No. 07-17388

IN THE UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

Americans for Safe Access,

Plaintiff-Appellant

v.

United States Department of Health and Human Services, *et al.*

Defendants-Appellees.

On Appeal from the
United States District Court for the
Northern District of California
District Court No. CV-3:07-01049-WHA

APPELLANT'S OPENING BRIEF

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CORPORATE DISCLOSURE STATEMENT

Plaintiff-Appellant Americans for Safe Access is a California non-profit corporation that does not have a parent corporation.

Dated: April 7, 2008

Joseph D. Elford

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STATEMENT OF JURISDICTION

I. Statutory Basis of Subject Matter Jurisdiction of the District Court

The district court had jurisdiction under 28 U.S.C. § 1331 to hear the federal causes of action brought under the Administrative Procedure Act, 5 U.S.C. § 701 *et seq* ("APA").

II. Basis of Jurisdiction in the Court of Appeals

The district court's judgment is appealable pursuant to 28 U.S.C. § 1291.

III. Timeliness

The district court entered judgment on November 20, 2007. (CR 58; ER 2)[1] Plaintiff/Appellant Americans for Safe Access ("ASA") filed its Notice of Appeal on December 20, 2007 (CR 59; ER 1), which is timely pursuant to Rule 4(a)(1)(B) of the Federal Rules of Appellate Procedure.

IV. Finality

This appeal is from a final judgment that disposed of all the issues before the district court.

STATEMENT OF ISSUES PRESENTED FOR REVIEW

ASA seeks judicial review under the APA of the Department of Health and Human Services' ("HHS") denial of ASA's Petition for correction of inaccurate

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[1] The following abbreviations will be utilized in this brief:
ER = Excerpts of Record;
CR = Clerk's Record.

information disseminated by HHS to the public that marijuana has no accepted medical use. The primary issue on appeal is whether the "Information Quality Act," 44 U.S.C. § 3516, note ("IQA," also referred to as the Data Quality Act) [included in Addendum, which is filed separately herewith], and the Paperwork Reduction Act of 1995, 44 U.S.C. § 3501 *et seq.* ("PRA"), which the IQA supplemented, and the implementing Guidelines of those two Acts, gave ASA a legal right to obtain a timely, substantive response to its IQA Petition, or whether, as the district court held, the IQA is merely hortatory and that Congress intended to allow agencies to obey the IQA's commands, or not, as they choose, free from all judicial review.

STATEMENT OF THE CASE

This is an appeal of the district court's dismissal of ASA's suit under the APA seeking judicial review of HHS' denial, or failure to act upon, ASA's Petition for correction of information under the IQA. In its first order and opinion, the district court granted HHS' motion to dismiss, but also granted ASA leave to amend its complaint: (1) "to raise the issue of whether defendant agencies violated a legal duty by not making a timely and substantive response to plaintiff's petition on its merits," and (2) to add a cause of action that the court should compel agency action "unlawfully withheld or unreasonably delayed" under the APA, 5 U.S.C. §

706(1). (ER 29-30) ASA duly amended its complaint on August 17, 2007. (CR 42; ER 10-23)

Nevertheless, in its second order and opinion, the district court granted HHS' motion to dismiss without leave to amend based on its view that "the IQA and OMB guidelines do not create a duty to perform legally required actions that are judicially reviewable" and the court could not compel agency action that is not legally required. (ER 7-9) Because the court disposed of the case on that basis, it concluded that it need not decide whether HHS had "unlawfully withheld or unreasonably delayed" a substantive final response to ASA's IQA Petition.

STATEMENT OF FACTS

I. Enactment and Relationship of the PRA and IQA

Recognizing serious issues with the way federal agencies manage information, Congress enacted the PRA in 1980 and has amended it several times to ramp up its demands of federal agencies. The IQA, which was enacted in 2000, represents Congress' latest supplementation of the PRA.

When the PRA was originally enacted, it only regulated information collection. Beginning around 1989, however, Congress became concerned with the growing use of the Internet and recognized that it needed to establish policy and controls, and have the Office of Management and Budget ("OMB") issue rules, that would regulate information dissemination as well. For example, Bob

Wise, Chairman of the House Government Information, Justice, and Agriculture Subcommittee, explained in 1989 hearings on the PRA:

> New technology is forcing us to reconsider how the federal government provides information to its citizens. . . . Congress needs to modernize information policy laws.
>
> OMB's policy guidance was issued under the authority of the Paperwork Reduction Act. But that Act contains few specifics on dissemination issues. Congress has not provided any clear direction for OMB's policy making efforts on information dissemination. We should use the paperwork reauthorization to define, *direct*, and limit the information dissemination policy functions of OMB.[2]

Ultimately, in 1995, Congress amended the PRA to address information dissemination and quality. The House and Senate committee reports contained virtually identical explanations of the broad purposes of the new information dissemination provisions:

> [The bill] promotes the theme of improving the quality and use of information to strengthen decisionmaking *and accountability* and to maximize the benefit and utility of information created, collected, maintained, used, shared, *disseminated*, and retained by or for the Federal Government.[3]

To address the quality of information disseminations by the federal government, the 1995 PRA added statements of purpose concerning the need for agencies to

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[2] *Reauthorization of the Paperwork Reduction Act and the Office of Information and Regulatory Affairs: Hearings Before the Legislation and National Security Subcomm. of the House Comm. on Government Operations*, 101st Cong. 23 (1989) (emphasis added) [included in Addendum, which is filed separately herewith].

[3] S. Rep. No. 104-8, at 35 (1995); H. R. Rep. No. 104-37, at 35 (1995) (emphasis added). The House report contains the word "agency" before "decisionmaking."

ensure the quality and utility of information they disseminate to the public, and the need to improve the accountability of OMB and federal agencies for the "policies and guidelines" established under the Act. 44 U.S.C. §§ 3501(2), (4) & (11). Congress mandated that the Director of OMB to promulgate "policies, principles, standards, and guidelines" to apply to agency dissemination of information to the public, 44 U.S.C. § 3504(d)(1); *see also* 44. U.S.C. § 3516, "Rules and regulations."

Three years passed, however, without OMB issuing any meaningful policies or guidelines that would hold federal agencies accountable for the quality and utility of information they disseminate to the public. This prompted the House Committee on Appropriations, in 1998, to include report language urging OMB to proceed to issue, within one year, rules that would ensure and maximize the quality of information disseminated to the public by federal agencies, and to ensure accountability by establishing "administrative mechanisms" by which affected persons could petition for correction of inaccurate agency information. H.R. Rep. No. 105-592, at 49-50 (1998).

After another year passed with no action by OMB, several members of Congress wrote OMB to inquire of its progress in complying with the report

language.[4] A hearing was held before the House OMB Appropriations Subcommittee in March of 2000, and several subcommittee members questioned OMB Director Jacob Lew about OMB's failure to issue rules.[5] In OMB's defense, the Director stated that the 1998 House report only urged OMB to act and did not mandate action, and that he was reluctant to issue the called-for rules because:

> We are concerned about a change of policy that would create rights of action where there aren't consequences. That is a tremendous expansion of potential litigation.
>
> * * *
>
> The problem is -- and this is not unique to this particular proposal -- there are many proposals where when you change the administrative process to create rights. There are also opportunities for review and delay.

Id. at 478. Still dissatisfied with OMB's lack of progress after further communications, the Committee inserted the IQA provision into the House OMB appropriations bill. H.R. Rep. No. 106-756, at 54-55 (2000).

This time, after "reconfirming its instructions," *id.*, an apparent reference to the 1998 report, the Committee made OMB's information dissemination

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[4] OMB responses to selected Congressional letters are in the hearings print, *infra* n. 5, at 512-17.

[5] *Hearings Before the Subcomm. on the Treasury, Postal Service, and General Government Appropriations of the House Comm. on Appropriations on appropriations for fiscal year 2001*, Part 3, "Executive Office of the President and Funds Appropriated to the President," 106th Cong. 477-79, 509-17 & 558 (March 28, 2000) [included in Addendum].

responsibilities mandatory. The IQA appropriations provision required OMB to proceed to issue guidelines within a year "*under sections 3504(d)(1) and 3516 of title 44,* United States Code [the PRA], 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 chapter 35 of title 44*, United States Code, commonly referred to as the Paperwork Reduction Act." 44 U.S.C. § 3516, note (Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515] (Dec. 21, 2000)) (emphasis added) [included in Addendum]. Most significantly for this case, the IQA also mandated OMB in its Guidelines to require 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 issued [by OMB]." *Id.* at § 515(b)(2)(A) (emphasis added).

