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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

AMERICANS FOR SAFE ACCESS, Plaintiff, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES and FOOD AND DRUG ADMINISTRATION, Defendants.	No. 3:07-cv-01049-WHA **MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO MOTION TO DISMISS** Date: November 15, 2007 Time: 8:00 a.m. Place: Courtroom of the Honorable William H. Alsup

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INTRODUCTION

The Department of Health and Human Services ("HHS") contends that the Information Quality Act is a nullity. It believes that it can ignore, or put off indefinitely, requests for correction of information under the statute and no court can tell it that it must comply. Congress, however, in enacting the Information Quality Act expected administrative agencies, at the very least, to respond substantively to requests for correction of information within a limited time and has required them to implement mechanisms for this to happen. This Court should compel HHS, which has dragged its feet for more than three years in responding to ASA's petition, to live up to its statutory obligations and provide ASA a substantive response soon.

THE INFORMATION QUALITY ACT AND ITS IMPLEMENTING GUIDELINES

Recognizing the need to ensure and maximize the quality of information disseminated by federal agencies, Congress enacted the Information Quality Act ("IQA") in December of 2000 as a supplement to the information dissemination provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. § 3501 *et seq.* ("PRA"). The PRA had required the Office of Management and Budget ("OMB") to issue "rules, regulations or procedures" to implement its provisions, 44 U.S.C. §§ 3504 & 3516, and required all federal agencies to follow those OMB rules, regulations and procedures, 44 U.S.C. § 3506(a)(1)(B), but it did not specify a timeframe for OMB implementation. Impatient with OMB's delays in implementing the PRA, *see* H.R. Rep. No. 105-592 at 49-50 (June 22, 1998), Congress enacted the IQA to require OMB to implement the information dissemination provisions of the PRA within a set period of time. The IQA is codified in the Statutory and Historical Notes to 44 U.S.C. § 3516, Pub. L. No. 106-554 § 1(a)(3), 114 Stat. 2763 (2000) (hereinafter "Section 515"), the provision of the PRA requiring OMB to issue rules, regulations, or procedures to exercise its PRA authority. The IQA required

OMB to issue guidelines providing policy and procedural guidance to all agencies for "ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by the agency," Section 515, § (b)(2)(A), and requiring them 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," Section 515, § (b)(2)(B) (emphasis added). This time, Congress gave OMB one year to do this, and one additional year for federal agencies to issue conforming guidelines. Section 515, § (b)(2). The PRA provisions which the IQA supplemented already required agencies to comply with policies issued by OMB to implement the Act. 44 U.S.C. § 3506(a)(1)(B).

In compliance with the IQA mandate, OMB promulgated, in 2002, final Guidelines, binding upon the agencies pursuant to 44 U.S.C. § 3506, defining "quality," "objectivity," "utility," and "integrity," and requiring the agencies to implement mechanisms allowing affected persons to seek and obtain correction of information disseminated by the agency in a timely fashion. *See* 67 Fed. Reg. 8452, 8459 (Feb. 22, 2002). The OMB Guidelines referred to an affected person seeking to obtain a correction as a "petitioner." 67 Fed. Reg. At 8454 & 8459.

HHS promulgated its conforming guidelines less than a year later. 67 Fed. Reg. 61343 (Sept. 30, 2002). In accordance with the OMB Guidelines, the HHS Guidelines define "quality" as "an encompassing term comprising objectivity, utility, and integrity." HHS Guideline D.2.a. These Guidelines recognize that "objectivity" requires that "disseminated information [be] presented in an accurate, clear, complete, and unbiased manner." HHS Guideline D.2.c. As for "utility," the Guidelines define that term as referring to the "usefulness of the information to its intended users, including the public. . . ." HHS Guideline D.2.b. Furthermore, the HHS

Guidelines recognize that agencies responsible for dissemination of "vital health and medical information" have additional responsibilities to "ensur[e] the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public." HHS Guideline D.2.c.2.

To carry out the requirement in the OMB Guidelines and the IQA and PRA for establishing a petition mechanism to allow affected persons to seek and obtain correction of information disseminated by the agency, the HHS Guidelines provide for: (1) an initial "request for correction" of information disseminated by HHS and (2) an administrative appeal, or "Information Quality Appeal." Like the OMB Guidelines, the HHS Guidelines refer to a person seeking correction of information as a "petitioner." HHS Guideline D.2.c.1.

