

FOR PUBLICATION

UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

W. SCOTT HARKONEN, M.D.,  
*Plaintiff-Appellant,*

v.

UNITED STATES DEPARTMENT OF  
JUSTICE; UNITED STATES OFFICE OF  
MANAGEMENT AND BUDGET,  
*Defendants-Appellees.*

No. 13-15197

D.C. No.  
4:12-cv-00629-  
CW

OPINION

Appeal from the United States District Court  
for the Northern District of California  
Claudia Wilken, Senior District Judge, Presiding

Argued and Submitted  
March 9, 2015—San Francisco, California

Filed September 8, 2015

Before: John T. Noonan, William A. Fletcher,  
and Andre M. Davis,\* Circuit Judges.

Opinion by Judge Noonan

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\* The Honorable Andre M. Davis, Senior Circuit Judge for the U.S. Court of Appeals for the Fourth Circuit, sitting by designation.

**SUMMARY\*\***

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**Information Quality Act**

The panel affirmed the district court's Fed. R. Civ. P. 12(b)(6) dismissal of Dr. W. Scott Harkonen's action seeking the correction of statements the United States Department of Justice made about Dr. Harkonen in a 2009 press release.

The Information Quality Act required the Office of Management and Budget to draft guidelines for federal agencies that disseminate information, and required each agency to issue its own agency-specific guidelines to correct disseminated information. The DOJ issued a 2009 press release concerning Dr. Harkonen's wire fraud conviction, and Dr. Harkonen alleged that DOJ's refusal to issue a correction was arbitrary and capricious.

The panel applied *Chevron* analysis, and held that the Office of Management and Budget's and DOJ's exclusion of press releases from the coverage of the Information Quality Act guidelines was not arbitrary and capricious, or manifestly contrary to the Information Quality Act. The panel also held that DOJ's exclusion of press releases applied to the press release of which Dr. Harkonen sought correction.

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\*\* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

**COUNSEL**

Mark E. Haddad (argued), Sidley Austin LLP, San Francisco, California; Coleen Klasmeier and Kathleen M. Mueller, Sidley Austin LLP, Washington, D.C., for Plaintiff-Appellant.

Melissa N. Patterson (argued) and Alisa B. Klein, Appellate Staff Attorneys, Melinda Haag, United States Attorney, and Stuart F. Delery, Assistant Attorney General, United States Department of Justice, Civil Division, Washington, D.C., for Defendants-Appellees.

William G. Kelly, Jr., Multinational Legal Services, PLLC, Driggs, Idaho, for Amicus Curiae Center for Regulatory Effectiveness.

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**OPINION**

NOONAN, Circuit Judge:

In this case we must decide whether the Administrative Procedure Act and the Information Quality Act confer the right to judicial review of a federal agency's refusal to correct allegedly false or misleading information published by the agency in a press release. Dr. W. Scott Harkonen argues that he has the right to obtain, and that the Department of Justice ("DOJ") has an obligation to provide, the correction of statements DOJ made about him in a 2009 press release. Not so, the government counters: Individuals have no such right, even if the information DOJ published was misleading, false, or even defamatory. We conclude that in the circumstances of

this case the government is correct, and therefore we AFFIRM.<sup>1</sup>

I.

A.

The Information Quality Act (“IQA”) was included as a brief note to the Consolidated Appropriations Act of 2001, Pub. L. No. 106-554, 114 Stat. 2763 (2000). The IQA required the Office of Management and Budget (“OMB”) to draft guidelines “that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information . . . disseminated by Federal agencies in fulfillment of the purposes and provisions” of the Paperwork Reduction Act. *Id.* § 515(a). The IQA further required each agency to which the guidelines applied to issue its own agency-specific guidelines and 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.* § 515(b)(2). OMB published its proposed guidelines with a request for public comment on June 28, 2001, an interim set of guidelines on September 28, 2001, and its final guidelines on February 22, 2002.

In formulating its guidelines, OMB attempted to balance several often-competing concerns. OMB recognized that “the fact that the Internet enables agencies to communicate

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<sup>1</sup> Because we find that Harkonen does not have the right to judicial review of DOJ’s refusal to correct information DOJ published about him, we do not reach his contention that some of the information was false.

information quickly and easily to a wide audience . . . increases the potential harm that can result from the dissemination of information that does not meet basic information quality guidelines.” Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication (“Final OMB Guidelines”), 67 Fed. Reg. 8452 (Feb. 22, 2002). OMB also recognized that “information quality comes at a cost.” *Id.* at 8453. Based on this concern, OMB instructed that “agencies should weigh the costs . . . and the benefits of higher information quality” during the formulation of their guidelines. *Id.* After receiving commentary from, among other sources, several federal agencies, OMB revised its definition of “dissemination” to exclude information distributed through press releases from coverage by the guidelines. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (“Interim Final OMB Guidelines”), 66 Fed. Reg. 49,718, 49,723, 49,725. (Sept. 28, 2001). OMB’s final guidelines maintained the exclusion of press releases from the definition of “dissemination.” Final OMB Guidelines, 67 Fed. Reg. at 8460.

