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 REPLY BRIEF

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Regulations

SUMMARY OF REPLY

In asking this Court to affirm the decision below, the Department of Health and Human Services ("HHS") makes three arguments that are repeated in various forms at various places in its brief. *First*, it contends that, although plaintiff relies exclusively on the Information Quality Act ("IQA") and Administrative Procedure Act ("APA") in asking this Court to order HHS to correct erroneous information it disseminates to the public, this case is really a premature effort, brought in the wrong forum, against the wrong agency, seeking to obtain a ruling under the Controlled Substances Act ("CSA") that marijuana should be rescheduled because it has accepted medical uses. *Second*, HHS contends that, even if the CSA does not provide the exclusive remedy for plaintiff's claims, there is no judicial review for claims that an agency has violated the IQA and its Guidelines, or at least not in this case, which is the ground on which the district court appears to have dismissed the case. *Third*, HHS argues that, although it has not yet provided a substantive reply to ASA's IQA Petition that was filed in October 2004, there is no basis for a court to order HHS to do so, even though OMB's and HHS's own Guidelines contemplate that a response will be given promptly, unless it makes the findings called for by its own Guidelines on use of other proceedings, which it has not done. The basic flaws in those arguments are summarized immediately below and spelled out in further detail in the remainder of this reply.

The main flaw in the CSA-exclusivity argument is that the relief sought under the CSA (rescheduling) and that under the IQA (correction of erroneously disseminated factual information) are not the same. Only DEA can grant the former and only HHS can grant the latter. Furthermore, although HHS contends that ASA is objecting only to statements made by HHS in 2001, ASA's IQA complaint relies heavily on statements disseminated after the IQA became effective and that were made outside any DEA proceeding. Finally, the petition to reschedule has been pending since 2002, with no final decision in sight, let alone in the time frame envisioned in HHS's IQA timeliness guidelines. This renders any potential remedy under the CSA inadequate in light of the IQA's timeliness requirement.

HHS also contends that, even if there were no CSA rescheduling petition pending, and even if the corrections sought by ASA had no relation to any other proceeding under any other law, there would be no judicial review of the failure of HHS to provide a substantive response to ASA's correction Petition. Like the district court, HHS sees the IQA as being limited to hortatory directives, with agencies free to respond to correction petitions or not, subject only to the possibility of OMB disapproval. But HHS has it backwards, as our opening brief makes clear: the APA sets up a presumption of judicial review, and HHS has offered nothing to show that Congress intended to preclude the courts from

reviewing even the most egregious failures to comply with the duty to respond to IQA correction requests of the kind filed by ASA. Moreover, none of the cases cited by HHS for the proposition that there is no judicial review of reports, press releases, etc., involved the IQA, which was a response to the inability of groups like ASA to force agencies to address, and correct claims that they have disseminated information that is not correct.

Third, ASA argues that, to the extent that HHS has not responded on the merits to its correction petition, it should be required to do so. In reply, HHS says that its failure to respond substantively for almost four years is not unreasonable, notwithstanding the timeliness requirements of the IQA Guidelines. In making this argument, HHS conveniently overlooks the fact that it has admitted that it has already done all the work in the form of its secret June 2006 response to DEA on the rescheduling petition, but has chosen not to make its response public. At the very least, ASA is entitled to have that response made public as HHS's answer to its correction Petition, and it is clear that HHS will not do so, absent a court order directing it to respond and making the response subject to review for compliance with the IQA quality standards. If that is not an "unreasonable" delay, without regard to the four years that the request has been pending, it is difficult to know what one would be.