The House bill covering OMB appropriations later was made part of the Consolidated Appropriations Act for Fiscal Year 2001 that became law on December 21, 2000. *See* H.R. Rep. No. 106-1033, at 396 (2000) (Conf. Rep.) ("Section 515. 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."). None of the Congressional reports on the IQA or the 1995 PRA, or any floor debate, addressed judicial review.[6]

II. OMB and HHS Implementation of the PRA and IQA

After public comment, OMB issued its government-wide Guidelines required by the IQA and PRA, first as interim final guidelines on September 28, 2001, 66 Fed. Reg. 49718-23 (Sept. 28, 2001), and then as supplemental final guidelines on February 22, 2002, 67 Fed. Reg. 8452-58 (Feb. 22, 2002) [included in Addendum]. The OMB Guidelines are written in predominantly mandatory language, while also containing language allowing agencies some discretion and flexibility for meeting their requirements. 66 Fed. Reg. at 49719 1st col.; 67 Fed. Reg. at 8452 3d col. For example, the Guidelines state that "[i]t is crucial that information Federal agencies disseminate meets these guidelines," and that "it is clear that agencies should not disseminate substantive information that does not meet a basic level of quality." *Id.* Furthermore, the OMB Guidelines state that they are "requirements," *id.*; 66 Fed. Reg. at 49720 1st col., 49721 2d col., 49723 1st col., 67 Fed. Reg. at 8456 2d col., 8458 2d col., and 8460 1st col., and

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[6] A report on a 1990 predecessor bill to the 1995 PRA stated that one purpose of a new PRA provision that would have required OMB "to provide uniform guidance interpreting the dissemination requirements . . . is to make it clearer that judicial review of agency dissemination decisions is available under the provisions of section 702 of the Administrative Procedure Act." H.R. Rep. No. 101-927, at 37 (1990).

repeatedly use the terms "shall," "must," "meet," "adhere," "comply," and "responsibilities."

To carry out the petition-correction mandate in the IQA, the OMB Guidelines provide for an administrative correction procedure that allows affected persons to "seek and obtain" correction of information that does not "comply" with the Guidelines. 67 Fed. Reg. at 8459 1st col.; *see* 44 U.S.C. § 3516, note, § 515(b)(2)(A). Meanwhile, the Guidelines provide flexibility to the agencies to correct information "in a manner appropriate to the nature and extent of the complaint." 67 Fed. Reg. at 8459 1st & 2d cols. The OMB supplemental final guidelines revisited the subject of the "complaint-and-correction" process, and added a requirement for an administrative appeal of an initial denial, as well as a requirement that each agency "specify appropriate time limits in which to resolve such requests for reconsideration." 67 Fed. Reg. at 8459 1st col. These Guidelines are binding on all federal agencies under 44 U.S.C. § 3506(a)(1)(B).

After OMB published its final government-wide Guidelines, all other federal agencies, including HHS, proceeded to draft agency-specific guidelines that conformed to the OMB Guidelines. These HHS' Guidelines, which were proposed for public comment and adopted by notice in the *Federal Register*, 67 Fed. Reg. 61344 (Sept. 30, 2002), addressed the timeliness requirement in the OMB Guidelines in the following mandatory terms:

Responsibility of the Agency

. . . . The agency will respond to all requests for correction within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date.

Appeals for Reconsideration

. . . .

. . . . The agency will respond to all requests for appeals within 60 days calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date.

HHS Guidelines, Part I, Sec. E [included in Addendum]. The HHS Guidelines also dealt with another issue involved in this case -- how to handle correction requests that relate to information issues being addressed in a different agency proceeding. The HHS Guidelines state:

Rulemakings and Other Public Comment Procedures

Existing public comment procedures for rule-makings and other formal agency actions already provide well established procedural safeguards that allow affected persons to raise information quality issues *on a timely basis*. Accordingly, agencies will use these existing procedures to respond to information quality complaints that arise in this process.

In cases where the agency disseminates a study, analysis, or other information prior to the final agency action or information product, *requests for correction will be considered prior to the final agency action or information product in those cases where in the agency's judgment issuing an earlier response would not unduly delay issuance*

> *of the agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination if the agency does not resolve the complaint prior to the final agency action or information product.*

Id. (emphasis added).

III. The HHS Information Disseminations Challenged by ASA

Pursuant to the complaint procedures established by OMB and HHS under the IQA, ASA sought the correction of statements disseminated by HHS that marijuana has no effective medical use. Under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, HHS has sole statutory responsibility for determining whether a substance such as marijuana has a "currently accepted use in medical treatment in the United States." 21 U.S.C. § 811(b) (2000). In 2001, in response to a marijuana rescheduling petition filed in 1995, HHS made statements, which it codified in the *Federal Register*, that marijuana has no medical use. 66 Fed. Reg. 20037, 20039 (April 18, 2001). Specifically, HHS declared:

> [T]here have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition.
>
> A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts. At this time, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana.
>
> [A] complete scientific analysis of all the chemical components found in marijuana has not been conducted. . . .
>
> * * *

> [M]arijuana has no currently accepted medical use in treatment in the United States.

66 Fed. Reg. 20037, 20039 (April 18, 2001). HHS admitted that such statements were not raised by, nor were necessary to, the adjudication of the marijuana rescheduling petition then pending before it, *see* 66 Fed. Reg. 20037, 20038 (April 18, 2001), yet it continues to disseminate these statements on its website to this day, *see* ER 15, at ¶9; *see also* Congressional Testimony of Dr. Robert Meyer, FDA's Director of the Office of Drug Evaluation II at the Food and Drug Administration's, Center for Drug Evaluation (April 1, 2004)) [available at http://www.fda.gov/ola/2004/marijuana0401.html]; "Inter-Agency Advisory Regarding Claims that Smoked Marijuana is Medicine," April 20, 2006 [available at http://www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html] ("no sound scientific studies supported medical use of marijuana for treatment in the United States").

IV. ASA's IQA Petition to HHS

ASA was formed as a Bay Area non-profit in 2002 to promote the use of marijuana for medicinal purposes and to combat HHS' false statements. (ER 12-13, at ¶7) As alleged in ASA's Complaint, with specific examples provided, inaccurate information regarding marijuana's lack of medical efficacy on government websites has deterred numerous individuals from discussing the subject with their physicians or seeking relief. (ER 13-15, at ER 15, at ¶8) One

such example involves ASA's Executive Director Steph Sherer ("Sherer"), who suffers from a condition known as torticollis, which causes her to experience inflammation, muscle spasms, and pain throughout her body, and decreased mobility in her neck. (ER 13, at ¶8(a)) Until November of 2001, Sherer did not believe that marijuana had medical use because of statements by the federal government that it did not; however, after Sherer suffered kidney damage from the large amounts of conventional pain killers she was taking, her physician recommended that she try marijuana. *Id.* Sherer heeded her physician's advice and has successfully used marijuana since November of 2001 to reduce her inflammation, muscle spasms, and pain. *Id.* Sherer founded ASA several months later to provide accurate information about the documented medical benefits of marijuana to others. *Id.*

Since its formation in 2002, ASA's membership has grown to more than twenty thousand, including many seriously ill persons who would have benefited from the use of marijuana for medical purposes, but who were deterred from doing so, in part, by HHS' statement that marijuana "has no currently accepted medical use in treatment in the United States." (ER 12-13, at ¶7) To overcome this and the other harmful effects of HHS' false statements, ASA implemented a campaign to educate the public about the recognized medical benefits of marijuana for certain conditions. *Id.* To this end, ASA has spent more than one hundred thousand

dollars and hundreds of hours of staff time producing and disseminating educational materials explaining that scientific studies demonstrate that marijuana is effective in treating symptoms associated with cancer, HIV/AIDS, multiple sclerosis, arthritis, gastrointestinal disorders, and chronic pain. *Id.* ASA is making headway, but the task of combating HHS' false statements continues to drain its limited resources and impedes ASA's other educational efforts. *Id.*

On October 4, 2004, ASA filed with HHS a "Request for Correction" (hereinafter "Petition"), pursuant to the IQA and the OMB and HHS IQA Guidelines, alleging that HHS was continuing to disseminate to the public statements that marijuana lacked any medical efficacy and that such statements were inaccurate and in violation of the information quality standards contained in the IQA and the HHS Guidelines. (ER 32-45) ASA sought to obtain specific corrections to the HHS statements, and cited many specific scientific studies and reviews that demonstrate the medical efficacy of marijuana for certain medical conditions. (ER 32-45) Most notably, ASA cited a 1999 comprehensive review of the medical marijuana issue, commissioned by the White House Office of National Drug Control Policy, and conducted by the Institute of Medicine, which is one of the National Academies that Congress has charged with providing scientific advice to the federal government. (ER 37-42)