DOJ subsequently issued its own agency-specific guidelines on October 4, 2002. *See* Information Quality: DOJ Information Quality Guidelines, available at <http://www.justice.gov/iqpr/information-quality> (updated Dec. 31, 2014). These closely mirrored the OMB final guidelines. *Id.* Relevant here, the scope of the guidelines “does not apply to 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.” *Id.* DOJ also expressly stated that the

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. Nothing in these guidelines affects any otherwise available judicial review of agency action.

*Id.*

## B.

W. Scott Harkonen is a medical doctor who served as Chief Executive Officer and member of the Board of Directors for InterMune, Inc. InterMune developed, marketed, and sold drugs, including a drug called Actimmune. Actimmune was approved by the FDA for the treatment of two rare disorders, chronic granulomatous disease and severe, malignant osteopetrosis. In October 2000, InterMune began a Phase III clinical trial (GIPF-001) to determine whether Actimmune would be effective in treating patients suffering from a different, more common disorder, idiopathic pulmonary fibrosis (“IPF”). Enrollment of 330 patients in the clinical trial was completed in October 2001. On August 27, 2002, Harkonen and other InterMune employees met with staff of the FDA to review the results of an interim analysis of the GIPF-001 study data. The FDA staff told Harkonen that because the study did not meet its primary endpoint—Actimmune had failed to reduce death or disease progression in the entire group of treated subjects—the

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data were insufficient for the FDA to grant approval for the use of Actimmune in the treatment of IPF.

Nonetheless, on August 28, 2002, Harkonen distributed a press release titled “InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF.” The first paragraph of the press release stated that the GIPF-001 study “demonstrate[d] a significant survival benefit in patients with mild to moderate disease randomly assigned to Actimmune versus control treatment.” The first paragraph concluded that “[t]here 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 third paragraph of the press release quoted Harkonen as stating, “Actimmune may extend the lives of patients suffering from [IPF].” The fourth paragraph quoted a study investigator as stating, “Actimmune should be used early in the course of [IPF] in order to realize the most favorable long-term survival benefit.” Not until the sixth paragraph did the press release again address the failure of the study to reach its primary endpoint. Even there, the press release described the failure as demonstrating “a strong positive trend in increased survival in the overall patient population.” The tenth paragraph quoted an InterMune officer as stating “we believe [there] is compelling rationale for consideration of Actimmune for the treatment of patients with [IPF].”

On March 18, 2008, the government indicted Harkonen on one count of wire fraud for making allegedly false statements in the press release, and one count of felony misbranding related to InterMune’s alleged off-label marketing and sale of Actimmune for IPF. Following a jury

trial, Harkonen was convicted on September 29, 2009, of wire fraud but was acquitted on the misbranding count. Harkonen's appeal of his criminal conviction and sentence was affirmed by this court on March 4, 2013. *United States v. Harkonen*, 510 Fed. App'x. 633 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 824 (2013).

On the day the verdict was announced, DOJ issued a press release titled "W. Scott Harkonen, Former Biotech CEO, Convicted of Wire Fraud." The DOJ press release included the two statements at issue in this case:

- "Mr. Harkonen lied to the public about the results of a clinical trial and offered false hope to people stricken with a deadly disease."
- "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 press release was posted on the DOJ website.

On February 11, 2010, during the pendency of his appeal of his conviction and sentence, Harkonen filed a "Request for Correction under Information Quality Guidelines" with DOJ. Harkonen requested that "the government issue a retraction of the statement in the September 29, 2009 press release that [he had] 'falsif[ied] test results,'" publish the retraction, and "remove the original September 29 press release from all official government websites."



On March 15, 2010, DOJ denied Harkonen's request, explaining in a letter to Harkonen's counsel that the request "falls outside the scope of the Department's guidelines," and further stating that "regardless of the guidelines' application, we do not believe a retraction is warranted under the circumstances." Letter from H. Marshall Jarrett, Director of the Executive Office for United States Attorneys, to Harkonen's Counsel. DOJ explained that under DOJ guidelines, "press releases . . . that announce, support or give public notice of information in DOJ" were excluded from coverage of the guidelines. *Id.* Further, DOJ maintained the challenged statement was correct. *Id.* DOJ admitted that while Harkonen did not change the study data, "he nevertheless used it to support his false and misleading conclusions." *Id.*

On April 20, 2010, Harkonen filed a "Request for Reconsideration under Information Quality Guidelines." DOJ rejected this request on July 2, 2010.