With regard to an initial petition, the Guidelines state that "[t]he 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." HHS Guideline E. If the initial petition is denied by HHS, the HHS Guidelines provide for an administrative appeal, and the "agency will respond to all requests for appeals 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." HHS Guideline E. Under the Guidelines, the agency must act on an IQA petition before the completion of another agency action where this would not unduly delay the other agency action and the petitioner has shown a reasonable likelihood of suffering actual harm from a delayed response. HHS Guideline E.

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STATEMENT OF FACTS

In response to a pre-IQA petition filed in 1995 to reschedule marijuana under the Controlled Substances Act ("CSA"), HHS made statements, which it codified in the *Federal Register* and which it continues to disseminate on government websites to this day, that marijuana has no accepted medical use in the United States. *See* 66 Fed. Reg. 20037, 20039 (April 18, 2001); First Amended Complaint ¶9. 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 assigned the Food and Drug Administration Controlled Substances Staff ("FDA") the task of assessing whether marijuana had any medical use. After four full years, the FDA concluded that marijuana had not met three of the five criteria it employs to determine whether a substance has a "currently accepted medical use." 66 Fed. Reg. 20037, 20051 (April 18, 2001).[1] Specifically, the FDA found:

> [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. . . .

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[1] These criteria are as follows:

a. The drug's chemistry is known and reproducible;
b. There are adequate safety studies;
c. There are adequate and well-controlled studies proving efficacy;
d. The drug is accepted by qualified experts;
e. The scientific evidence is widely available.

Id. (citing *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994)).

Based on these findings, HHS determined that marijuana "has no currently accepted medical use in treatment in the United States." 66 Fed. Reg. 20037, 20039 (April 18, 2001). HHS has subsequently continued to disseminate this statement, or its equivalent, in Congressional testimony, and in statements directed at the general public disseminated on its website. First Amended Complaint ¶9.

Plaintiff's Request for Correction of Information under the IQA ("petition") to HHS contended that these statements are patently false, but that many people believe them. *See* First Amended Complaint ¶¶3, 7 & 21. The First Amended Complaint further alleges that, as a result, numerous seriously ill persons have foregone the use of marijuana, even though taking it would have dramatically improved their lives. First Amended Complaint ¶8.

To combat HHS's false statements that marijuana has no accepted medical value, plaintiff Americans for Safe Access (ASA") implemented a campaign to educate the public about the true benefits of marijuana. First Amended Complaint ¶7. 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. First Amended Complaint ¶7. ASA is making headway, but the task of combating HHS's false statements continues to drain its limited resources and impedes ASA's other efforts to improve the access of seriously ill persons to medical marijuana. *See* First Amended Complaint ¶7.

Then, ASA discovered a legal remedy. Because the IQA requires federal agencies to disseminate truthful information and provides a mechanism to ensure this, ASA filed with HHS a petition to correct information disseminated by HHS regarding the medical use of marijuana on

October 4, 2004. *See* First Amended Complaint ¶15.[2] ASA's petition sought the correction of the four statements disseminated by HHS about medical marijuana quoted above. *See* First Amended Complaint ¶15; Petition at 1-3. The petition explained in detail why each statement is false and provided an extensive discussion of the numerous peer-reviewed scientific studies proving this. *See* First Amended Complaint ¶15; Petition at 5-10. In addition, the petition details why these statements violate the objectivity and utility requirements of the IQA. *See* First Amended Complaint ¶15; Petition at 5-10.

Over the next nineteen months, HHS responded to the petition with evasion and delay. On December 1, 2004, HHS sent ASA an interim response to its October 4, 2004, petition. First Amended Complaint ¶17. HHS stated that it had not yet completed its review of the ASA petition, due to other agency priorities and the need to coordinate agency review, with no mention of competing priorities. First Amended Complaint ¶17. HHS contended that it needed to consult with the Drug Enforcement Administration ("DEA"), which was considering a new petition filed on October 9, 2002, to reschedule marijuana, in order to prepare a response to ASA's petition, and that it hoped to provide a response within the next 60 days. *See* First Amended Complaint ¶17. By letter dated December 20, 2004, ASA protested that HHS, by consulting with DEA, was inexcusably expanding its review to include considerations outside the scope of ASA's petition and that such expansion would unduly delay an administrative response to the requested correction of information. First Amended Complaint ¶18. In particular, the rescheduling petition raises the issue of marijuana's relative abuse potential compared to other drugs, which is not at issue in ASA's IQA petition. Nevertheless, HHS