Over the next six months, HHS responded to the Petition with evasion and delay. After issuing three conclusory "interim responses" to the ASA Petition stating that it needed more time to respond (ER 46-47, 50 & 51), HHS issued a "response" on April 20, 2005 (ER 52-53). In it, HHS stated that it would not respond to the substance of the ASA Petition because the OMB and HHS Guidelines provide that agencies can address information correction issues through other proceedings, and HHS would evaluate the ASA petition issues in the course of a proceeding being conducted by DEA -- not HHS -- in response to a legally unrelated petition for the rescheduling of marijuana under the Controlled Substances Act. (ER 53) HHS did not state that it would provide ASA with any further response to its Petition, only that it would review the issues in the course of the DEA proceeding. (*See* ER 53)

On May 19, 2005, ASA filed an administrative appeal with HHS. (ER 54-57) The ASA appeal protested that the Guidelines did not allow HHS to postpone deciding ASA's petition until the conclusion of a different proceeding being conducted by another agency. (ER 56-57) ASA also argued that HHS was violating its own IQA Guidelines that require HHS to provide a timely response to petitions and which state that the agency will not defer petition issues to another proceeding where an immediate response to the IQA petition will not delay the other proceeding and there is a reasonable likelihood that harm would result from

delay caused by a deferral. (ER 56-57) ASA alleged that use of the DEA proceeding to address the issues raised by its Petition would likely result in long delays and harm resulting from the continued dissemination by HHS of the erroneous material regarding the medical uses of marijuana. (ER 56-57)

Again, HHS responded with delay. Commencing on July 28, 2005, HHS sent ASA a series of five more interim responses to its appeal over a period of more than eleven months. (ER 58-62) Finally, on July 12, 2006, HHS issued a "response" to the ASA appeal. (ER 65-66) The response again stated that HHS would address the ASA Petition only by providing recommendations to the DEA in connection with a marijuana rescheduling petition that had been pending since October 9, 2002, and that it expected to do so by September 2006. (ER 66) The HHS response did not indicate that HHS would provide any further response to ASA or state when the DEA proceeding would conclude. (*See* ER 66) The HHS response again made no mention of the limitations in its own Guidelines on not deferring petition issues to another proceeding if an earlier response would not delay the other proceeding and there was a reasonable likelihood of harm due to delay from a deferral. (*See* ER 66) This suit followed on February 21, 2007. (CR 1) As of this date, HHS has apparently made no recommendation to DEA and provided no further response to ASA's IQA Petition.

V. The District Court's Two Orders and Opinions

In its first order and opinion tentatively dismissing the ASA suit, the district court held that: (1) the IQA provides only an administrative remedy and does not create any legal right to the correction of information or establish meaningful standards for judicial review, and (2) there was no final HHS action to review because (a) the agency's response to the ASA appeal was not "substantive" and (b) ASA had failed to plead that the IQA grants a legal right to the correction of information.[7] (*See* ER 27-30) The opinion observed that the IQA contains no judicial review provision and only directed agencies to establish "*administrative mechanisms*" (emphasis in original) for obtaining correction of information that does not comply with the OMB Guidelines. (ER 27) The court's opinion placed almost exclusive reliance on three out-of-circuit opinions,[8] which the district court found "persuasive." (ER 28) The court granted ASA leave to amend its complaint to allege that HHS had refused to correct the challenged information "as legally required by the IQA," and to request a declaratory judgment that HHS had

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[7] ASA had alleged, however, that the suit was being brought "to redress the deprivation of rights secured to them under the . . . Data Quality Act, and HHS guidelines implementing the DQA. . . ." (CR 1, at 3 ¶4).

[8] *Salt Inst. v. Thompson*, 345 F.Supp.2d 589 (E.D. Va. 2004), *aff'd sub nom. Salt Inst. v. Leavitt*, 440 F.3d 156 (4th Cir. 2006); *In re Operation of the Missouri River System Litigation* ("*Missouri River*"), 363 F. Supp.2d 1145 (D. Minn. 2004), *vacated in part and aff'd in part on other grounds*, 421 F.3d 618 (8th Cir. 2005), *cert. denied*, 347 U.S. 1097 (2006).

"unlawfully withheld or unreasonably delayed" final agency action under 5 U.S.C. § 706(1). (ER 30-31) ASA duly amended its complaint on August 17, 2007. (CR 42; ER 10-23)

In its second order and opinion, the district court dismissed the ASA suit without leave to amend, holding that "the IQA and OMB guidelines do not create a duty to perform legally required actions that are judicially reviewable." (ER 8) This conclusion was based on its view that "[g]uidelines are by nature advisory" and its agreement, as in its initial opinion, with the holding of the district court decision in *Salt Institute*, that "agency dissemination of advisory information that has no legal impact has consistently been found inadequate to constitute final agency action and is thus unreviewable." (ER 7-8) The district court further concluded that "neither the IQA nor the OMB Guidelines provide judicially manageable standards that would allow meaningful judicial review to determine whether an agency properly exercised its discretion . . . ." (ER 8 [quoting *Salt Institute*]) The court added that the OMB Guidelines give agencies discretion in stating that agencies "are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved," and that such discretion, although it relates solely to the relief to be accorded when a violation of the IQA has been found, renders the agency action not legally required. (ER 8 [quoting 67 Fed. Reg. At 8458]) Neither district court

opinion contains any mention or discussion of the PRA provisions incorporated by reference into the IQA, nor do they examine in any detail the full wording and nature of the OMB and HHS Guidelines.

SUMMARY OF THE ARGUMENT

Congress has long expressed concerns about the handling of information by federal agencies. In 1980, Congress enacted the PRA with the aim of controlling federal information collections from the public. Then, in 1995, Congress expanded the PRA to instruct OMB to develop guidelines to ensure the quality and utility of information that all federal agencies disseminate to the general public. *See* 44 U.S.C. § 3504(d)(1). OMB, however, did not respond to this instruction in a timely fashion, which prompted Congress, through the enactment of the IQA in 2000, to mandate that OMB issue guidelines ensuring and maximizing the quality, objectivity, utility and integrity of information disseminated by federal agencies within one year. *See* 44 U.S.C. § 3516, note. OMB issued its IQA Guidelines one year later, and those Guidelines are binding on all federal agencies under 44 U.S.C. § 3506(a)(1)(B) and as legislative rules.

Despite the legally binding nature of the OMB IQA Guidelines, the district court found that they did not determine legal rights and were merely advisory. In reaching this conclusion, the district court relied almost exclusively on decisions from other Circuits that only superficially addressed the issue and are contrary to

the established precedent of this Court and the United States Supreme Court. (*See* ER 7-8 & 28) The plain language of the PRA and IQA and their implementing Guidelines establishes that they provide a judicially enforceable right to "obtain" a correction, if warranted, under the Guidelines, and that they impose legally binding requirements on all agencies to provide timely substantive responses to IQA petitions. *See* 44 U.S.C. § 3516, note; 67 Fed. Reg. at 8459 1st col.

In holding that ASA has no legal remedy, the district court misapplied the applicable standards of the APA. Final agency action on an administrative petition is expressly subject to judicial review under the APA, unless judicial review has been clearly precluded by Congress or unless the action has been clearly committed to agency discretion. *See* 5 U.S.C. § 701; *Japan Whaling Ass'n v. American Cetacean* Soc'y, 478 U.S. 221, 230 n.4 (1986). HHS' action here is final because it marked the consummation of the petition process and conclusively denied ASA's request for a correction of inaccurate information disseminations. In addition, the OMB IQA Guidelines, which are also "policies, principles, standards, and guidelines" and "rules, regulations, or procedures" under the PRA, 44 U.S.C. §§ 3504(d)(1) and 3516, are binding and judicially enforceable "legislative rules" under well-established criteria because they: affect rights, were promulgated through *Federal Register* notice-and-comment procedures, cite the legislative

authority for their promulgation, and contain mandatory requirements. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 316-17 (1979).

Neither the PRA, the IQA, nor the Guidelines preclude judicial review or commit action to agency discretion. To the contrary, they provide meaningful and manageable standards for judicial review of HHS' denial of ASA's Petition and require a substantive response.

Moreover, the HHS response to the ASA Petition appeal was a final agency "denial" of the Petition -- rather than a "failure to act" -- that was arbitrary and capricious in violating, and declining to address, its own and the OMB Guidelines by not providing a timely substantive response; instead, deferring the issues to another proceeding being conducted by another agency (DEA) with no time constraints. *See Norton v. Southern Utah Wilderness Alliance* ("*SUWA*"), 542 U.S. 55, 63 (2004). Alternatively, final agency action in the form of a substantive final response has been "unlawfully withheld or unreasonably delayed" under the APA. *See* 5 U.S.C. § 706(1).

STANDARD OF REVIEW

The dismissal of a complaint based on federal law requires *de novo* review on appeal, and in its review, the Court construes the facts alleged in the complaint in the light most favorable to the plaintiff. *Equity Lifestyle Properties, Inc. v. County of San Luis Obispo*, 505 F.3d 860, 865 (9th Cir. 2007) (collecting cases).