On June 8, 2011, Harkonen filed another request for correction with the DOJ, requesting the retraction of the statement in the DOJ press release that Harkonen "divert[ed] precious financial resources from the VA's critical mission of providing healthcare to this nation's military veterans." DOJ denied this request on August 4, 2011, and denied Harkonen's request for reconsideration on October 7, 2011.

On February 8, 2012, Harkonen filed a complaint in the U.S. District Court for the Northern District of California, claiming DOJ's denials of his requests for correction under Information Quality Guidelines was arbitrary and capricious, an abuse of discretion, and contrary to law (Count I), and that the exclusion of press releases from DOJ's and OMB's

Information Quality Guidelines was arbitrary and capricious, an abuse of discretion, and contrary to law (Counts II and III). Harkonen sought declaratory judgments that DOJ's denials of his requests for correction and DOJ's and OMB's exclusion of press releases from their guidelines were arbitrary and capricious, an abuse of discretion, and contrary to law. He sought a permanent injunction requiring DOJ to retract the press release statements about falsifying test results and diverting financial resources from the VA, and to remove the press release from all official government websites.

On December 3, 2012, the district court granted the government's motion to dismiss under Rule 12(b)(6). Harkonen timely appealed.

## II.

We review *de novo* a district court's dismissal for failure to state a claim under Rule 12(b)(6). *ASARCO, LLC v. Union Pac. R.R. Co.*, 765 F.3d 999, 1004 (9th Cir. 2014). In order for Harkonen to prevail, he must be able to assert a cause of action for the violation of a legal right. Absent a statutory provision, an individual can not assert a cause of action against the government for the dissemination of inaccurate, incorrect, or defamatory information. *See Salt Inst. v. Leavitt*, 440 F.3d 156, 158 (4th Cir. 2006) (“[T]here is no general common law right to . . . informational correctness . . .”). It is against this backdrop that we must inquire as to whether Congress intended the IQA to provide individuals a right to judicial review of a federal agency's rejection of a request to obtain correction of information disseminated by the government.

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**A.**

Harkonen argues that the APA provides for judicial review of DOJ's denial of his correction requests under the IQA. The IQA directs 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." Consolidated Appropriations Act of 2001, Pub. L. No. 106-554, 114 Stat. 2763 (2000). The guidelines "apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies." *Id.* The guidelines "shall . . . require that each Federal agency to which the guidelines apply . . . 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.* The IQA further establishes an administrative mechanism that enables OMB to track the "number and nature of complaints received by" each covered agency and "how such complaints were handled by the agency." *Id.*

The focus of the IQA, as stated in Section 515(b), is on the quality of information shared by federal agencies, and on ensuring broad access to information. *Id.* Thus, the IQA creates an administrative system designed to permit federal agencies and OMB to monitor and improve the information used and disseminated by federal agencies. Harkonen argues on appeal that the IQA imposes an obligation on the DOJ to correct information disseminated by the agency, and creates a right under the APA to judicial review of DOJ decisions not to correct this information. (Harkonen denied in the district

court that he was arguing the IQA created a private right of action, claiming instead that his claim arose under the APA). The government argues the IQA does not authorize courts to review the correctness of information disseminated by an agency.

We have no reason in this case to reach the broad question of whether the IQA confers upon a private individual the right to seek judicial review of the correctness of all information published by the government. Here, both OMB and DOJ excluded press releases from the coverage of the IQA guidelines. If these decisions were within the agencies' authority, the review and correction mechanisms required by § 515(b)(2) do not apply to press releases, and neither OMB nor DOJ had an obligation to review for correctness the DOJ press release about Harkonen. Thus, our review must begin with the threshold question of whether OMB and DOJ had the authority to exclude press releases from the coverage of the IQA guidelines.

## B.

### 1.

Whether OMB's and DOJ's decisions to exclude press releases from the coverage of the IQA guidelines were within their authority is analyzed using the familiar two-step framework established by *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). At the first step, if Congress "has directly spoken to the precise question at issue . . . the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842. The issue here is whether the IQA unambiguously expressed

the intent of Congress to include press releases in the guidelines.

The analysis begins with the plain language of the statute. *Resident Councils of Wash. v. Leavitt*, 500 F.3d 1025, 1034 (9th Cir. 2007). The relevant provision of the Act states:

The guidelines under subsection (a) 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).

Consolidated Appropriations Act of 2001, Pub. L. No. 106-554, 114 Stat. 2763 (2000).

