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

EXCERPTS OF RECORD

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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. C-07-01049 WHA **NOTICE OF APPEAL**

Notice is hereby given that plaintiff Americans for Safe Access in the above named case hereby appeals to the Court of Appeals for the Ninth Circuit from the final judgment entered in this action on November 20, 2007.

DATED: December 20, 2007

Respectfully Submitted,

/s/ Joseph D. Elford
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AMERICANS FOR SAFE ACCESS

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

AMERICANS FOR SAFE ACCESS,

Plaintiff,

v.

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and the U.S. FOOD AND DRUG ADMINISTRATION,

Defendants.
/

No. C 07-01049 WHA

JUDGMENT

For the reasons stated in the accompanying order granting motion to dismiss, **FINAL JUDGMENT IS HEREBY ENTERED** in favor of defendants and against plaintiff. The Clerk **SHALL CLOSE THE FILE.**

IT IS SO ORDERED.

Dated: November 20, 2007.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

AMERICANS FOR SAFE ACCESS,

Plaintiff,

v.

The U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and the U.S. FOOD AND DRUG ADMINISTRATION,

Defendants.
/

No. C 07-01049 WHA

ORDER GRANTING MOTION TO DISMISS

INTRODUCTION

In this Administrative Procedure Act action, plaintiff Americans for Safe Access seeks to compel the United States Department of Health and Human Services to provide a "substantive" response to its petition to correct statements regarding the accepted medical use and efficacy of marijuana. Plaintiff filed its first amended complaint on August 17, 2007.

On motion to dismiss pursuant to Rule 12(b)(6), this order addresses the following two questions: (1) What constitutes an "agency action" under 5 U.S.C. 706(1), the provision of the APA which allows a court to "compel agency action unlawfully withheld or unreasonably delayed," and (2) Is adherence to guidelines promulgated under the requirements of the Information Quality Act legally required? This order finds that it is not necessary to reach a conclusion as to the first question because plaintiff has not shown that the action it seeks to compel is legally required. This order therefore **GRANTS** defendants' motion to dismiss.

STATEMENT

The Information Quality Act of 2000 directed the Office of Management and Budget to issue guidelines "that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies . . . ." Pub. L. No. 105-554 § 1(1)(3) [Title V. § 515] (Dec. 21, 2000) (published at 44 U.S.C. 3516 note 4(a)). The IQA directed OMB to include the following provisions in its guidelines: (1) that federal agencies issue their own guidelines not more than one year after OMB issues its guidelines; (2) that agencies "establish administrative mechanisms allowing affected person to seek and obtain correction of information maintained and disseminated by the agency that does not comply with [the OMB guidelines];" and (3) that agencies periodically report to the director of OMB the nature and number of complaints and how they were handled. *See* 44 U.S.C. 3516 note 4(b)(2).

The OMB guidelines, finalized on February 22, 2002, stated the following as to information-correction procedures:

> To facilitate public review, 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. These administrative mechanisms shall be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices.
>
> i. Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.
>
> ii. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration.

67 Fed. Reg. at 8459.

On October 1, 2002, pursuant to the IQA and the OMB guidelines, the United States Department of Health and Human Services implemented its own guidelines. The HHS guidelines established an information-correction procedure as follows:

> Based on a review of the information provided, the agency will determine whether a correction is warranted and if so, what action to take. The agency will respond to the requestor by letter or e-mail. The agency's response will explain the findings of the review and the actions that the agency will take, if any. The response will consider the nature and timeliness 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. The response will describe how the complainant may request reconsideration. 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.
>
> If the individual submitting the complaint does not agree with the agency's decision (including the corrective action), the complainant may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal shall state the reasons why the agency response is insufficient or inadequate. Complainants shall attach a copy of their original request and the agency response to it, clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal to the specific agency appeals address.
>
> The agency official who handles the original complaint will not have responsibility for resolving the appeal. 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.

http://aspe.hhs.gov/infoquality/Guidelines/index.shtml.

