined that it was accurate." GB 28. The government misstates the record.

As explained in detail in our Opening Brief (12-19), a DOJ official reviewed both of Dr. Harkonen's petitions and made an initial determination that the DOJ press release was accurate. But when Harkonen sought reconsideration pursuant to the administrative review mechanisms provided by the OMB and DOJ guidelines, DOJ's final decisions did not incorporate these findings or rely on the supposed accuracy of the DOJ press release. Instead, DOJ based its final decisions solely on the fact that "the guidelines do not apply because the statement of which [Harkonen] complain[s] was disseminated in a press release." ER0180 (denying first petition); *see also* ER296 ("because the Guidelines do not apply to press releases, the Department was not required to respond substantively" to Harkonen's second petition).

The government has not cited any authority that would permit a court, in an action for judicial review of a final agency action pursuant to the APA, to affirm the agency's decision based on a rationale in a preliminary decision that was then challenged on reconsideration and abandoned in the agency's final decision. To our knowledge, all the case law is to the contrary. *See supra* at 3; AOB 45.

A. The IQA Does Not Permit The Exclusion Of Press Releases From The OMB And DOJ Guidelines

The government asks this Court to defer to OMB's decision to exempt press releases from the OMB guidelines because the IQA does not define the term "dissemination." GB 29. That request should be denied.

A court is not required to defer to an agency's construction of a statute whenever Congress fails to include a definition of each operative word. A court must require the agency to follow the intent of Congress if the statute is clear, and permit the agency to "go no further than the ambiguity will fairly allow" if the statute is ambiguous. *Arlington v. FCC*, 133 S. Ct. 1863, 1874 (2013). Here, the statute is clear: the OMB guidelines "shall" apply to "information disseminated by Federal agencies." 44 U.S.C. § 3516, note. The government does not even attempt to explain how the exclusion of press releases (which even DOJ admits "disseminate" information, *see* AOB 48 & n.5) is consistent with that statutory text. It is not. The agency's proffered construction conflicts with the text, and this Court should therefore reject it. *See* AOB 46-49.

The government does try to manufacture ambiguity by criticizing Harkonen's additional reliance on Section 3504(d)(1) of title 44, which states that OMB "shall develop and oversee the implementation of policies, principles, standards, and guidelines" to "apply to Federal agency dissemination of public information, *regardless of the form or format* in which such information is

disseminated." 44 U.S.C. § 3504(d)(1) (emphasis added). Again, the plain text easily sweeps in press releases, yet the government says Section 3504(d)(1) is irrelevant because it is a section of the Paperwork Reduction Act and "is not part of the IQA." GB 29. The government is wrong. The first sentence of the IQA expressly links the two statutes. It directs OMB to "issue guidelines *under sections 3504(d)(1)* and 3516 of title 44 . . . 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*." 44 U.S.C. § 3516, note (emphases added). Here, too, the agency construction contravenes the plain text and must be rejected.

Although the IQA ambiguously extends to press releases, if there were any ambiguity, it would mean only that OMB must explain why it excluded press releases from the guidelines and how that exclusion is consistent with the purpose of the IQA. *See, e.g.*, *Burlington Truck Lines, Inc. v. United States*, 371 US 156, 167 (1962) (setting an agency decision aside as arbitrary and capricious where "[t]here are no findings and no analysis here to justify the choice made, no indication of the basis on which the Commission exercised its expert discretion"). OMB never did this. *See* AOB 49-53. This failure to provide a reasonable explanation distinguishes the exclusion of press releases from the other exclusions referenced by the government (GB 29), such as the exclusion for documents used

in administrative adjudications that the D.C. Circuit upheld in the *Prime Time* case. *See Prime Time*, 599 F.3d at 685 (citing OMB's explanation that there are "'well-established procedural safeguards and rights to address the quality of adjudicatory decisions'" and the OMB guidelines should not provide "'parties to such adjudicative proceedings any additional rights of challenge or appeal'").

The Court should hold DOJ accountable to Congress's clear mandate. Here, DOJ issued final decisions denying review of the accuracy of information in a DOJ press release solely because the information was disseminated in a press release. Those decisions are arbitrary, capricious and contrary to the IQA. On that basis alone, this Court should reverse the district court's decision and hold that DOJ is accountable under the IQA for the accuracy of the information disseminated in DOJ press releases.

B. The DOJ Press Release Contains False Statements About Dr. Harkonen.

The government's final argument is that this Court should affirm on the grounds that DOJ initially offered but then abandoned in its final decisions. Should the Court reach this issue, it should still reverse the district court's decision, because the DOJ press release misrepresented the conduct for which Dr. Harkonen was convicted in two respects.

1. The government argues that the affirmance of the conviction proves the accuracy of the statement in the DOJ press release that Dr. Harkonen "'lied to the

public about the results of a clinical trial'" by "'falsifying test results.'" GB 26 (quoting ER55-56). It does not.