I. THE CONTROLLED SUBSTANCES ACT DOES NOT PROVIDE AN "ADEQUATE" ALTERNATIVE REMEDY, AS REQUIRED IN ORDER TO PRECLUDE APA REVIEW

In enacting the information dissemination provisions of the Paperwork Reduction Act and the IQA, Congress recognized that inaccurate agency information disseminated to the public can cause harm by itself, without any regulatory or adjudicative action. In implementing the IQA through its Guidelines, OMB confirmed this obvious fact by requiring that agencies resolve information correction petitions on a timely basis. HHS has nonetheless refused to respond to the merits of ASA's correction Petition filed in October 2004, while continuing to disseminate its erroneous information regarding the absence of any medical use for marijuana. Its sole response was to tell ASA to wait for the conclusion of the DEA proceedings, which began in 2002, with no end in sight.[1]

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[1] For the 1995 rescheduling petition, the DEA took more than six years to provide a final determination. *See Gettman v. DEA*, 290 F.3d 430 (D.C. Cir. 2002); *see also United States v. Cannabis Cultivators Club*, 5 F.Supp.2d 1086, 1102 (N.D. Cal. 1998) ("The Court doubts whether a rescheduling petition is a reasonable alternative for all seriously ill patients whose physicians have recommended marijuana for therapeutic purposes. . . . Needless to say, it hardly seems reasonable to require an AIDS, glaucoma, or cancer patient to wait twenty years if the patient requires marijuana to alleviate a current medical problem."). An earlier rescheduling petition was pending for more than twenty-two years before it was denied. *See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994). And even once DEA issues a final scheduling determination, any court challenge to that determination would likely take several more years.

When the agencies were drafting their own Guidelines to conform to the OMB Guidelines, the issue arose as to how to handle requests for correction of information on a timely basis when the information was at issue in another proceeding. In response, OMB allowed the agencies to incorporate into their Guidelines the language now in the HHS Guidelines, stating that the agency will act on the information correction request, and not use the other proceedings if responding to the IQA petition promptly will not delay the other proceedings and there is a reasonable likelihood that persons will be harmed by not providing a prompt IQA response. *See* HHS Guidelines, Part I, Sec. E [included in Addendum]; Memorandum to the President's Management Council from OIRA Administrator John D. Graham, dated Sept. 5, 2002, attachment p. 1, item 2 [available at http://www.whitehouse.gov/omb/inforeg/pmcmemo.pdf].[2]

As the ASA Complaint alleges, the inaccurate information on lack of medical efficacy being disseminated by HHS is currently causing direct harm to ASA and to seriously ill patients who are being misinformed. Yet HHS contends that ASA and those patients must wait some indefinite time, likely years, to have the information corrected because a suit to force correction of the information can

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[2] Timeliness is especially critical here, since this case involves highly influential medical information, as the HHS IQA Guidelines recognize. *See* HHS Guidelines, Part I, Sec. D.2.c.2 & E [included in Addendum]. Harm that arises from failure to disseminate accurate and timely influential medical information is likely to be irreparable.

only be brought pursuant to the review provisions of the Controlled Substances Act after DEA (not HHS) makes a final scheduling decision. Not only is that approach inconsistent with the IQA's goal of promptly correcting erroneous information that is being disseminated by federal agencies, but the claim that 21 U.S.C. § 877 of the CSA is the exclusive remedy for addressing the information issues raised by this case is unsupportable for several reasons.

First, ASA's IQA Petition alleged that HHS was continuing to disseminate the inaccurate statements concerning lack of medical efficacy made in connection with the 2001 DEA rescheduling determination on government websites, "such as" those containing the rescheduling determination. (ER 35) The ASA Petition also cited scientific studies published after the 2001 DEA determination as the basis for its correction Petition. (ER 37-38 & 43-45) In its First Amended Complaint, ASA specifically cited similar HHS information disseminations issued since 2001 consisting of HHS Congressional testimony in 2004 and its "Inter-Agency Advisory" of 2006. (ER 15 ¶ 9; *see also* May 15, 2002, HHS Press Release [available at http://www.hhs.gov/news/press/2002pres/marijuana.html] (stating inaccurately, "[s]o far, there has been little scientific evidence that smoked marijuana can serve as a therapeutically useful drug" and contending that the 1999 IOM report "concluded that research so far has not demonstrated a therapeutic benefit."). Thus, ASA is challenging not just the HHS information on medical

efficacy appended to the 2001 DEA determination or that might be a part of a future DEA scheduling determination; ASA is also challenging HHS's current and ongoing dissemination of similar statements, and those similar disseminations have no connection with a DEA rescheduling request. Because those disseminations could never be challenged under the CSA, the CSA cannot be the sole avenue for judicial review of their accuracy.