[2] Copies of the Petition, the initial agency response, ASA's appeal, the final agency response to the appeal, and all agency interim responses can be accessed at http://aspe.hhs.gov/infoquality/requests.shtml, item 20.

provided a series of interim responses over the next several months stating that it needed additional time to coordinate agency review. First Amended Complaint ¶19. Finally, on April 20, 2005, HHS denied ASA's petition without presenting any evidence that its statements about the lack of medical efficacy of marijuana are justified. First Amended Complaint ¶19. HHS made no mention of its IQA Guideline D.2.c.2, which requires it to ensure the "timely flow of vital information from agencies to medical providers, patients, health agencies, and the public." *See* First Amended Complaint ¶19.

On May 19, 2005, ASA filed an appeal of the HHS rejection of its October 4, 2004, petition, pursuant to the HHS Guidelines. *See* HHS Guideline E; First Amended Complaint ¶20. ASA's appeal protested that: (a) HHS was evading its information quality responsibilities and delaying a response in contravention of its Guidelines, in particular, by referring the issues raised by the ASA petition to an agency outside HHS; (b) the issues raised by ASA's request for correction under the Information Quality Act are different and more limited than those raised in the DEA rescheduling proceeding, so that merging the proceedings would not permit HHS to consider the information quality issues "on a timely basis," as required by the HHS Guidelines, and (c) HHS had ignored its Guidelines stating that information quality petitions must be acted upon in a timely fashion and not transferred to another proceeding where there is a reasonable likelihood that persons were suffering actual harm from the inaccurate information being disseminated by the agency. First Amended Complaint ¶21. ASA alleged that "seriously ill persons represented by ASA are suffering from being misled about the medical benefits of marijuana [by HHS]." First Amended Complaint ¶21.

Again, commencing on July 28, 2005, HHS sent ASA a series of five interim responses to its appeal over a period of more than eleven months, stating only that the agency required

additional time to coordinate agency review to prepare a response and that its "goal is to have a response to your appeal within 60 days of the date of this letter." First Amended Complaint ¶22. After these five "interim" responses, HHS sent ASA a final response on July 12, 2006, effectively denying the appeal without addressing the scientific evidence. *See* First Amended Complaint ¶22. HHS merely noted that it anticipated providing a recommendation to the Drug Enforcement Administration ("DEA") in connection with a marijuana rescheduling petition pending before the DEA since October 9, 2002, by September of 2006. First Amended Complaint ¶22. HHS did not give any indication that it would provide a further response to ASA, and it still has not provided any further response. ASA, then, filed this action on February 21, 2007.

On July 24, 2007, this court granted HHS's motion to dismiss the original complaint and granted ASA leave to amend the complaint "to proceed on a theory that defendants unlawfully withheld or delayed agency action by not giving a substantive response to plaintiff's petition." *Americans for Safe Access v. Department of Health and Human Services*, 2007 WL 2141289 at *5 (N.D. Cal. July 24, 2007). ASA has done this, which precipitated this second motion to dismiss the complaint.[3]

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[3] ASA continues to maintain that HHS'S July 2006 "response" to its appeal was a "denial" within the meaning of the APA, rather than a failure to act, and that this "final agency action" was arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law because it violated the OMB and HHS Guidelines. *See Norton v. Southern Utah Wilderness Alliance* ("*SUWA*"), 542 U.S. 55, 63 (2004); *United States v. Bean*, 537 U.S. 71, 76 n.4 (2002); *Center for Biological Diversity v. Brennan*, 2007 WL 2408901 at *13 (N.D. Cal. Aug. 21, 2007). While ASA reserves the right to renew these contentions on appeal, it will not reargue them here.