The issue here is whether “disseminated” unambiguously applies to information contained in a press release. The IQA does not define “disseminated.” *See generally id.* Nor does the Paperwork Reduction Act, which the IQA amended. *See* 44 U.S.C. §§ 3501–3521 (using, but not defining, “disseminated” in multiple provisions). There is minimal legislative history for the IQA, and the scope of “disseminated” appears not have been discussed at all. FEDERAL ADMINISTRATIVE PROCEDURE SOURCEBOOK 779–80 (William F. Funk et al. eds., 4th ed. 2008). The overall structure of the IQA indicates that Congress had two concerns. First, Congress was concerned that information *shared* by Federal agencies, Sec. 515(b)(1), be of maximal “quality, objectivity, utility, and integrity,” Sec. 515(a). Second, Congress was concerned that access to information possessed by Federal agencies be ensured. Sec. 515(b)(1). Neither of these concerns reflects, or even suggests, an intent by Congress that *all* information released by the government fall under the ambit of the guidelines.

The only other appellate court to examine this issue has found the IQA to have committed the definition of “disseminated” to OMB’s discretion. *Prime Time Int’l Co. v. Vilsack*, 599 F.3d 678, 685 (D.C.C. 2010).

Because Congress was silent on the definition of “dissemination,” and left OMB at least some discretion to determine how broadly “dissemination” applied, we must proceed to the second step of the *Chevron* analysis.

## 2.

If a statute is ambiguous with respect to a specific issue, the second step of the *Chevron* analysis establishes that “the

question for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. If "Congress has left a gap for the administrative agency to fill, we . . . must uphold the administrative regulation unless it is arbitrary, capricious, or manifestly contrary to the statute." *Defenders of Wildlife v. Browner*, 191 F.3d 1159, 1162 (9th Cir. 1999) (internal quotation marks omitted).

Here, Congress left a gap in the IQA for OMB and DOJ to fill regarding the definition of "disseminated." Thus, the highly deferential standard of review at Step Two of the *Chevron* analysis applies. This analysis leads to the conclusion OMB's and DOJ's exclusion of press releases was not arbitrary and capricious, or manifestly contrary to the statute.

Government agencies make extensive use of press releases. In formulating its guidelines, and specifically its definition of the scope of "dissemination," OMB balanced several concerns. OMB recognized that "the fact the Internet enables agencies to communicate information quickly and easily to a wide audience . . . increases the potential harm that can result from the dissemination of information that does not meet basic information quality guidelines." Final OMB Guidelines, 67 Fed. Reg. at 8452. OMB also recognized that "information quality comes at a cost." *Id.* at 8453. After considering comments received from, among others, several federal agencies, OMB revised its definition of "dissemination" to exclude information distributed through press releases. Interim Final OMB Guidelines, 66 Fed. Reg. at 49,725. Given the deference accorded to agency interpretations of ambiguous statutes and the careful consideration OMB, and DOJ, gave to the relevant issues, we

find that excluding press releases from the ambit of the IQA guidelines was “a permissible interpretation of the statute.” *Prime Time Int’l*, 599 F.3d at 685.

3.

Having determined that DOJ’s exclusion of press releases from the ambit of the IQA guidelines was within the discretion accorded to the agency, the only remaining question is whether DOJ’s exclusion of press releases applies to the press release of which Harkonen seeks correction.

An agency’s interpretation of its own regulations is entitled to judicial deference unless that interpretation is “plainly erroneous or inconsistent with the regulation.” *Auer v. Robbins*, 519 U.S. 452, 461 (1997). The scope of DOJ’s guidelines “does not apply to 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.” Information Quality: DOJ Information Quality Guidelines, available at <http://www.justice.gov/iqpr/information-quality> (updated Dec. 31, 2014). DOJ’s determination that the 2009 press release fell within its exclusion of press releases is neither erroneous nor inconsistent with the scope of dissemination as defined in the agency-specific guidelines. Therefore, DOJ’s determination is accorded *Auer* deference.

### III.

Harkonen relies heavily on this court’s decision in *Barber v. Widnall*, 78 F.3d 1419 (9th Cir. 1996). There, a retired Air Force pilot sought correction of his military records under a federal statute providing “the Secretary ‘*may* correct any



military record . . . when the Secretary considers it necessary to correct an error or remove an injustice.” *Id.* at 1423 (quoting 10 U.S.C. § 1552). However, in *Barber* there was no question that the plaintiff’s military records fell within the scope of § 1552; clearly, the plaintiff had the right to invoke the administrative process that had been created to evaluate requests for corrections of military records. The issue in *Barber* was not that the Secretary refused to put the request through the administrative process. In fact, that process had been conducted extensively, resulting in the inability of the Air Force Board for Correction of Military Records to reach consensus and the Secretary’s subsequent denial of the request. *Id.* at 1422. Here, the guidelines clearly exclude press releases from the coverage of the guidelines and hence from application of the administrative review process for correction. Thus, Harkonen’s primary challenge is not to a decision made after a review, but rather is a challenge to OMB’s and DOJ’s interpretation of the IQA that excluded press releases from the definition of disseminated information. Because this challenge fails the test established by *Chevron, U.S.A., Inc.*, Harkonen’s references to *Barber* are inapposite.

**AFFIRMED.**