Second, HHS argues that this case is really a challenge to the 2001 DEA scheduling decision. While that ruling attached the HHS statements concerning lack of medical efficacy, those HHS statements were not a basis for the DEA decision and therefore could not have been challenged under the CSA, 21 U.S.C. § 877 ("§ 877), which provides for review only of a "final decision" by DEA. The DEA determination stated: "DEA's denial of your petition is based exclusively on the scientific and medical findings of HHS, with which DEA concurs, that lead to the conclusion that marijuana has a high potential for abuse." 75 Fed. Reg. 20038 3d col. (2001).[3] If medical effectiveness of marijuana was not at issue in the 2001 proceeding, ASA cannot be precluded from raising that issue now in this challenge under Section 704 of the APA, which provides that "Agency action made reviewable by statute and final agency action *for which there is no other adequate*

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[3] In addition, the 2001 rescheduling decision stated: "You do not assert in your petition that marijuana has a currently accepted medical use in treatment in the United States. . . ." *Id.*

remedy in a court are subject to judicial review." 5 U.S.C. § 704 (emphasis added).

The principal defense raised by HHS is that the information issues raised in this proceeding could only be challenged on review of a final DEA scheduling determination at some time in the future pursuant to § 877. For this proposition, HHS cites and quotes a Ninth Circuit decision, *Pub. Util. Comm'r of Or. v. Bonneville Power Admin.*, 767 F.2d 622 (9th Cir. 1985) ("*PUCO*"), and the District of Columbia Circuit decision in *Telecommunications Res. And Action Ctr. v. FCC*, 750 F.2d 70 (D.C. Cir. 1984) ("*TRAC*"). But *PUCO* stated only that the APA "provides additional support for our conclusion" because "[t]here is no reason to believe appellate review will be inadequate." 767 F.2d at 627. The court also stated that "petitioners have failed to demonstrate they face any irreparable injury that is not correctable on review of final BPA action." *Id.* at 630. Likewise, in *TRAC*, the court ruled that review was not permissible under § 703 of the APA because it found "untenable any suggestion that appellate review of nonfinal agency action may be inadequate due to Courts of Appeals' inability to take evidence. [Footnote omitted]." 750 F.2d at 78. [4]

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[4] Section 703 reflects the same basic considerations of adequacy and preclusion as § 704, and cases in which exclusive jurisdiction is an issue often cite it in addition to § 704. Section 703 states: "The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence *or inadequacy thereof*, any applicable

Moreover, neither of those decisions presented factual situations remotely analogous to this case, and HHS ignores the determinative language of § 704 of the APA concerning "adequate remedy" and the extensive case law interpreting that provision that supports ASA's position that its claims can be precluded only if the alternative remedy is adequate, which it is not. The most obvious reason why CSA review would be inadequate is that DEA might preclude ASA from contesting HHS's underlying findings by stating only its conclusion that marijuana does not have a "currently accepted medical use," without expressly citing HHS's underlying findings regarding the three contested criteria for medical efficacy employed by HHS.

A leading case interpreting the "adequate remedy" language of § 704, not mentioned by HHS, is *Bowen v. Massachusetts*, 487 U.S. 879 (1988), which was decided after *PUCO* and *TRAC*. In *Bowen*, the Supreme Court rejected an HHS claim that the district court lacked jurisdiction to review HHS's denial of Medicaid reimbursements because the Claims Court had exclusive jurisdiction over monetary claims. The Court first noted that its "leading opinion," *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), explains that § 704 "manifests a congressional intention that it cover a broad spectrum of administrative actions, and this Court has echoed that theme by noting that the Administrative Procedure

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form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction. . . ." 5 U.S.C. § 703 (emphasis added).