ARGUMENT

I. ASA HAS STANDING TO PURSUE ITS CLAIMS UNDER THE APA

To avoid adjudication of ASA's claims under the APA, HHS contends that ASA has failed to state a case or controversy sufficient to confer Article III standing. *See* Memorandum in Support of Defendants' Motion to Dismiss Plaintiff's Amended Complaint, filed October 11, 2007 ("Second Motion to Dismiss"), at 9-10. As was established in ASA's opposition to the first motion to dismiss, ASA has organizational standing to litigate its claims both because HHS's false statements deplete its resources and they frustrate ASA's mission. *See* Memorandum of Points and Authorities in Opposition to Motion to Dismiss, filed June 21, 2007, at 9-17; *cf. Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982); *Fair Housing of Marin v. Combs*, 285 F.3d 899, 905 (9th Cir. 2002). Likely for these reasons, this Court implicitly rejected the government's arguments on standing when it issued its opinion and order dismissing ASA's original complaint with leave to amend.[4]

II. ASA HAS STATED A CLAIM THAT HHS HAS UNLAWFULLY WITHELD OR UNREASONABLY DELAYED A SUBSTANTIVE RESPONSE TO ITS IQA PETITION

A. Legal Standards

Because an administrative agency's unjustified delay undermines public confidence in the administrative process, *see Smith v. Illinois Bell Tel. Co.*, 270 U.S. 587, 591 (1926), and signals a "breakdown of regulatory processes," *Cutler v. Hayes*, 818 F.2d 879, 897 n.156 (D.C. Cir. 1987), the APA requires courts to "compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1); *see also* 5 U.S.C. § 555(b) ("With due regard for the

[4] HHS also contends that plaintiff's interests as an advocacy organization are outside the zone of interests of the IQA, which deprives it of prudential standing. *See* Second Motion to Dismiss at 10 n.7. ASA has explained why this is not so, *see* Opposition to Motion to Dismiss at 16-18, and this Court has implicitly agreed with ASA's position.

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."). To qualify for such relief under § 706(1), a plaintiff must assert "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, 61-63 (2004) (emphasis in original); *accord Center for Biological Diversity v. Veneman*, 394 F.3d 1108, 1111 (9th Cir. 2005). Once a plaintiff has shown this, the court will proceed to determine whether the agency's delay is unreasonable. *See infra* at 14-15**.** If so, the court must compel the agency to act, even if it does not dictate a particular result. *See SUWA*, 542 U.S. at 65; *Forest Guardians v. Babbitt*, 164 F.3d 1261, 1268-69 (10th Cir. 1998).

B. HHS's Failure to Provide a Substantive Response to ASA's IQA Petition Is a "Discrete Agency Action"

As an initial matter, HHS mischaracterizes a plaintiff's burden to obtain compulsion of agency action under the APA. Although the Ninth Circuit has analogized the *forms* of relief available under § 706(1) of the APA to an action for mandamus, *see Independence Mining Co. v. Babbitt*, 105 F.3d 502, 506-07 (9th Cir. 1997), it *analyzes* the substance of claims brought under the APA differently from those brought under the Mandamus and Venue Act, 28 U.S.C. § 1361. *See id.* at 507 n.6 ("we question the applicability of the traditional mandamus remedy under the MVA where there is an adequate remedy under the APA"). So long as a plaintiff can show that the "agency failed to take a discrete agency action that it is required to take," he is entitled to a determination of the reasonableness of the agency's delay under the APA. *See SUWA*, 542 U.S. at 61-63. A plaintiff need not, in addition, demonstrate all the requisites for relief under the Mandamus Act, such as a ministerial duty and a clear and certain claim, as HHS contends. *See*

Independence Mining, 105 F.3d at 507 n.6; *cf.* Second Motion to Dismiss at 11 (citing *Oregon Natural Resources Council v. Harrell*, 52 F.3d 1499, 1508 (9th Cir. 1995)).[5]