Plaintiff filed an information-correction request with HHS on October 4, 2004, asking HHS to correct information it was disseminating about the medical use of marijuana (Compl. ¶ 15). Specifically, plaintiff disagrees with defendants' statements that marijuana "has no currently accepted medical use in treatment in the United States" (Compl. ¶ 1). HHS responded on December 1, 2004, stating that it needed to consult with the Drug Enforcement Administration, which was contemporaneously reviewing a petition to reschedule marijuana, in order to provide a response. Plaintiff protested this response as inexcusable delay, but HHS

nevertheless continued to state that it needed more time to coordinate agency review (Compl. ¶¶ 18–19). On April 20, 2005, HHS denied plaintiff's information-correct petition, and plaintiff appealed on May 19, 2005. Subsequently, HHS made a series of interim responses noting that the process was still ongoing, and on July 12, 2006, noted that it anticipated providing a response by September 2006 in connection with a marijuana rescheduling petition pending before the DEA. According to plaintiff, this marked the conclusion of the administrative IQA petition process, as plaintiff was left without additional avenues of recourse (Compl. ¶¶ 19–22)).

Plaintiff filed suit on February 21, 2007, seeking declaratory and injunctive relief under the Administrative Procedure Act. On July 24, 2007, this Court granted defendants' motion to dismiss the original complaint for failure to state a claim under Rule 12(b)(6), but granted plaintiff leave to amend to proceed on a theory that defendants unlawfully withheld or delayed agency action by not providing a *substantive* response to plaintiff's information-correction petition. Plaintiff did so amend its complaint, and filed its amended complaint on August 17, 2007. Defendants then filed a second motion to dismiss under Rule 12(b)(6) on October 11, 2007.

ANALYSIS

1. "FINAL" AGENCY ACTION UNDER SECTION 706(1).

The APA allows judicial review of federal agency action that is either "made reviewable by statute [or] final agency action for which there is no other adequate remedy in a court." 5 U.S.C. 704. It also directs the reviewing court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. 706(1). A claim under Section 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*, 542 U.S. 55, 64 (2004).

Plaintiff argues that an action under Section 706(1) only needs to be a "discrete" action, not a "final agency action," stating that "courts have routinely entertained suits under the APA for denials of administrative petitions" (Opp. 11). Plaintiff cites numerous cases on this point, all of which are similarly unhelpful inasmuch as they all address final agency actions.

Defendants, however, note several decisions, including two district court decisions within the Ninth Circuit that have squarely addressed this question and have held that Section 706(1) requires that the action sought to be compelled must be final agency action. *See Elhaouat v. Miller*, 2007 WL 2332488 at *3 (E.D. Penn., Aug. 9, 2007); *High Sierra Hikers Ass'n v. United States Forest Serv.*, 436 F. Supp. 2d 1117, 1140 (E.D. Cal., June 8, 2006); *Friends of Yosemite Valley v. Scarlett*, 439 F. Supp. 2d 1074, 1086 (E.D. Cal., July 19, 2006). Ultimately it is not necessary for this order to rule on the question because plaintiff fails to meet the second requirement under Section 706(1); that the action to be compelled is legally required.

2. ACTION LEGALLY REQUIRED.

"[T]he only action that can be compelled under the APA is action legally *required*." *Norton*, 542 U.S. at 63. In this case, plaintiff argues that defendants have unreasonably delayed in making a substantive response, but a delay "cannot be unreasonable with respect to action that is not required." *Id.* at 63 n.1. Plaintiff argues that the language in the IQA, which directs the OMB to issue guidelines that would "require" agencies to issue their own guidelines that would allow "affected persons to seek and obtain correction of information" creates a legal requirement (Opp. 12) (quoting 67 Fed. Reg. 8452, 8459 (Feb. 22, 2003)). Furthermore, plaintiff notes that the OMB guidelines state that agencies "shall specify appropriate time periods for agency decisions." *Ibid.* As stated above, the HHS guidelines direct the agency to respond to requests for correction and appeals within sixty days.

Defendants rely on *Salt Institute v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006), in which the Fourth Circuit held that the IQA "creates no legal rights in any third parties." Defendants further argue that the HHS guidelines do not impose a strict deadline because they only state that "[t]he agency will respond to all requests for correction within 60 calendar days of receipt," and if the requests requires more than 60 days, the agency "will inform the complainant that more time is required and indicate the reason why." http://aspe.hhs.gov/infoquality/Guidelines/index.shtml. Plaintiff does not dispute that defendants *did* respond but, instead, argues that defendants' response amounted to a "nonsubstantive final denial" (Compl. ¶ 22).