Act's 'generous review provisions' must be given a 'hospitable' interpretation." 487 U.S. at 904. The Court, then, found that the Claims Court's jurisdiction to grant the requested relief was "doubtful" and that § 704 should not be interpreted to bar equitable relief. Of particular relevance to the present case, the Court found that, without equitable relief, the State could experience harm while the matter was awaiting the opportunity for Claims Court review, and that the Claims Court could neither grant equitable relief nor act in any fashion "so long as the Federal Government has not yet" acted in a manner allowing Claims Court review. *Id.* at 906.

The present case is directly analogous to *Bowen.* ASA and the patients it serves by providing information about medical marijuana would be harmed while awaiting review under § 877, and thus it has sought declaratory and equitable relief to halt the unlawful conduct of HHS that the IQA proscribes. (ER 21-22) The relief available under § 877, in addition to not being able to remedy present harm in a timely manner, could only vacate the DEA scheduling determination and could not prevent HHS from disseminating further inaccurate information in the future similar to what it is now disseminating outside the context of a DEA rescheduling proceeding. Furthermore, making CSA review the sole remedy would be inconsistent with HHS's own OMB-approved Guidelines, as discussed *supra*, requiring timely action on correction petitions outside the confines of other HHS

proceedings (not to mention proceedings of entirely separate agencies such as DEA), except in limited circumstances that HHS has never claimed exist in this case.

Ninth Circuit cases subsequent to *PUCO,* in which an argument of exclusive jurisdiction under a statute other than the APA was raised, have also involved consideration whether the other statute provided an adequate alternative remedy. These authorities are consistent with *Bowen* and further demonstrate why the CSA remedy is inadequate. *See Tucson Airport Auth. v. General Dynamics Corp.*, 136 F.3d 641, 645-46 (9th Cir. 1998) (Claims Court remedy was not adequate under §704 because it did not have the general equitable powers of a district court to grant prospective relief); *Marshall Leasing, Inc. v. United States*, 893 F.2d 1096, 1100-01 (9th Cir. 1990) (Claims Court remedy was not adequate because it had declined in the past to review claims for equitable relief from DEA property forfeitures); *cf. Sable Communications v. FCC*, 827 F.2d 640, 642 (9th Cir. 1987) (alternative remedy found to be adequate). To like effect are decisions in the District of Columbia Circuit subsequent to *TRAC. See El Rio Santa Cruz Neighborhood Health Ctr., Inc. v. HHS*, 396 F.3d 1265, 1269-75 (D.C. Cir. 2005) (district court jurisdiction was not precluded because alternative remedy was of doubtful adequacy, relying on *Abbot Laboratories* and *Bowen*); *Transohio Savings Bank v. Dir., Office of Thrift Supervision*, 967 F.2d 598, 607-08 (D.C. Cir. 1992)

(Claims Court did not provide adequate remedy because it could not grant equitable relief).

At bottom, the CSA remedy proposed by HHS is little more than an illusion. It is not currently available, and there is no reasonable expectation that there will be a DEA decision to review any time soon, thereby assuring that ASA and the patients that it seeks to help will continue to suffer injuries from HHS's violations of the IQA into the indefinite future. Even when there is judicial review under the CSA, the most that can come from this is an order respecting rescheduling, which, like the 2001 decision, might or might not say anything about the issue of the medical use of marijuana. And even if there were a rescheduling, HHS could still continue to disseminate the statements to which ASA objects, since HHS will not be a party to a court proceeding under the CSA, nor would that court have the power in a rescheduling case to order a correction of erroneous information that HHS is currently disseminating outside the rescheduling context, in violation of the separate IQA statute.[5]

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[5] At the end of its brief, in footnote 5, HHS also makes a brief and insufficient attempt to challenge ASA's standing by quoting a statement from *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982) that is not central to the Court's standing holding and which ignores the many other cases, both in this Court and other circuits, that have applied the broad principles in *Havens* beyond the Fair Housing Act. *See, e.g., Legalization Assistance Project of Los Angeles County Fed'n of Labor (AFL-CIO) v. INS*, 976 F.2d 1198, 1204 (9th Cir. 1992) (challenge to immigration eligibility regulations), *vacated on other grounds*, 510 U.S. 1007 (1993); *El Rescate Legal Serv., Inc. v. Exec. Office of Immig. Review*,