HHS also misstates what a plaintiff must show to demonstrate a discrete agency action subject to judicial review under § 706(1). Whereas HHS contends that plaintiff fails to meet the prerequisites for relief under § 706(1) because "the 'agency action' sought to be compelled must qualify as 'final agency action,'" Second Motion to Dismiss at 12-14, this is not the standard. In *SUWA*, the Supreme Court explained that a "discrete agency action" subject to review under § 706(1) is defined by 5 U.S.C. § 551(13), which defines "agency action" to include an agency "denial" of "relief" ("or the equivalent" thereof), or "failure to act" with regard to "relief." *See SUWA*, 542 U.S. at 62-63; 5 U.S.C. § 551(13). 5 U.S.C. § 551(11)(C), in turn, defines "relief" to include agency "action on the application or petition of, and beneficial to, a person." Thus, under the plain wording of the APA, the denial of, or failure to act upon a petition – in this case, a petition for the correction of information under the IQA – constitutes a discrete "agency action" subject to review under § 706(1). Consequently, courts have routinely entertained suits under the APA for denials of administrative petitions. *See*, *e.g., American Rivers and Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004) (reviewing delayed response to petition brought under Endangered Species Act "FERC is obligated *under the APA* to respond to the 1997 petition") (emphasis in original); *Barber v. Widnall*, 78 F.3d 1419, 1421-22 (9th Cir. 1996)

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[5] This conclusion is buttressed by the distinction between agency action that is "unlawfully withheld" from agency action that is "unreasonably delayed." Whereas agency action that is "unlawfully withheld" involves an agency's failure to act within a statutorily prescribed deadline, "unreasonable delay" is based on a "rule of reason" and involves the court's consideration of multiple factors. *See Biodiversity Legal Foundation v. Badgley*, 309 F.23d 1166, 1176-77 n.11 (9th Cir. 2002); *Forest Guardians v. Babbitt*, 164 F.3d 1261, 1270-73 (10th Cir. 1998). HHS's contention is that there must be a clear, non-discretionary, ministerial duty, which implies the enforcement of a strict deadline. This is inconsistent with the legal definition of "unreasonable delay," which is not so rigid.

(reviewing Air Force denial of a "request for correction" of a military record, which the Court referred to as a "petition"); *Miller v. Lehman*, 801 F.2d 492 (D.C. Cir. 1986) (administrative petition to correct military records); *Spencer Enterprises, Inc., v. United States*, 345 F.3d 683, 688 (9th Cir. 2003) (administrative petition for immigrant investor visa); *Mendez-Gutierrez v. Ashcroft*, 340 F.3d 865 (9th Cir. 2003) (administrative petition for immigrant asylum); *Chang v. United States*, 327 F.3d 911 (9th Cir. 2003) (administrative immigration petition); *Keating v. FAA*, 610 F.2d 611 (9th Cir. 1979 (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); *Dickson v. Secy. of Defense*, 68 F.3d 1396 (D.C. Cir. 1995) (petition for waiver of time limits on filing of petition for correction of military records); *see also Air Brake Systems v. Mineta*, 357 F.3d 632, 645-46 (6th Cir. 2004) (noting in dicta that agency action on petition to promulgate or revise a motor vehicle safety standard would be subject to APA review).

C. HHS Is Legally Required to Provide a Substantive Response to ASA's IQA Petition

Both the PRA and the IQA, as well as the OMB and HHS Guidelines, make clear that an agency is legally required to take action on a petition for correction of information. The PRA states that agencies are "responsible for . . . complying with . . . policies established by the Director [of OMB]." 44 U.S.C. § 3506(a)(1)(B). And the IQA, which is part of the PRA, mandated that OMB issue guidelines that would "require" each Federal agency to establish administrative mechanisms "allowing affected persons to seek *and obtain* correction of information . . . ." Sec. 515(b)(2)(B) (emphasis added); *see also* 67 Fed. Reg. 8452, 8459 (Feb. 22, 2003) (OMB IQA Guidelines reiterating same requirement). Additionally, the OMB Guidelines state that agencies "shall specify appropriate time periods for agency decisions" on petitions for correction. 67 Fed. Reg. 8452, 8459 (Feb. 22, 2003); *see* HHS Guideline E

(requiring agency to respond to IQA petitions within 60 days). The use of terms "require" and "obtain," and the requirement to specify time periods for agency response, make clear that an agency is legally required to respond in a timely fashion to a petition for correction of information.