Questions of statutory interpretation and other questions of law are reviewed *de novo, Skaff v. Meridien N. Am. Beverly Hills, LLC*, 506 F.3d 832, 837 (9th Cir. 2007); *Stoner v. Santa Clara County Office of Educ.*, 502 F.3d 1116, 1120-21 (9th Cir. 2007), as are mixed questions of law and fact in which legal issues predominate, *In re Brawders*, 503 F.3d 856, 866 (9th Cir. 2007). Whether an agency rule is interpretive or legislative is also a question of law reviewed *de novo*. *Erringer v. Thompson*, 371 F.3d 625, 629 (9th Cir. 2004); *Hemp Indus. Ass'n v. U.S. Drug Enforcement Admin.*, 333 F.3d 1082, 1086 (9th Cir. 2003).

ARGUMENT

I. THE IQA AND PRA AND THEIR IMPLEMENTING "GUIDELINES" PROVIDE A LEGAL RIGHT TO A DECISION ON A CORRECTION PETITION, AND HHS' DENIAL OF ASA'S IQA APPEAL IS A FINAL AGENCY ACTION SUBJECT TO JUDICIAL REVIEW UNDER THE APA

HHS violated the IQA and its implementing Guidelines when it failed to provide a substantive response to ASA's IQA Petition. The OMB Guidelines require HHS to provide a timely response to requests for correction of information under the IQA. 67 Fed. Reg. at 8459 1st col. Although the agency may use "existing public comment procedures for rule-makings and other formal agency actions [that] already provide well established procedural safeguards that allow affected persons to raise information quality issues *on a timely basis*," the HHS Guidelines require it to act upon IQA requests promptly, without deferring the

request to another proceeding "where in the agency's judgment issuing an earlier response would not unduly delay issuance of the agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination if the agency does not resolve the complaint prior to the final agency action or information product." (HHS Guidelines, Part I, Sec. E) Thus, HHS has violated both the OMB Guidelines, as well as its own.

Indeed, the district court did not conclude that HHS did not violate the IQA and its Guidelines; instead, it declined to review the agency's actions, finding that the IQA creates no legally binding obligations on HHS to comply with the statute or its Guidelines. This decision was erroneous.

A. Agency Action on an Administrative Petition for Correction of Injurious Information is a Discrete Type of Agency Action Expressly Covered by the APA, and the IQA and PRA Do Not Preclude Judicial Review

Agency denial, or failure to act upon, an IQA petition for correction of information is an "agency action" on an "application or petition" for "relief" or "the equivalent thereof" expressly covered by the APA. 5 U.S.C. §§ 701(b)(2), 551(11) & (13). Such agency actions are subject to APA judicial review if they are "final," 5 U.S.C. § 702, unless the relevant "statutes preclude judicial review" or the agency action is one "committed to agency discretion by law," 5 U.S.C. § 701. Rather than focus on the APA, and pointing to a statute *precluding* judicial review, the district court looked instead to the IQA for a provision *authorizing* judicial

review. However, it is the APA, not the IQA, that provides the right to judicial review sought by ASA.

All petitions for relief are, under the APA, expressly a type of "agency action" subject to judical review, and judicial review of agency action is available under the APA whether or not another statute provides for judicial review. *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990); *Japan Whaling Ass'n v. Am. Cetacean Soc'y*, 478 U.S. 221, 230 n. 4 (1986); *Chrysler Corp. v. Brown*, 441 U.S. 281, 316-17 (1979); *Ashley Creek Phosphate Co.*, 420 F.3d 934, 939 (9th Cir. 2005); *Cetacean Comty. v. Bush*, 386 F.3d 1169, 1176-77 (9th Cir. 2004). Moreover, the term "agency action" is to be interpreted liberally, encompassing virtually every way in which an agency might exercise its authority. *Whitman v. Am. Trucking Ass'ns*, 531 U.S.457, 478 (2001); *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 238 n.7 (1980). Final agency action is presumed to be reviewable, unless there is clear and convincing evidence that Congress intended to preclude judicial review. *Japan Whaling Ass'n v. Am. Cetacean Soc'y*, 478 U.S. 221, 230 n.4 (1986); *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986); *Graham v. Fed. Emergency Mgmt. Agency*, 149 F.3d 997, 1005 (9th Cir. 1998). No such evidence is present here, and the district court erred in presuming that judicial review was unavailable unless the IQA provided for it.

The PRA itself, the basic underlying statute here, shows that Congress understood the necessity of clearly precluding judicial review, if that were, in fact, its intention. For example, the information *collection* provisions of the PRA, which are not at issue here, contain an express provision that precludes judicial review. 44 U.S.C. § 3507(d)(6) ("The decision by the Director to approve or not act upon a collection of information contained in an agency rule shall not be subject to judicial review."). Here, by sharp contrast, the information *dissemination* provisions of the PRA and IQA, which are the provisions involved in this case, do not contain any such preclusion. Under the maxim of statutory construction *inclusio unius est exclusio alterius*, this omission of a provision precluding judicial review in the very same statute means that Congress intended that the usual rule, under which APA judicial review is available, would apply. *See, e.g., Sanford v. Memberworks, Inc.*, 483 F.3d 956, 965 (9th Cir. 2000) ("Where Congress includes particular language in one section of a statute but omits it in another . . . , it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quoting *Keane Corp. v. United States*, 508 U.S. 200, 208 (1993)).

For these reasons, the federal courts, including this Court, have routinely reviewed agency denials of administrative petitions under the APA. *See, e.g., Spencer Enterprises, Inc., v. United States*, 345 F.3d 683, 687-88 (9th Cir. 2003)

(administrative petition for immigrant investor visa); *Keating v. FAA*, 610 F.2d 611, 612 (9th Cir. 1979) (administrative petition to FAA for waiver of "age 60 Rule"); *Zeneca, Inc. v. Shalala*, 213 F.3d 161, 166 n.7 (4th Cir. 2000) (administrative petition for stay of administrative action); *Am. Horse Prot. Ass'n v. Lyng*, 812 F.2d 1, 3-4 (D.C. Cir. 1987) (denial of APA § 553(e) rulemaking petition).

Particularly noteworthy are the closely analagous cases involving APA review of a "request for correction" of military records under 10 U.S.C. § 1552.[9] *Barber v. Widnall*, 78 F.3d 1419, 1420, 1423 (9th Cir. 1996) (request referred to as a "petition"); *Sanford v. United States*, 399 F.2d 693 (9th Cir. 1968); *Mueller v. Winter*, 485 F3d 1191, 1198 (D.C. Cir. 2007); *Dickson v. Sec'y of Defense*, 68 F.3d 1396, 1401 (D.C. Cir. 1995); *see also Miller v. Lehman*, 801 F.2d 492, 496 (D.C. Cir. 1986) ("Both parties to this appeal agree 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."); *Neal v. Sec'y of the Navy*, 639 F.2d 1029, 1036-37 (3d Cir. 1981). The case at hand, which also involves a petition for correction of information, should also be subject to APA review.

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[9] 10 U.S.C. § 1552(a)(1) states: "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. . . ."

B. *The HHS Denial Was a "Final" Agency Action Because the Plain Language of the IQA Establishes a "Right" to a Correction that Complies with the Guidelines, and that Right Was "Determined" by the HHS Denial of the ASA Petition*

Notwithstanding the strong presumption of judicial reviewability under the APA, the district court found that it could not review HHS' response to ASA's IQA petition because even a denial of such petition does not amount to "final agency action" under the APA. (ER 6-8 & 29-30) In essence, the district court found the IQA and its Guidelines to be merely advisory and committed to agency discretion. Contrary to the district court's decision, precedent from the Supreme Court and this Court establish that HHS' decision not to respond substantively to ASA's IQA petition constitutes a "final agency action" that is judicially reviewable under the APA.

In *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997), the Supreme Court stated that, "as a general matter," for an agency action to be considered "final" and reviewable, the action must be one by which "rights or obligations have been determined," or from which "legal consequences will flow . . . ." This Court has followed this formulation of the requirements for finality. *Hale v. Norton*, 476 F.3d 694, 697 (9th Cir. 2007), *cert. denied sub nom. Hale v. Kempthorne* (2007); *Or. Natural Desert Ass'n v U, S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006).

The HHS denial of ASA's Petition was a "determination" of its "right" to "obtain" a correction of information in compliance with the Guidelines

promulgated by HHS and OMB. When OMB declined to issue rules providing an administrative petition mechanism, Congress not only mandated such a mechanism in the IQA, but it also added the word "obtain" to emphasize that affected persons would have a right to a response complying with the new OMB Guidelines. To this end, the IQA states that the petition mechanism in the Guidelines must allow affected persons "to *seek and obtain* correction of information maintained and disseminated by the agency *that does not comply with the guidelines issued [by OMB].*" (Emphasis added) The words "seek and obtain," together with the requirement that the correction "comply" with the OMB Guidelines establish in plain language a right to a correction of information that does not comply with the Guidelines.