II. HHS MISSTATES THE TEST FOR "FINAL AGENCY ACTION" AS REQUIRING "LEGAL CONSEQUENCES," EVEN UNDER THE IQA

HHS asserts that, to be final, an agency action must "determine rights or obligations' *from which* 'legal consequences [would] flow.'" Brief for the Appellees ("AB") at 17 (emphasis added). This misstates the test articulated by the Supreme Court in *Bennett v. Spear,* 520 U.S. 154 (1997) on which the government principally relies. In *Bennett*, the Supreme Court stated that, "as a general matter," an agency action is final if it is an action "by which 'rights or obligations have been determined,' *or* from which 'legal consequences will flow.' . . ." *Id.* at 178 (emphasis added; quotation and citations omitted). The word "or" is, of course, important and the formulation of the *Bennett* test without the "or" is an

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959 F.2d 742, 748 (9th Cir. 1991) (immigration case) (alternative holding); *Fla. State Conf. of NAACP v. Browning*, 522 F.3d 1153, 1164-66 (11th Cir. 2008) (challenge to voter registration information requirements); *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 469 F.3d 129, 132-33 (D.C. Cir. 2006) (challenge to FDA requirements for experimental drugs); *Am. Canoe Ass'n v. City of Louisa Water & Sewer Comm'n*, 389 F.3d 536, 546-47 (6th Cir. 2004) (alleged violation of Clean Water Act monitoring and reporting requirements). Under *Havens* and cases relying on *Havens*, Article III standing is established if the challenged agency action has caused the plaintiff to expend and divert resources in furtherance of its mission, which is indisputably the case here. *See* Appellant's Opening Brief ("AOB") at 31 n.12; First Amended Complaint (ER 12-13 ¶7 & 20 ¶23).

HHS invention. In *Bennett* there were "legal consequences" involved, but finality is also satisfied where legal rights have been determined, as in this case.[6]

In this case, HHS, by denying ASA's IQA Petition, determined ASA's right to "obtain" a timely correction of information disseminations that ASA claims are inaccurate and otherwise do not comply with the IQA and OMB's standards for quality, objectivity, and utility. While HHS states in a conclusory fashion that ASA has no right to a correction (relying primarily on the *Salt Institute* decision, which is addressed below), it fails to quote the plain language of the IQA -- giving petitioners a right to "seek and obtain" a correction complying with the OMB Guidelines. *See* 67 Fed. Reg. at 8459 1st col. HHS also dismisses the many cases granting APA review of denials of other petitions for relief that uniformly recognize or assume that denial of a petition that is provided for in legislation is a determination of a right, even if there are no direct legal consequences flowing from the denial. In particular, in cases cited by ASA in its Opening Brief that reviewed denials of requests for corrections of military records, the petitions were

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[6] The *Bennett* test for finality has an element of redundancy, since a determination of a legal right could also be considered a legal consequence. The Ninth Circuit has stated the requirements for finality somewhat differently, but with no discernible difference in outcomes: "The finality element must be interpreted in a pragmatic and flexible manner," with the "core question" being "whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties." *Or. Natural Desert Ass'n v. U.S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006).

acted on by the agency, and judicial review undertaken, whether there were any ancillary legal consequences or not, since in no case was that a requirement to obtain court review. (AOB 26) (collecting cases)[7]

In addition, as noted by ASA previously, denial of a petition for relief is a discrete type of agency action covered by the APA without reference to legal consequences, and the Supreme Court has stated that the APA covers virtually every type of agency action, *Whitman v. Amer. Trucking Ass'ns*, 531 U.S. 457, 478 (2001); *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 238 n.7 (1980), unless it is clearly precluded, committed absolutely to agency discretion, lacks finality, or there is an adequate alternative remedy. (AOB 24)