To overcome its legal duty to provide a timely substantive response to ASA's IQA petition, HHS cites *Salt Institute v. Leavitt*, 440 F.3d 156 (4th Cir. 2006), for the propositions that the IQA does not create any legal right to the correction of information enforceable in the courts and it "creates no legal rights in any third parties." Second Motion to Dismiss at 14-15 (citing *Salt Institute*, 440 F.3d at 159). Initially, the Fourth Circuit's opinion in *Salt Institute* was based exclusively on standing, *see id.* at 156, which is no longer at issue here. *See supra* at 9. Moreover, the Circuit opinion in *Salt Institute* makes no mention of, and contains no analysis of, the judicial review provisions of the APA; nor does it address the key plain language of the IQA ("obtain correction of information maintained and disseminated by the agency that does not comply with the [OMB] guidelines"), the pertinent OMB guideline requirements for petitions and the standards for quality of information, and the PRA provisions requiring agencies to comply with the OMB guideline requirements, 44 U.S.C. § 3506, issued pursuant to 44 U.S.C.§§ 3504 and 3516 and the IQA. More significantly, there is a crucial difference between the *Salt Institute* case and this one, as it currently stands. Whereas the plaintiffs in *Salt Institute* were requesting that the court direct a particular agency response to the IQA petition in the form of correction of information, ASA's First Amended Complaint seeks a different form of relief under § 706(1) – that the agency be compelled to provide *some* substantive response. *Cf. American Rivers and Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004) ("We are not concerned here with what answer FERC might ultimately give the petitioners; rather, we are reviewing its

failure to give them *any* answer for more than six years") (emphasis in original); *see also SUWA*, 542 U.S. at 63-64 (noting that Attorney General's Manual on the APA states that § 706(1) empowers a court only to compel an agency "to take action upon a matter, without directing *how* it shall act") (emphasis in original) (quoting Attorney General's Manual on the Administrative Procedure Act at 108 (1947)). To be entitled to a judicially compelled response under § 706(1), a plaintiff need only show that the requested agency action -- a substantive response to an IQA petition -- is "legally required," not that its own legal rights will be determined, which was the question in *Salt Institute*. Congress and OMB require administrative agencies, at the very least, to respond to IQA petitions. *See supra* at 12-13. This bare minimum compliance with the IQA and its Guidelines is all that ASA's third cause of action requests.

D. HHS's Delay in Responding to ASA's IQA Petition Is Unreasonable

The test for determining whether agency action has been unreasonably delayed is based on a "rule of reason," which includes consideration of the factors developed by the District of Columbia Circuit in *Telecommunications Research & Action Ctr. v. FCC* (*"TRAC"*), 750 F.2d 70, 80 (D.C. Cir. 1984); *see 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 non-exhaustive six *TRAC* factors 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, the 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."

750 F.2d at 79-80 (internal citations omitted); *see Brower*, 257 F.3d at 1068-69; *Independence Mining*, 105 F.3d at 507.

Rather than attempt to demonstrate the reasonableness of its more than three-year delay in responding substantively to ASA's IQA petition, HHS contends that it may put off a resolution forever, so long as it provides a "response" to the petition every 60 days. *See* Second Motion to Dismiss at 17-18 (citing HHS Guideline E). This cynical interpretation of HHS's IQA responsibilities not only does great violence to the obvious intent of the cited Guideline and the IQA, but it evidences the lack of justification for HHS's delay.

ASA filed its petition with HHS on October 4, 2004. After three interim responses, HHS, on April 20, 2005, stated that it had no obligation to provide a substantive response to ASA's petition. Notably, HHS provided no explanation why it needed so long to state this legal conclusion, which it must have known for months. More offensive still, after HHS announced to ASA that it was transferring ASA's IQA petition to the DEA, it delayed for over a year in responding to ASA's appeal before repeating to ASA that "HHS currently is in the process of concluding its comprehensive review of the publicly available peer reviewed literature on marijuana in order to make a recommendation to the DEA as to whether marijuana should continue to be controlled under the CSA." *See* First Amended Complaint ¶22. HHS still has not stated that it will ever provide a substantive response to ASA's petition; instead, it estimated that it would complete its analysis by September of 2006 and that would transmit this analysis, along with the July 12, 2007, response *to the DEA*. *See* First Amended Complaint ¶22 (emphasis added). For all anyone outside of these agencies knows, HHS may already have completed its analysis and forwarded it to the DEA without informing ASA.