Indeed, Congress' inclusion of the ability to "obtain" correction of information where appropriate under the IQA and its Guidelines indicates that Congress expected that IQA petitions would be acted upon by federal agencies and, if that response is arbitrary and capricious under the APA, it would be reviewed by the courts. *Cf. McNary v. Haitian Refugee Ctr.,* Inc., 498 U.S. 479, 496 (1991) (noting that Congress is presumed to legislate with awareness of the presumption of judicial review of administrative action) (citing *Bowen Michigan*

Academy of Family Physicians, 476 U.S. 667, 670 (1986)).[10] But even if there were no specific right in the IQA to "obtain" a correction of information, courts have understood statutory provisions providing for correction of military records through a "request for correction" under 10 U.S.C. § 1552(b), to be judicially reviewable. *See* case cited *supra* at 26. The established authorities on APA review of agency action on petitions in general indicate that, when Congress has provided for an administrative petition mechanism, the courts presume that APA judicial review is available, unless it is clearly established that the agency action is committed to its discretion. *See supra* at 20.

The district court, however, held to the contrary because it did not address the legislative language and, instead, summarily relied upon three out-of-circuit

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[10] The use of the words "seek and obtain," or similar words, in legislation to indicate a right or authority, sometimes expressly referring to a "right" to seek and obtain, is common. *See, e.g.*, 15 U.S.C. § 1681g(a)(2)(C)(ii)(6) (providing for statements to consumers that they "may request and obtain a credit score"); 49 U.S.C. § 47533(3) (referencing the authority of the Secretary of Transportation to "seek and obtain" legal remedies); 26 U.S.C. § 1445(c)(1)(C) (allowing a taxpayer to "seek and obtain" a refund); Pub. L. No. 105-85, Div. A, Title V, § 532(b) (Nov. 18, 1997) 111 Stat. 1739 (requiring applicants to Armed Forces to sign a release allowing the Secretary of Defense to "request and obtain" the applicant's medical records); 28 U.S.C. § 613(c) ("right" of a certifying or disbursing officer of the judicial branch to "apply for and obtain" a decision from the Comptroller General on a question of law); 2 U.S.C. § 1904(c) (giving certifying officers of the Capitol Police "the right to apply for and obtain" a decision from the Comptroller General on a question of law); 44 U.S.C. § 308(c)(2) (giving certifying officers of the GPO the "right to apply for and obtain" a decision from the Comptroller General on a question of law); 2 U.S.C. § 142c) (giving certifying officers of the Library of Congress the "right to apply for and obtain" a decision from the Comptroller General on a question of law).

published decisions construing the IQA in other contexts.[11] In *Salt Institute*, the Fourth Circuit summarily stated that "the IQA . . . does not create any legal right to information or its correctness." 440 F.3d at 159. That statement might be construed to support the conclusion that ASA has no right to obtain a response from HHS to its correction petition, but the actual claims asserted by the Salt Institute in that case are so different from the claims made here than no such conclusion would be proper.

As the opinion of the Fourth Circuit spells out in detail, the plaintiffs in *Salt Institute* objected to certain conclusions that the defendant had drawn about the adverse effects of the use of salt in the diets of Americans, but it did not request that the agency immediately correct them. Instead, it sought copies of the raw data underlying two studies on which the agency relied in order to bolster its case. The problem for plaintiffs was that the agency did not have possession of the studies, and hence the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA") could not be used to compel the agency to provide them. And the Shelby Amendment, which required certain person receiving grants to conduct studies to make the studies available to the public, subject to FOIA, was also not available because the studies

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[11] *Salt Inst. v. Thompson*, 345 F.Supp.2d 589 (E.D. Va. 2004), *aff'd sub nom. Salt Inst. v. Leavitt*, 440 F.3d 156 (4th Cir. 2006); *In re Operation of the Missouri River System Litigation* ("*Missouri River*"), 363 F. Supp.2d 1145 (D. Minn. 2004), *vacated in part and aff'd in part on other grounds*, 421 F.3d 618 (8th Cir. 2005), *cert. denied*, 347 U.S. 1097 (2006).

at issue pre-dated the effective date of that Amendment. Plaintiffs then sought to use the IQA to obtain those studies, and it was in that context that the Fourth Circuit ruled that plaintiffs had no legal right under the IQA (or the Guidelines) to them. That holding is surely correct, but it is just as surely irrelevant to this case, which is not an attempt to use the IQA to avoid limitations under FOIA, but rather is a direct usage of the very request for correction mechanism that the IQA mandates be established by all federal agencies, including HHS.[12]

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[12] The court of appeals in *Salt Institute* dismissed for want of standing, because it concluded that one element of standing is that the plaintiff allege a violation of a legal right, which the plaintiffs there did not establish. The district court in *Salt Institute* also dismissed for lack of standing, on the theory that the plaintiffs could not show a concrete injury in fact from the denial of access to information, a ruling not embraced by the court of appeals. In this case, HHS argued below that ASA lacked standing for similar reasons, but the district court did not accept that argument. Given the fact that it is HHS' refusal to respond to ASA's correction Petition, and the fact that ASA has had to spend more than $100,000 to attempt to correct HHS' erroneous statements about the medical uses of marijuana (ER 12-13, at ¶7), it has surely suffered a concrete injury in fact from HHS' refusal to have standing to maintain this action. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (holding that an organization meets the requisites for Article III standing if it alleges that purportedly illegal action increases the resources the group must expend to further its mission); *Fair Housing of Marin v. Combs*, 285 F.3d 899, 904-05 (9th Cir. 2002) (same); *El Rescate Legal Services, Inc. v. Executive Office of Immigration Review*, 959 F.2d 742, 748 (9th Cir. 1991) ("The allegation that the EOIR's policy frustrates these [the advocacy organization's] goals and requires the organizations to expend resources in representing clients they otherwise would spend in other ways is enough to establish standing.") (citing *Havens*); *see also La. ACORN Fair Hous. v. LeBlanc*, 211 F.3d 298, 305 (5th Cir. 2000) ("an organization could have standing if it had proven a drain on its resources resulting from counteracting the effects of the defendant's actions"). If HHS renews its standing argument in this Court, ASA will respond further in its reply brief.

At the urging of HHS, the district court also cited as further authority the decision from the District of Minnesota in *In re Operation of the Missouri River Sys. Litig.* ("*Missouri River*"), 363 F. Supp.2d 1145 (D. Minn. 2004), *vacated in part and aff'd in part on other grounds*, 421 F.3d 618 (8th Cir. 2005). At the conclusion of a very lengthy decision dealing with the flood control plans for the Missouri and Mississippi Rivers, with multiple parties and many claims, the court reached the IQA claim that was raised by one group of plaintiffs in a section of the opinion called "Collateral Claims." *Id.* at 1168 & 1174-75. It does not appear that the plaintiffs had filed a correction petition, and their claim may have been very similar to that in the *Salt Institute* case: "Specifically, they argue that Federal Defendants failed to comply with their request for 'information and science' regarding the augmented spring pulse and proposed default flow plan scheduled for March 2006." *Id.* at 1174. Unlike *Salt Institute*, the court did not find lack of standing but concluded that the decisions under the IQA were committed to agency discretion, without even mentioning the leading case on the subject, *Citizens to Preserve Overton Park v. Volpe,* 401 U.S. 402 (1971), discussed *infra.* Because its very brief analysis fails to take account of the basic principles governing a defense of "committed to agency discretion by law," this Court should not follow that decision in this case. *See Ip v. United States*, 205 F.3d 1168, 1176 n.13 (9th Cir. 2000) (declining to follow Seventh Circuit because it only stated "a conclusion

without any supporting premises"); *accord Abatie v. Alta Health & Life Ins. Co.*, 458 F.3d 955, 967 (9th Cir. 2006); *Freund v. Nycomed Amersham*, 347 F.3d 752, 765 (9th Cir. 2003); *see also United States v. Gadsen*, 332 F.3d 224, 227 (4th Cir. 2003) (same for Fourth Circuit).