Defendants also contend that the OMB guidelines do not *mandate* a substantive response, but instead "underscore the 'flexibility' that the guidelines give the agencies" (Reply 16). Guidelines are by nature advisory, but the Ninth Circuit has recognized that "[a]n agency's regulations *may* create judicially enforceable duties." *Lowry v. Barnhart*, 329 F.3d 1019, 1022 (9th Cir. 2003) (emphasis added). In *Salt Institute v. Thompson*, 345 F. Supp. 2d 589, 602 (E.D. Va., Nov. 15, 2004), however, Judge Gerald Lee considered whether an agency's actions under the IQA and the OMB guidelines were judicially reviewable and stated that "[a]gency dissemination of advisory information that has no legal impact has consistently been found inadequate to constitute final agency action and thus is unreviewable by federal courts under the APA." That decision held 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 in deciding a request to correct a prior communication." *Ibid.* The OMB guidelines give discretion to agencies by stating that "agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved." 67 Fed. Reg. at 8458.

In addition to the holding in *Salt Institute*, other courts have held similar language to allow discretion on the part of agencies, and render action not legally required. *See Steenholdt v. FAA*, 314 F.3d 633, 638 (D.C. Cir. 2003) (regulations allowing rescission of a designation for any reason the administration considers appropriate not judicially reviewable).

This order agrees that the IQA and OMB guidelines do not create a duty to perform legally required actions that are judicially reviewable. Since plaintiff has not shown that the action it seeks to compel is legally required, defendants' motion to dismiss for failure to state a claim must be **GRANTED**.

CONCLUSION

Plaintiff has failed to show that defendants have unreasonably delayed the performance of a legally required duty. For the above reasons, defendants' motion to dismiss for failure to

state a claim pursuant to Rule 12(b)(6) is hereby **GRANTED**. Further leave to amend is unwarranted. The Clerk shall close the file.

IT IS SO ORDERED.

Dated: November 20, 2007.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE

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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. C-07-01049 WHA **FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

I. INTRODUCTION

1. Despite numerous peer-reviewed scientific studies establishing that marijuana is effective in treating AIDS wasting syndrome, muscle spasticity, emesis, appetite loss, and

chronic pain, the Department of Health and Human Services ("HHS") continues to tell the public that marijuana "has no currently accepted medical use in treatment in the United States." This action is filed under the Information Quality Act, 44 U.S.C. § 3516, Statutory and Historical Notes, P.L. 106-554 ("Information Quality Act" or "IQA"), and the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*, to correct this and related false and misleading statements, as the Information Quality Act requires.

2. In 1995 and again in 2000, Congress recognized a problem with the quality and integrity of information disseminated by federal agencies, which prompted it to enact legislation to ensure the "quality, objectivity, utility, and integrity of information" disseminated by federal agencies. 44 U.S.C. § 3516, Statutory and Historical Notes, P.L. 106-554, Sec. 1(a)(3). Pursuant to this Act, HHS has a legal duty to consider petitions from the public to correct erroneous statements that it has disseminated and to correct information that does not comply with IQA guidelines. Here, nearly three years ago, plaintiff Americans for Safe Access ("ASA") submitted such a petition to HHS with respect to particular HHS claims that marijuana has no medical use. In support of its petition, ASA supplied citations to numerous scientific studies confirming the medical efficacy of marijuana, including a report from the prestigious National Institute of Medicine ("IOM") that was commissioned by the White House's Office of National Drug Control Policy ("ONDCP").

3. HHS responded by engaging in inexcusable delay and, ultimately, on July 12, 2006, HHS issued a nonsubstantive final denial of ASA's request, stating that it expected the issue to be resolved by the Drug Enforcement Administration ("DEA") in a different administrative proceeding Left with no other administrative recourse, ASA filed the instant suit challenging HHS' arbitrary and unlawful behavior, since the federal government's false

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statements deter sick and dying persons from seeking to obtain medicine that could provide them needed, and often life-saving, relief. When it comes to medical marijuana, HHS has failed in its avowed mission of "protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves."