Although Congress did not expressly provide a timetable for responses to IQA petitions, it required OMB to "issue guidelines ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by the agency," Section 515, § (b)(2)(A), and "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," Section 515, § (b)(2)(B). OMB, in its guidance to agencies, stated that "agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines." 67 Fed. Reg. 8452, 8459 (Feb. 22, 2002). The PRA makes the OMB Guidelines binding on all federal agencies. 44 U.S.C. § 3506(a)(1)(B).

In compliance with the OMB Guidelines, HHS, in a section entitled "Responsibility of the Agency," issued Guidelines requiring "[t]he agency [to] 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." HHS Guideline E. HHS's own Guidelines, therefore, recognize that 60 days is, in general, a reasonable time for it to respond to IQA petitions. Despite this, HHS so far has taken *nearly twenty times* this long and still has given no substantive response to ASA's petition. Especially when considered in light of HHS's gross failure to meet its estimated September 2006 date for concluding its analysis of marijuana as medicine, which it claimed in July of 2006 that was "in the process of concluding," *see*

http://aspe.hhs.gov/infoquality/request&response/20d7.pdf, this delay is unreasonable.[6] *Cf. Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1157 (D.C. Cir. 1983) (holding that OSHA's delay of three years in issuing standard regulating industrial exposure to ethylene oxide was unreasonable and compelling agency to act); *Sandoz, Inc. v. Leavitt*, 427 F.Supp.2d 29, 41 & n.13 (D.D.C. 2006) (holding that HHS's delay in acting on a new drug application for nearly 1000 days was unreasonable; "The defendant's briefing is particularly troubling in that it seems to take *TRAC* and *In Re Barr*[, 930 F.2d 72, 75 (D.C. Cir. 1991)] as *de facto* invitations for the FDA to not comply with Congress' mandates." "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 at 420); *Raymond Proffitt Foundation v. EPA*, 930 F.Supp. 1088, 1103 (E.D. Pa. 1996) (holding that nineteen month delay by EPA in preparing and publishing proposed regulations setting forth revised or new water quality standard for state was unreasonable and compelling agency to act).

Furthermore, HHS has violated its IQA Guidelines by transferring ASA's petition to the DEA in connection with a different, farther-reaching, and much slower process. Although the HHS Guidelines allow the agency to use existing procedures to respond to IQA complaints that arise in "rule-making 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," HHS Guideline E, no such procedure exists here. The marijuana rescheduling process is

[6] 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 review in less than 19 months. *See* http://www.iom.edu/CMS/3775/5608.aspx; http://books.nap.edu/openbook.php?record_id=6376&page=1. 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. This is not a complicated rule-making.

exceedingly slow -- far too slow to qualify as providing a timely alternative. One marijuana 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). Another was pending for more than six. *See Gettman v. DEA*, 290 F.3d 430 (D.C. Cir. 2002). The current rescheduling petition has been pending since October 9, 2002, with no end in sight. Although HHS has told ASA that it anticipated a conclusion by September of 2006, it is clear at this point that HHS's predictions of resolution anytime soon cannot be trusted. Whereas the IQA requires a prompt and timely response to requests for correction of information, the marijuana rescheduling process does not provide this.[7] HHS's failure to abide its own Guidelines providing that it will not transfer information correction petition issues to another proceeding if responding to the petition in a timely fashion would not unduly delay the other proceeding and the petitioner has shown a reasonable likelihood of actual harm from the transfer, further reveals the unreasonableness of HHS's delay. *Cf. Center for Biological Diversity v. Abraham*, 218 F.Supp.2d 1143, 1164 (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.").

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[7] This Court has expressed its frustration with the pace of this process as follows:

> The Court doubts whether a rescheduling petition is a reasonable alternative for all seriously ill patients whose physicians have recommended marijuana for therapeutic purposes. For example, such a petition was filed in 1972 and did not receive a final ruling from the Administrator of the Drug Enforcement Agency until 1992, and a final decision on appeal until 1994. *See Alliance for Cannabis Therapeutics v. Drug Enforcement Administrator*, 15 F.3d 1131 (D.C. Cir. 1994). 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.

United States v. Cannabis Cultivators Club, 5 F.Supp.2d 1086, 1102 (N.D. Cal. 1998).