HHS cites this Court's decision in *City of San Diego v. Whitman*, 242 F.3d 1097, 1101 (9th Cir. 2001), for its assertion that *Bennett v. Spear* stated that "legal consequences" must flow from a determination of a right. Not only is the quotation from *City of San Diego* inaccurate, but that case actually supports ASA's position here. The agency action challenged in *City of San Diego* was a letter

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[7] HHS attempts to distinguish those petition cases on the basis that they concerned information personal to the petitioners. (AB at 19-20 n.3) There is no legal or logical basis for such a distinction. The APA covers all petitions for relief and all types of final agency action, regardless whether they involve personal information. Once actual harm is established as an element of Article III standing, as it has here, *see* note 5, *supra,* a petition for relief from that harm provided for by statute or regulation comes within the APA. This is consistent with the Supreme Court's many pronouncements concerning the broad reach of the APA and the language and legislative history of the IQA.

response to an inquiry from the City requesting information, and the agency stated that the City must file an application and proceed through the administrative process on the application. This Court agreed and held that the agency action would not be final until all administrative appeals on an application were concluded. Here, ASA has fully exhausted all administrative remedies, including an administrative appeal, and, therefore, this case falls squarely within the procedural posture that the *City of San Diego* ruled is subject to judicial review.

Other cases cited by HHS for the proposition that "legal consequences" are required are similarly inapposite because none involved the IQA. By enacting the IQA in 2000, Congress provided for a right to "seek and obtain" a correction of erroneous information, and the denial of that right surely had legal and practical consequences in the eyes of Congress. To take the opposite position would be to impute to Congress an intent to pass a wholly hortatory statute, under which the agencies would be free to respond to correction petitions or not, and the courts could do nothing even to require a substantive response. Nothing in the IQA or the APA supports that result, and so whatever the cases cited by HHS that arose outside the IQA context may hold, they have no bearing on this IQA case, which is far more analogous to, and even more compelling than, the correction of military records cases than to any decision cited by HHS.

Recognizing that the IQA changed the administrative and judicial landscape regarding claims that an agency has disseminated incorrect information, HHS seeks refuge in the Fourth Circuit's decision in *Salt Institute v. Leavitt,* 440 F.3d 156 (4th Cir. 2006). There is language in both the decisions of the Fourth Circuit and the district court that could be read to support HHS, but only if taken out of context and without regard for the very narrow, and very different, relief that was sought in that case, as compared to this one.

As ASA explained in its Opening Brief (AOB 30-31), although the Salt Institute relied on the IQA, it did not seek correction of any records in the lawsuit that it filed. Rather, recognizing that it needed additional information, it sought to use the IQA to obtain such information through the defendant, because other statutes were not available for various reasons. In ASA's view, the opinion of the Fourth Circuit, read as a whole, is entirely clear on what relief was sought there (and what was not sought), such that the decision has no bearing on this case. But if there is any doubt, the oral argument there, made by the same counsel who drafted the government's brief here, removes it by stating:

> So then we come to what they call their request to correct information. And I would be happy to address all the legal issues that would have arisen if they had actually made a request, but reading from their letter to the agency -- and they say this in various forms throughout the letter -- This is page A-39 -- "Because this petition is based solely on the agency's failure to make study data publicly available, petitioners do not at this time request or recommend the challenged information be removed from public view; however, should petitioners determine

> upon review of data that the interpretations cannot be reproduced, petitioners reserve the right to pursue additional Data Quality Act [IQA] challenges." Which is fine -- *we're not saying that there could never be a ripe question about whether you could get judicial review of a correction request under the IQA, we just don't have one here.*

Appellant's Request for Judicial Notice, filed herewith at 16:46-17:39 (emphasis added).[8] The Fourth Circuit's opinion contains absolutely no analysis of the APA or IQA that would support a ruling that there is no right to a correction in a case properly presenting a denial of a correction petition. This Court should not lightly assume that a sister circuit would dispose of an important case of first impression with no analysis when the most reasonable explanation for its lack of analysis is that the claim before it did not seek judicial review of a valid petition for correction.