The government quotes a sentence of the opinion stating that witnesses testified in the criminal trial that the InterMune press release "'misrepresented'" the clinical trial results. GB 26. The government ignores, however, the theory of falsity advanced by the prosecution and its witnesses. The prosecutors alleged that Dr. Harkonen drew *false conclusions* from the clinical trial results, but they acknowledged that Dr. Harkonen did *not falsify the clinical trial results themselves*. *See* AOB 12-13 & 55-56. Nothing in this Court's affirmance of the conviction alters that critical fact. On the contrary, every witness who testified that the press release "misrepresented" the results proceeded from the belief that a clinical study lacking statistically significant p-values on its pre-specified endpoints cannot demonstrate anything, and thus it was false for the InterMune press release to say that the clinical trial results "demonstrated" a benefit. *See* Petition for Rehearing En Banc at 8-9, *United States v. Harkonen*, Nos. 11-10209, at 8-9 (filed Mar. 29, 2013) (citing evidence from criminal trial record).

Scientists regularly disagree about the conclusions to be drawn from data. But scientists do not condone the falsification of the results themselves, which obviously corrupts any attempt to analyze or draw conclusions from the data. *See* AOB 13-14 & n.3, 55-56. The DOJ press release falsely reported that Dr.

Harkonen was convicted of the latter, when, in fact, he was convicted only of the former. *Compare* ER0056 (DOJ press release stating that Dr. Harkonen "'lied to the public about the results of a clinical trial'" and "'falsifying test results damages the foundation of the clinical trial process and undermines public trust in our system for drug approval'"), *with* ER0186 (sentencing hearing transcript where the prosecutor admits that "there was no falsification of data here" and Harkonen was prosecuted for allegedly falsifying "the conclusions that could be drawn from the data"). An agency seeking to adhere to the IQA's standard of objectivity in the dissemination of information would easily see the need for a correction to ensure that the public did not misunderstand the actual grounds for the prosecution and conviction. An agency decision that "runs counter to the evidence before the agency" is arbitrary and capricious and must be set aside. *See, e.g.*, *Earth Island Inst. v. U.S. Forest Serv.*, 442 F. 3d 1147, 1157 (9th Circuit 2006), *abrogated on other grounds*, *Winter v. NRDC, Inc.*, 555 U.S. 7 (2008).

2. DOJ also arbitrarily denied the request for correction of the statement that Dr. Harkonen's conduct "divert[ed] precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans." ER56. Again, the government claims that the affirmance of the conviction establishes the accuracy of the DOJ press release. *See* GB 26. Again, the government is mistaken.

That the InterMune press release may have been "capable of influencing the decisions of doctors to prescribe" Actimmune (*United States v. Harkonen*, 510 Fed. App'x 633, 636 (9th Cir. 2013) (mem.), *petition for cert. filed*, 82 U.S.L.W. 3090 (Aug. 5, 2013) (No.13-180)), is irrelevant, for the DOJ press release did not claim that the InterMune press release *could have diverted* resources from the VA. The DOJ press release claimed that the InterMune press release *did in fact divert* resources from the VA. ER0056. But DOJ conceded at sentencing that it had no basis for restitution, and has never produced—either in the criminal proceedings or in the administrative record below—a single VA document showing any loss or harm to the VA resulting from the conclusions in the InterMune press release. *See id.* at ER0292. DOJ's inability to provide *any* evidentiary support for the factual assertion in its press release means that its refusal to correct its false and misleading statement about the effect of Dr. Harkonen's conduct is arbitrary and capricious and contravenes the requirement in the DOJ guidelines that "disseminated information" will be "accurate" and "unbiased" and will be "achieved by using reliable data sources . . . and documenting methods and data sources." Addendum E at 4; *see also, e.g.*, *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1214 (9th Cir. 1998) (setting aside as arbitrary and capricious an agency decision that "contains virtually no references to any material in support of" its conclusions); AOB 59.

CONCLUSION

Because there is judicial review under the APA, and the denials of Harkonen's requests for correction were arbitrary, capricious and contrary to the text and purpose of the IQA, the district court decision must be reversed. The district court should be instructed to remand to DOJ to determine the appropriate corrective action.

Respectfully Submitted,

Dated: October 8, 2013

/s/ Mark E. Haddad

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

Coleen Klasmeier
Kathleen M. Mueller
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
Telephone: (202) 736-8000
Facsimile: (202) 736-8711

Attorneys for Defendant W. Scott Harkonen

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Circuit Rule 32-1, this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 4,854 words, according to the word count function of Microsoft Word, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B) (iii).

Dated: October 8, 2013

/s/ Mark E. Haddad
Mark E. Haddad

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 October 8, 2013.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

Dated: October 8, 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