C. *The OMB and HHS Guidelines are Legislative Rules Establishing Legal Requirements for the Quality of Agency-Disseminated Information and the Procedural Requirements for Petitions for Correction*

The district court held, in its second opinion, that it could only compel agency action that is legally required, and that "the IQA and OMB guidelines do not create a duty to perform legally required actions that are judicially reviewable." (ER 8) The district court's conclusion appears to be premised on its assumption that "[g]uidelines are by nature advisory," and that the IQA Guidelines contain discretionary language. (ER 7-8) The OMB and HHS IQA Guidelines, however, are legislative rules that contain legal requirements, and are not merely "advisory."[13]

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[13] Although it is not necessary for the Guidelines to be legislative rules in order to serve as the basis for judicial review, it is clear that these Guidelines are. In *INS v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1997) the Supreme Court stated that judicial review could be based on an agency's "settled policy," as well as rules. *See also Alcarez v. INS*, 384 F.3d 1150, 1162 (9th Cir. 2004) (informal policy memoranda provided basis for judicial review); *Spencer Enterprises v. United States*, 345 F.3d 683, 688, 691 (9th Cir. 2003); *Mendez -Gutierrez v. Ashcroft*, 340 F.3d 865, 868 (9th Cir. 2003); *Steenholdt v. FAA*, 314 F.3d 633, 638, 639 (D.C. Cir. 2003); *Padula v. Webster*, 822 F.2d 97, 100 (D.C. Cir. 1987).

While the IQA requires agencies to promulgate "guidelines," the use of the term guidelines does not mean that such guidelines are discretionary and do not have the force and effect of law. Numerous authorities in the Supreme Court, the Ninth Circuit, and other Circuits have found "guidelines" to be legally binding. *See, e.g., Or. Natural Res. Council Fund v. Goodman*, 505 F.3d 884, 889 (9th Cir. 2007) (National Forest Plan guidelines are binding); *United States v. Hernandez-Castro*, 473 F.3d 1004, 1006-07 (9th Cir. 2007) (portions of Federal Sentencing Guidelines are still legally binding); *Pacific Coast Fed'n of Fishermen Ass'n v. Nat'l Marine Fisheries Serv*, 265 F.3d 1028, 1031-32 (9th Cir. 2001) (National Forest Plan standards and guidelines were binding); *Wallace v. Christensen*, 802 F.2d 1539, 1551-52 (9th Cir. 1986) (en banc) (Parole Commission "guidelines" were "regulations"); *see also Sussman v. U.S. Marshals Serv.*, 494 F.3d 1106, 1120 n. 8 (D.C. Cir. 2007) (OMB "guidelines and regulations" were binding if promulgated with notice and comment); *BFI Waste Sys. of N. Am. v. FAA*, 293 F.3d 527, 529 (D.C. Cir. 2002) (FAA Order in its Handbook referred to as binding guidelines). For more than fifteen years, the Supreme Court held that the Federal Sentencing Guidelines were binding, until it decided, in *United States v. Booker*, 543 U.S. 220, 233-34 (2005), that they raised Constitutional issues, which is not the case here.

Moreover, the term "guidelines" is not by any means the sole term used in the IQA and PRA. The IQA was enacted as a supplement to the PRA, and expressly incorporates sections 3504(d)(1) and 3516 of the PRA, as well as the rest of the PRA. 44 U.S.C. § 3516, note. Thus, OMB is required to issue IQA Guidelines "under" those PRA sections and "in fulfillment of the purposes and provisions of [the PRA]." *Id.* Section 3504(d)(1) mandates that OMB "develop and oversee the implementation of policies, principles, standards, and guidelines" for every kind of public information disseminated by federal agencies. And Section 3516 requires OMB, under the heading of "Rules and regulations," to promulgate "rules, regulations, or procedures" necessary to exercise its authority under the PRA. *Cf. Ram v. INS*, 243 F.3d 510, 514 & n.3 (9th Cir. 2001) (section heading in a statute may be used to interpret section's meaning). Significantly, the PRA, as incorporated into the IQA, establishes that the OMB "guidelines" are legally binding on HHS. *See* 44 U.S.C. § 3506(a)(1)(B) (agencies are responsible for "complying with . . . policies established by the Director [of OMB]"). Therefore, the term "guidelines" in the IQA must be considered shorthand for the "rules, regulations, or procedures" or "policies, principles, standards, and guidelines" required under the PRA.[14]

[14] Many statutes combine the term "guidelines" with other terms, such as "regulations" or "standards," as in this case. 16 U.S.C. § 1604(g) (Secretary of Agriculture is required to promulgate National Forest Plan "regulations . . . that set

Decisions by the Supreme Court and this Circuit provide a number of criteria for deciding whether a rule is a binding "legislative" or "substantive" rule that has the force and effect of law[15]:

- Does the rule affect the rights of third parties or is it intended simply for internal guidance?
- Does the language of the rule indicate that it is intended to be binding?
- Was the rule promulgated pursuant to a specific statutory grant of authority, and did the agency invoke that authority?
- Was the rule published in the *Federal Register* for public notice and comment?

See Chrysler Corp. v. Brown, 441 U.S. 281, 301-03 (1979); *Erringer v. Thompson*, 371 F.3d 625, 630-31 (9th Cir. 2004); *Moore v. Apfel*, 216 F.3d 864, 868-69 (9th

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. . . out guidelines and standards"); 18 U.S.C. § 4303(a)(1) (repealed effective 2005) (Parole Commission was required to promulgate "rules and regulations establishing guidelines"); 5 U.S.C. § 552a(v)(1) (requiring OMB to develop and prescribe Computer Matching and Privacy Act "guidelines and regulations"); 5 U.S.C. § 552(a)(4)(A)(i) (agencies required to promulgate regulations and guidelines conforming to guidelines promulgated by OMB); 33 U.S.C. § 1314(b) (EPA required to publish Clean Water Act "regulations, providing guidelines for effluent limitations").

[15] The term "guidelines" is not a term in the APA, and the Guidelines here come within the APA definition of a "rule" as an "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. . . ." 5 U.S.C. §§ 701(b)(2) & 551(4).

Cir. 2000); *Lowry v. Barnhart*, 329 F.3d 1019, 1022 (9th Cir. 2003); *United States v. Fifty-Three (53) Eclectus Parrots*, 685 F.2d 1131, 1136 (9th Cir.1982).

The IQA Guidelines meet all these criteria for legislative rules. They affect the rights of third parties, namely, those who are seeking corrective action by the agency, and they are binding on those third parties, as well as the agency itself, as indicated both by their mandatory wording, *see supra* at 8-9, and by reason of 44 U.S.C. § 3506(a)(1)(B) (agencies are responsible for "complying with . . . policies established by the Director [of OMB]"). The "Guidelines" state that they are promulgated specifically pursuant to the IQA authority, and they went through public notice and comment procedures before being published in the *Federal Register*. Thus, for all these reasons, Congress made the Guidelines mandatory, and under the established authorities compliance with them is subject to judicial review.

II. BECAUSE THE IQA AND ITS GUIDELINES PROVIDE MEANINGFUL AND MANAGEABLE STANDARDS FOR JUDICIAL REVIEW, AGENCY RESPONSE TO CORRECTION PETITIONS ARE NOT COMMITTED TO AGENCY DISCRETION BY LAW UNDER THE APA

Nor, as the district court summarily stated, was the denial of ASA's IQA Petition an action that Congress committed to agency discretion by law. *Cf.* 5 U.S.C. § 701(a)(2). There is a strong presumption in favor of judicial review, and Congressional intent to preclude judicial review under either § 701(a)(1) or (2),

must be shown by clear and convincing evidence. *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670-74 (1986). Preclusion from judicial review of agency actions committed to agency discretion by law applies only in those "rare instances" where a statute is drawn "in such broad terms that in a given case there is no law to apply." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410-13 (1971); *City of Los Angeles v. U.S. Dept. of Commerce*, 307 F.3d 859, 869 n. 6 (9th Cir. 2002); *Helgeson v. Bureau of Indian Affairs*, 153 F.3d 1000, 1003 (9th Cir. 1998); *Beno v. Shalala*, 30 F.3d 1057, 1066-67 (9th Cir. 1994).

Under the APA, agency action can be reviewed for "abuse of discretion," even if the statute or implementing rules provide substantial discretion, so long as there are "meaningful" or "manageable" standards available to judge how an agency should exercise its discretion and the action has not been committed to agency discretion absolutely. Such standards can be applied by the court even though the statute itself appears at the outset to give the agency unfettered discretion, if standards to judge the agency's exercise of discretion can be found in agency rules, policy, or practice. *INS v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1997); *Newman v. Apfel*, 223 F.3d 937, 942-43 (9th Cir. 2000); *Socop-Gonzales v. INS*, 208 F.3d 838, 843-44 (9th Cir. 2000); *Greater Los Angeles Council on Deafness, Inc. v. Baldridge*, 827 F.2d 1353, 1361 (9th Cir. 1987).