HHS makes the related argument that its decision on the ASA IQA Petition is not a final agency action reviewable under the APA because HHS is in the process of giving additional consideration to the issue in the current DEA proceeding, albeit without any time limit. This argument is meritless. HHS has issued a final denial of a petition for relief, which is discrete agency action under the APA. That HHS might give the issue additional consideration in the future

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[8] This Court may take judicial notice of the appellate materials in another case cited by a party as precedent. *McConnell v. United States*, 478 F.3d 1092, 1096 n.4 (9th Cir.), *cert. denied*, __U.S.__, 128 S.Ct. 649 (2007); *see also Boivin v. U.S. Airways, Inc.*, 446 F.3d 148, 158 (D.C. Cir. 2006) (citing oral argument tape at 52:32).

does not detract from the finality of HHS's denial of ASA's Petition. *Cf. Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1037-38 (D.C. Cir. 2002) (agency intent to continue to consider a matter does not mean a determination it has made is not final as a matter of law), *modified on reh'g*, 293 F.3d 539 (D.C. Cir. 2002); *Am. Petroleum Inst. v. U.S. EPA*, 906 F.2d 729, 739-40 (D.C. Cir. 1990) (possibility of future agency action is not sufficient to foreclose review of a definitive action; otherwise "review could be deferred indefinitely"). The decision of HHS to deny ASA's Petition by telling ASA that its sole remedy is under the CSA is as final as it has to be before judicial review is proper. Having demonstrated in Part I, *supra*, that the CSA is not the sole path for judicial review of the denial of ASA's Petition under the IQA, HHS should be directed to provide a substantive response to the merits of the correction petition that ASA filed nearly four years ago.

III. HHS SHOULD BE ORDERED TO RESPOND SUBSTANTIVELY TO ASA'S PETITION BECAUSE ITS FAILURE TO DO SO CONSTITUTES UNREASONABLE DELAY UNDER APPLICABLE LAW

In the district court, HHS was less than clear about whether its replies to ASA were responses to the petition that amounted to a final agency decision. Therefore, in its amended complaint, ASA added a claim for unreasonable delay, which the district court also rejected. HHS's main argument on this point is that agencies have essentially unlimited discretion under the IQA to respond to a

correction petition, and thus courts cannot compel agencies to provide a response on the merits, no matter how unreasonable the delay.[9] The Court need reach the unreasonable delay issue only if it concludes that there is a question about whether HHS has a duty to make any substantive response to ASA's correction Petition.

The OMB and HHS Guidelines make clear that petitions for corrections of information should be resolved within a matter of months, not years, especially when they concern matters affecting public health. Moreover, HHS apparently *has* responded substantively *to DEA* on the issue of whether marijuana has medical use, but has kept this response secret, not even giving a copy to ASA or the Court. (AB 7-8) Thus, assuming that HHS's apparent reliance on the DEA proceedings as its substantive response is misplaced, there can be no doubt that the delay is unreasonable. HHS, nonetheless, contends that a court can order it to make a substantive response only if its Guidelines leave it with "no discretion whatever." (AB 20 & 22) That is not the law, and the Guidelines provide for discretion on the

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9 HHS asserts that it has a high degree of discretion on whether or not to defer information issues raised by correction petitions to other proceedings, such as the CSA proceeding that has been under way since 2002. To support this assertion, it states that its Guidelines provision on deferral (the last provision in the Guidelines) provides that it "may" resolve the petition promptly, rather than defer to the other proceedings. (AB 5 & 22) That Guideline provision, however, states that HHS "will" provide a response rather than defer it if certain conditions are met. That mandatory language was provided to the agencies by OMB, which is responsible for interpreting the IQA and the government-wide guidelines. *See supra* at 6.

relief to be accorded when erroneous information is found, not on the duty to respond.