What is most troubling about HHS's evasiveness and delay in responding to ASA's petition, however, is that the information involved is vital to the health of thousands of Americans. Numerous courts have recognized that "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake." *See, e.g., Brower v. Evans*, 257 F.3d 1058, 1068-69 (9th Cir. 2001) (quoting *Telecommunications Research & Action Ctr. v. FCC* ("*TRAC*"), 750 F.2d 70, 80 (D.C. Cir. 1984)); *Independence Mining Co. v. Babbitt*, 105 F.3d 502, 507 (9th Cir. 1997) (same); *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1157 (D.C. Cir. 1983). Consequently, HHS's own Guidelines provide that agencies responsible for dissemination of "vital health and medical information" have additional responsibilities to "ensur[e] the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public." HHS Guideline D.2.c.2. HHS, the federal agency charged with safeguarding the health of the American public, has brazenly disregarded its responsibilities under these Guidelines. Its pattern of delay and evasion suggests that, unless this Court intervenes and requires a response within a time certain, HHS will delay a providing a substantive response to ASA's IQA petition indefinitely.

As if this were not enough, it is clear that HHS has acted in bad faith in its treatment of the ASA petition. Although a finding of bad faith is not necessary for this Court to hold that HHS's delay in providing a definitive response to ASA's IQA petition is unreasonable, *TRAC*, 750 F.2d at 80 (quotation omitted), it is one factor that courts may consider, *see Independence Mining Co. v. Babbitt*, 105 F.3d 502, 510 (9th Cir. 1997); *Chevron U.S.A. Production Co. v. O'Leary*, 958 F.Supp. 1485, 1498 (E.D. Cal. 1997). Indeed, "[i]f the court determines that the agency [has] delay[ed] in bad faith, it should conclude that the delay is unreasonable." *Independence Mining*, 105 F.3d at 510 (quoting *Cutler v. Hayes,* 818 F.2d 879 (D.C.Cir.1987));

Chevron, 958 F.Supp at 1498; *see also McGrail & Rowley, Inc. v. Babbitt*, 986 F.Supp. 1386, 1391 (S.D. Fla. 1997), *aff'd* 226 F.3d 646 (11th Cir. 2000) (noting that the court may go beyond the administrative record where agency may have acted in bad faith). HHS's bad faith is manifested in numerous ways here. It delayed nearly two years before stating its legal conclusion that it need not respond directly to ASA's IQA petition when it must have known this all along. It violated its own Guidelines regarding transfer of IQA petitions. It violated its own Guidelines requiring it to state its reasons for delay in each of its responses to ASA, which it did not do. Moreover, even while telling ASA that "a comprehensive review [of the efficacy of marijuana for medical use] is essential to ensure that [HHS's] recommendation [to the DEA] is accurate" and [t]o address whether or not marijuana has a currently accepted medical use in the United States prior to completing our comprehensive review would prejudge the outcome of this process," *see* http://aspe.hhs.gov/infoquality/request&response/20d7.pdf, HHS felt confident enough of its knowledge of the state of the science on April 20, 2006, to disseminate on its FDA website an Inter-Agency Advisory reaffirming its previously disseminated conclusion that "marijuana . . . has no currently accepted medical use in treatment in the United States. . . ." *See* http:/www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html. HHS has acted in bad faith in its treatment of ASA's petition, dragging the process out intentionally solely for the purpose of delay.

III. THERE ARE NO OTHER LEGAL BARRIERS TO A JUDICIAL RESOLUTION OF ASA'S CLAIM OF AGENCY DELAY UNDER § 706(1)

Near the conclusion of its brief, HHS summarily repeats arguments it made previously, namely, that: the agency action requested by ASA is committed to agency discretion by law; the statements at issue were not disseminated by it; and ASA had an adequate remedy in court under the CSA. *See* Second Motion to Dismiss at 17-20. ASA already addressed these arguments in

its opposition to the first motion to dismiss, *see* Memorandum of Points and Authorities in Opposition to Motion to Dismiss, filed June 21, 2007, at 25-33, and this Court should reject them for the same reasons.

CONCLUSION

For all of the foregoing reasons, the motion to dismiss should be denied in its entirety and the Court should maintain jurisdiction over all of ASA's claims, since a substance response by HHS to ASA's IQA petition may constitute "final agency action" subject to judicial review under the APA.

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Respectfully Submitted,

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