The district court erred in taking the position that some limited discretion in the OMB Guidelines as to remedy -- requiring an agency "to undertake only the degree of correction that it considers appropriate for the nature and timeliness of the information involved" -- made all decisions under the IQA "committed to agency discretion by law." (*See* ER 7-8) That ruling is incorrect for several reasons. *First*, the district court's reliance on the District of Columbia Circuit's decision in *Steenholdt v. FAA*, 314 F.3d 633 (D.C. Cir. 2003), as holding that "similar language" renders an agency action not legally required is misplaced. (*See* ER 8) The language addressed in *Steenholdt* is quite different from the IQA and the OMS and HHS Guidelines because both the statute and the implementing rules *in Steenholdt* provided "unfettered" discretion to take action "for any reason the Administrator considers appropriate." 314 F.3d at 638. Such complete abdication of discretion to the administrative agency is not present here.

Second, and most relevant for this case, the portion of the HHS Guidelines relied upon by the district court provides an agency with discretion only after a dissemination has been found to violate the IQA and the Guidelines. (ER 8 [citing 67 Fed. Reg. at 8458]) Here, the proper remedy to correct an erroneous information dissemination is not yet at issue, since HHS has failed to provide *any* substantive response to ASA's IQA Petition. It is one thing to provide an agency with substantial (albeit not unlimited) discretion at the remedy stage; it is quite

another to say that it is free to disregard the entire IQA that Congress specifically added to deal with problems precisely like those involved in this case.

Both the IQA itself and the implementing Guidelines provide meaningful and manageable standards to review the HHS final action for abuse of discretion. The statute contains the standards of "objectivity" and "utility," and requires "correction" of information for "accuracy." 44 U.S.C. § 3516, note. The OMB (and HHS) Guidelines expand upon these standards to define "objectivity," in part, as requiring presentation of information "in an accurate, clear complete, and unbiased manner . . . within a proper context" and with identification of the sources and supporting data and methods. 67 Fed. Reg. at 8459 3d col. & 8460 1st col.; HHS Guidelines, Part I, D, 2, c [included in Addendum]. Furthermore, the OMB Guidelines contain standards to ensure that the agency's action on a petition for correction is timely, requiring that agencies "specify appropriate time periods" for initial action on petitions, and that they "specify appropriate time periods in which to resolve" appeal of an initial denial. 67 Fed. Reg. at 8459 1st col. And the HHS Guidelines expand upon this requirement to specify the conditions under which the agency will provide a timely response to a petition in cases where the information issues are under consideration in another proceeding. HHS Guidelines, Part I, Sec. E. These are manageable standards, and they at least require HHS to provide a substantive response to a correction petition that is in compliance with the OMB

and HHS Guidelines, such as the one filed by ASA. The HHS Guidelines do not give HHS absolute discretion to defer consideration of ASA's petition to await the outcome of another proceeding being conducted by another agency, as the district court apparently concluded. Instead, they provide clear standards to be applied in deciding whether a deferral is appropriate.

Numerous decisions from the Supreme Court and this Court and others demonstrate how narrow the committed to agency discretion exception is and how little in the way of statutory or regulatory guidance is considered sufficient to provide meaningful or manageable standards for judging whether agency action is arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. In the seminal case of *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971), the Supreme Court held that the Secretary of Transportation's decision to authorize construction of an expressway through a public park did not fall within the "committed to agency discretion" exception because that exception is "very narrow" and the highway statute provided sufficiently meaningful standards in stating that the Secretary of Transportation shall not approve a project that requires the use of public parkland unless there was no "feasible and prudent" alternative. *Id.* at 411. The IQA's requirements of and "objectivity and "utility," which are defined in the OMB and HHS Guidelines, are far more manageable. *See also Newman v. Apfel*, 223 F.3d 937, 943 (9th Cir. 2000) ("reliable" and "currently

available" information were meaningful standards); *Socop-Gonzales v. Ashcroft*, 208 F.3d 838, 843-44 (9th Cir. 2000) ("in exceptional situations" was meaningful standard); *Keating v. FAA.*, 610 F.2d 611, 612 (9th Cir. 1979) ("may" grant an exemption if "in the public interest" provided a meaningful standard); *Dickson v. Sec'y of Defense*, 68 F.3d 1396, 1401-04 (D.C. Cir. 1995) (10 U.S.C. § 1552, providing that the Secretary "may excuse a failure to file [a request for correction]" when "in the interests of justice" was meaningful standard).

Rather than abide the reasoning of these cases, the district court relied upon the district court decisions in *Missouri River* and *Salt Institute* for its conclusion that agency actions on IQA petitions for correction are committed to agency discretion by law. These decisions, however, are contrary to Supreme Court and Ninth Circuit precedent and are not analogous to this case. The *Missouri River* case determined that *the IQA* did not provide meaningful or manageable standards for review, but the court did not examine the applicable precedents cited and discussed above (or any other for that matter), and did not inquire whether the standards could be found in agency rules. The district court decision in *Salt Institute* simply noted that there was some limited discretionary language in the IQA Guidelines, and on that basis found that the Guidelines could not provide meaningful and manageable standards. This was contrary to both Supreme Court and Ninth Circuit precedent, which hold that even substantial

discretion does not prevent a court from conducting APA review for "abuse of discretion."

III. HHS HAS VIOLATED THE LEGAL REQUIREMENTS OF THE GUIDELINES AND THE IQA AND ABUSED ITS DISCRETION BY NOT PROVIDING A SUBSTANTIVE FINAL RESPONSE

A. HHS' Denial of ASA's IQA Petition Was a "Final Agency Action" That Is Judicially Reviewable

The APA definition of "agency action," 5 U.S.C. § 551(13), distinguishes between a "denial" and a "failure to act." The district court construed the HHS response to ASA's petition appeal as a "failure to act," therefore finding that there had not yet been "final" agency action. The district court erred in this regard.

The HHS response to the ASA appeal was both the consummation of the agency's petition review process and a "denial" of the petition, rather than a failure to act. A "failure to act," as opposed to a "denial," means that the agency has not acted at all, not that it has furnished an inadequate response that was unlawful or an abuse of discretion. In *Norton v. Southern Utah Wilderness Alliance* ("*SUWA*"), 542 U.S. 55, 63 (2004), the Supreme Court stated: "A 'failure to act' is not the same thing as a 'denial.' The latter is the agency's act of saying no to a request; the former is simply the omission of an action without formally rejecting a request . . . ." *See also United States v. Bean*, 537 U.S. 71, 76 n.4 (2002) (the APA distinguishes between denial and failure to act, and different terms imply different meanings); *Center for Biological Diversity v. Brennan*, 2007 WL

2408901 at *13 (N.D. Cal. Aug. 21, 2007) (a "failure to act" under the APA is a "complete failure of an agency to act at all").

The district court appears to have missed this distinction, because it stated in its opinion that "[t]he agency has not yet passed on the merits of the information-correction petition, so the agency process has not yet run its course." (ER). This, however, is not how a "denial" versus a "failure to act" is determined. HHS did not fail to act, and it indicated its action was final because it did not indicate that it contemplated any further response to ASA. HHS stated that any further evaluation and recommendation would be furnished to DEA, not to ASA, and did not give any definite time for a further response to ASA, whether by HHS or DEA. ER 66; *see Sierra Club v. U.S. Nuclear Regulatory Comm'n*, 862 F2d 222, 225 (9th Cir. 1988) (the fact that the NRC expressly maintained its authority to review an Appeals Board decision as a full Commission did not destroy the finality of the Appeals Board decision); *Am. Petroleum Inst. v. U.S. EPA*, 906 F.2d 729, 739-40 (D.C. Cir. 1990) (possibility of future agency action could not foreclose review of a definitive action; otherwise "review could be deferred indefinitely"). Therefore, HHS acted in a manner that was "arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law" by giving a final response that was in violation of its own Guidelines and the OMB Guidelines concerning timeliness and deferral of issues to other proceedings. HHS' denial of ASA's IQA Petition causes

the precise harm that the IQA was designed to prevent – a failure to timely correct inaccurate information disseminated by federal agencies.

Furthermore, agency action is arbitrary and capricious under the APA if it fails to provide a reasoned explanation that includes a discussion of the relevant factors. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 508 F.3d 508, 526 (9th Cir. 2007); *Pacific Coast Fed'n of Fishermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 265 F.3d 1028, 1034 (9th Cir. 2001) ("Essentially, we must ask whether the agency considered the relevant factors and articulated a rational connection between the facts found and the choice made."). The HHS final response to ASA's IQA appeal did not address at all, or comply with, the "relevant factors" in HHS' own Guideline provisions that limit when it can defer issues to another proceeding. *Cf.* HHS Guidelines, Part I, Sec. E. The HHS denial is therefore arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law under the APA.