First, HHS inaccurately cites *Norton v Southern Utah Wilderness Alliance,* 542 U.S. 55 (2003) ("*SUWA*"), as holding that jurisdiction under APA § 706(1) is "limited to the enforcement of 'a specific, unequivocal command,' the ordering of a precise, definite act . . . about which [an official] had no discretion whatever." (AB 20) The language quoted by HHS came from a number of pre-APA cases (1932, 1888, 1838) that *SUWA* quotes in exploring the case law leading to the enactment of § 706(1). But that was not the Court's holding, which was that "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*." *Id.* at 64 (emphasis in original).[10] The Court then went on to find that the BLM management plan under review was not specifically required because it was broad

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[10] The Court focused almost exclusively on the "unlawfully withheld" portion of 706(1), referring to the "unreasonably delayed" portion of 706(1) only in a single footnote, stating: "Of course §706(1) also authorizes court to 'compel agency action . . . unreasonably delayed' -- but a delay cannot be unreasonable with respect to action that is not required." *Id.* at 64 n.1. ASA's First Amended Complaint alleged both that HHS has "unlawfully withheld or unreasonably delayed" final agency action within the meaning of § 706(1). (ER 21) Since ASA filed its Opening Brief, the District of Columbia Circuit has decided another case that distinguishes between a "denial" and a "failure to act." *Kaufman v. Mukasey*, 524 F.3d 1334, 1338 (D.C. Cir. 2008) ("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* AOB 43-44.

and programmatic and lacked "the specificity requisite for agency action" and that § 706(1) does not apply to a "[g]eneral deficiency in compliance." *Id.* at 66. The Court contrasted such a general deficiency under a "broad statutory mandate" with "the failure to issue a ruling" that was a "*discrete* agency action." *Id.* (emphasis in original). Yet this is precisely what HHS failed to do here with respect to ASA's information correction Petition that is specifically authorized by the IQA.

Prior to *SUWA*, this Court interpreted § 706(1) to require a court to compel agency action unreasonably delayed, even in the absence of a firm deadline. *Biodiversity Legal Fdn. v. Badgley*, 309 F.3d 1166, 1177 n.11 (9th Cir. 2002) (citing *Brower v. Evans,* 257 F.3d 1058, 1068 (9th Cir. 2001)), which applied the *TRAC* factors); *see also San Francisco BayKeeper v. Whitman*, 297 F.3d 877, 885-86 (9th Cir. 2002). Nothing in *SUWA* or subsequent Ninth Circuit case law contravenes those decisions. *See Alvarado v. Table Mountain Rancheria,* 509 F.3d 1008 (2007).

To be sure, the OMB and HHS Guidelines provide for HHS to exercise its discretion in connection with IQA correction petitions, but that discretion applies only after the agency has found that the correction petition has merit, and the issue is what relief is appropriate.[11] Providing for agency discretion at the relief stage is

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[11] The preamble to the final OMB government-wide Guidelines states that "agencies must apply these standards flexibly, and in a manner appropriate to the nature and timeliness of the information to be disseminated." 67 Fed. Reg. 8452,

plainly sensible because it cannot be known in advance the myriad relevant circumstances, as well as the nature and significance of an error, and hence what relief is appropriate. But the fact that the Guidelines specifically provide for agency discretion at the relief stage, and say nothing about discretion as to the duty of an agency to respond, underscores ASA's argument that the IQA's mandate that ASA may "seek and obtain" a correction gives HHS no discretion to refuse to reply at all or to delay a reply indefinitely. Accordingly, ASA also has a valid claim under § 706(1).

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: July 7, 2008

Respectfully submitted,

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8453 2d col. The HHS Guidelines state that the response to a petition "will consider the nature and timeliness of the information of the information involved and such factors as the significance of the correction on the use of the information, the magnitude of the correction and the resource requirements for the correction." HHS Guidelines, Part 1, Sec. E [included in Addendum].

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 6,256 words.

Dated: July 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 and Mark Stern, Department of Justice, Civil Division, Appellate Staff, Room 7235, 950 Pennsylvania Ave., N.W., Washington, D.C. 20004, this seventh day of July, 2008.

Joseph D. Elford