B. Alternatively, HHS has Unlawfully Withheld and Unreasonably Delayed its Required Substantive Response

If, on the other hand, HHS' response to ASA's Petition is construed as something short of a final agency action, then the district court erred in failing to compel HHS to respond substantively to ASA's Petition. The APA requires a reviewing court to "compel agency action unlawfully withheld or unreasonably

delayed." 5 U.S.C. § 706(1).[16] "[A] claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take.*" *Norton v. Southern Utah Wilderness Alliance* ("*SUWA*"), 542 U.S. 55, 64 (2004) (emphasis in original); *Center for Biological Diversity v. Veneman*, 394 F.3d 1108, 1111 (9th Cir. 2005). As demonstrated above, a decision on a petition for relief is a discrete type of agency action under the APA definitions, and the IQA, PRA, and the HHS and OMB Guidelines require HHS to take action on such petitions and correct information that does not comply with those Guidelines.

The courts, including this Court, distinguish between required agency actions that are "unlawfully withheld" and those that are "unreasonably delayed." Agency action is "unlawfully withheld" when a statute specifies a time within which the agency must act. In such case, the court has no discretion, and must compel the agency to act once it has exceeded the statutory timeframe. *Biodiversity Legal Fdn. v. Badgley*, 309 F.3d 1166, 1177 n.11 (9th Cir. 2002); *Forest Guardians v. Babbitt*, 164 F.3d 1261, 1271-72 (10th Cir. 1998).

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[16] The requirement for an agency to act within a reasonable time also appears in 5 U.S.C. § 555(b), which states: "With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it."

Here, however, there does not appear to be a statutory timeframe for agency action. In such cases, the Ninth Circuit determines whether agency action has been unreasonably delayed by considering the "*TRAC*" factors developed by the District of Columbia Circuit in *Telecommunications Research & Action Ctr. v. FCC* ("*TRAC*"), 750 F.2d 70, 79-80 (D.C. Cir. 1984). The Ninth Circuit has adopted the TRAC factors. *Brower v. Evans*, 257 F.3d 1058, 1068-69 (9th Cir. 2001); *Independence Mining Co. v. Babbitt*, 105 F.3d 502, 507 (9th Cir. 1997). These nonexhaustive *TRAC* factors, as summarized in *Brower* and *Independence Mining*, are as follows:

> (1) [T]he time agencies take to make decisions must be governed by a "rule of reason"[;] (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason[;] (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake[;] (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority[;] (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed."

Although Congress did not provide an indication of the speed with which it expected the agency to act on an IQA petition, it did command OMB to issue its Guidelines, and those Guidelines contain a timeliness requirement that makes 60 days the norm for acting on both initial petitions and appeals. The HHS Guidelines

expand upon this timeliness requirement, and HHS has violated its own Guideline provisions on timeliness and deferrals.

The facts in the administrative record demonstrate unreasonable delay as a matter of a "rule of reason" and by applying the *TRAC* factors. It has been well over three years since ASA filed its Petition with HHS on October 4, 2004, and the OMB and HHS Guidelines contemplate a final substantive response within a matter of months rather than years. *See* HHS Guidelines, Part I, Sec. E. In addition, HHS stated in its final, nonsubstantive, response and denial of July 12, 2006, that it expected to complete its review of the issue and provide a recommendation to DEA by September 2006. To ASA's knowledge, HHS still has not done this.[17]

Such delay is particularly unreasonable when, under the *TRAC* factors, "human health and welfare are at stake." *See Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1157-59 (D.C. Cir. 1983) (OSHA delay of three years in regulating toxic chemical was unreasonable, and agency order to issue a

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[17] It bears noting that, when the White House Office of National Drug Control Policy requested the Institute of Medicine ("IOM") to review the issue, the IOM panel – comprised of experts who had many other time-consuming professional obligations – completed its comprehensive review in less than 19 months, including public meetings. *See Marijuana and Medicine: Assessing the Science Base* (published March 17, 1999). Unlike the IOM, HHS is not starting from scratch and has had the advantage of having the IOM Report available to it, as well as its prior analysis in connection with the earlier marijuana rescheduling petition and the ASA Petition.

proposed rule within 30 days); *Sandoz, Inc. v. Leavitt*, 427 F.Supp.2d 29, 40-41 & n.13 (D.D.C. 2006) (HHS delay of nearly 1000 days in acting on a new drug application was "egregious";" "The plaintiff is entitled to an end to this 'marathon round' of 'keep-away and soon.'") (quoting *In re American Rivers and Idaho Rivers United,* 372 F.3d 413, 420 (D.C. Cir. 2004)); *Raymond Proffitt Found. v. U.S. EPA*, 930 F.Supp.1088, 1102-04 (E.D. Pa. 1996) (nineteen month delay by EPA in publishing proposed water quality standard was unreasonable); *see also Ctr. for Biological Diversity v. Abraham*, 218 F.Supp.2d 1143, 1163-64 (N.D. Cal. 2002) ("This order finds it significant that DOE has now missed two sets of deadlines—the statutory deadlines, and the ones it set for itself.").

The administrative record does not indicate that expediting the delayed action here would have any effect "on agency activities of a higher or competing priority." *Cf. TRAC*, 750 F.2d at 80. To the contrary, HHS told ASA that it expected to complete its review more than eighteen months ago. (ER 66)

Meanwhile, people are being harmed. The "nature and extent of the interests prejudiced by delay" by HHS in failing to respond substantively to ASA's Petition are both ASA's interest in carrying out its mission and conserving its resources for that mission, and the interests of seriously ill patients who might benefit from accurate information, as indicated by the examples of affected

individuals in the ASA complaint and the publicity that HHS position has received. These are important interests being prejudiced by the delay.

Furthermore, although the Court "need not find any impropriety lurking behind agency lassitude" in order to hold that agency action is unreasonably delayed," *cf. TRAC*, 750 F.2d at 80, the complete failure of HHS to provide any reasonable explanation for its extensive delays and ignoring of the standards in its own Guidelines would support an inference of bad faith, and bad faith is a factor that courts may consider determinative in finding a delay unreasonable. *See Independence Mining Co. v. Babbitt*, 105 F.3d 502, 510 (9th Cir. 1997) ("'If the court determines that the agency [has] delay[ed] in bad faith, it should conclude that the delay is unreasonable.'"); *Chevron, U.S.A. Prod. Co. v. O'Leary*, 958 F.Supp. 1485, 1498 (E.D. Cal. 1997). Even while HHS insisted to ASA that it needed to conduct a comprehensive review of the medical efficacy issue, it nevertheless proceeded to issue a media advisory reaffirming its determination that "marijuana . . . has no currently accepted medical use in treatment in the United States. . . ." *See* "Inter-Agency Advisory Regarding Claims that Smoked Marijuana is Medicine," April 20, 2006 [available at http://www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html]. HHS has no credible explanation for its failure to provide ASA a substantive answer. Unless

the judiciary intervenes, HHS will continue to thumb its nose at the requirements of the IQA and will delay a response to ASA indefinitely.

RELIEF SOUGHT

The HHS response to the ASA Petition appeal was a denial of the Petition and was final agency action. It determined legal rights and was the consummation of the agency's petition process. There are meaningful and manageable standards in both the IQA and the Guidelines to guide judicial review of the current final response and any future substantive final response. Therefore, this Court should direct the district court to issue a declaratory judgment that the HHS denial was arbitrary and capricious for not being substantive and timely, in violation of its Guidelines, and it should order the district court (a) to direct the agency to issue a substantive response within 60 days, and (b) to review that response under the arbitrary and capricious standard for compliance with the Guidelines. Alternatively, if the current HHS response is not viewed as final agency action because it is nonsubstantive, the district court should be ordered (a) to direct the agency to issue a final substantive response within 60 days, and (b) to review that response under the arbitrary and capricious standard.

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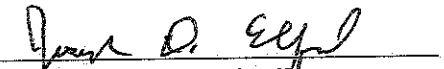
CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed and the case remanded for further proceedings on the merits of ASA's correction petition.

DATED: April 7, 2008

Respectfully submitted,



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CERTIFICATION REGARDING BRIEF FORM

I, Joseph D. Elford, certify pursuant to Fed.R.App.P. 32(a)(7)(B) and Ninth Circuit Rule 32-1, that the attached brief is proportionately spaced, has a typeface of 14 points, and contains 12,841 words.

Dated: April 7, 2008

Joseph D. Elford

STATEMENT OF RELATED CASES

I am aware of no related cases pending in this Court.

Dated: April 7, 2008

Joseph D. Elford

CERTIFICATE OF SERVICE

I hereby certify that two copies of the foregoing were served, via second day Federal Express mail, upon Alisa Klein, Mark Stern, Department of Justice, Civil Division, Appellate Staff, Room 7235, 950 Pennsylvania Ave., N.W., Washington, D.C. 20004, this seventh day of April, 2008.

I hereby certify that an original and fifteen copies of the foregoing were served, via Federal Express ground transportation, upon the Clerk, U.S. Court of Appeals for the Ninth Circuit, 95 Seventh St., San francisco, CA 94103, this seventh day of April, 2008.

Joseph D. Elford