II. JURISDICTION AND INTRADISTRICT ASSIGNMENT

4. Plaintiff ASA brings this action on behalf of itself and its members to redress the deprivation of rights secured to them under the APA, the Information Quality Act, and HHS' Guidelines implementing the IQA, 67 Fed.Reg. 61343 (Sept. 30, 2002).

5. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1361.

6. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) and Local Rule 3-5(b) because plaintiff ASA maintains its headquarters in Oakland, California, which is in this judicial district, and a substantial portion of the events giving rise to the complaint occurred in this judicial district.

III. THE PARTIES

7. Plaintiff AMERICANS FOR SAFE ACCESS ("ASA") is a non-profit corporation headquartered in Oakland, California that has as its primary purpose working to expand and protect the rights of patients to use marijuana for medical purposes, including providing outreach and education to the public regarding the use of marijuana for medical purposes. ASA's members and constituents include seriously ill persons who would have benefited from the use of marijuana for medical purposes, but who were deterred from using marijuana to ease their suffering, in part, by HHS' statement that marijuana "has no currently accepted medical use in treatment in the United States." ASA has devoted significant resources to combat this and

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related false statements, including the expenditure of 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. HHS' failure to correct its false statements that marijuana does not have any currently accepted medical use in treatment in the United States adversely affects the membership and constituency of ASA and causes ASA to suffer injury to its ability to carry out its mission, as well as causing ASA to suffer economic loss in staff pay, funds expended to produce educational materials, and in the inability to undertake other efforts to improve the access of seriously ill persons to medical marijuana.

8. Despite HHS' dissemination of false and misleading information about the effectiveness of marijuana in relieving the pain of victims of certain diseases, four ASA members obtained the correct information and it dramatically improved their lives.

a. For instance, ASA's Executive Director, Steph Sherer, suffers from a condition known as torticollis, which causes her to experience inflammation, muscle spasms, pain throughout her body, and decreased mobility in her neck. Until November of 2001, Ms. Sherer did not believe that marijuana had medical use, due to statements that it did not on federal websites; however, after Ms. Sherer suffered kidney damage from the large amounts of conventional pain killers she was taking, her physician recommended that she try marijuana. Ms. Sherer heeded her physician's advice and has successfully used marijuana since November of 2001 to reduce her inflammation, muscle spasms, and pain. Ms. Sherer founded ASA to share medical information with others in April of 2002.

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b. Victoria Lansford ("Lansford") is also an ASA constituent and member who resides in Blackfoot, Idaho. Ms. Lansford suffers from fibromyalgia, which causes her to suffer severe chronic pain and muscle spasms. Until 2002, Lansford used a regimen of pain medications, including a morphine patch and Oxycontin, because she did not believe marijuana had medical use, due in part to HHS' statements. In 2002, on the recommendation of her sister, Lansford started using medical marijuana to treat her chronic pain and muscle spasms. This use of marijuana has significantly improved Ms. Lansford's health and she has been able to stop using the highly addictive Oxycontin.

c. Jacqueline Patterson is an ASA member and constituent who resides in Bolinas, California. Patterson has cerebral palsy, which among its other symptoms impairs Patterson's speech and causes her to suffer muscle spasticity and pain. Until June of 2001, Ms. Patterson did not believe that marijuana was medicine because of the federal government's statements that it was not, but her husband eventually convinced her to try it. Since beginning to use medical marijuana, Ms. Patterson has significantly improved her ability to speak and rarely suffers the serious muscle spasms she experienced in her right arm.

d. Shane Kintvel is an ASA member and constituent who experiences chronic pain and muscle spasms as a result of a serious back injury. Until 2002, Mr. Kintvel, of Golden, Colorado, used conventional prescription pain medications, including morphine, to treat his chronic pain. He was led to believe that marijuana would not be effective for this purpose from information he received from his doctors and his review of federal government websites. In approximately July of 2002, however, Mr. Kintvel began using marijuana in place of prescription medications. According to the progress measured by Dr. Michael McMillan, Mr. Kintvel's current treating physician, Kintvel is now completely mobile, has discontinued his use

of morphine, and has lost more than fifty pounds that he had gained from taking large amounts of morphine and being unable to exercise.

9. Defendant DEPARTMENT OF HEALTH AND HUMAN SERVICES ("HHS") is an administrative agency of the federal government with its headquarters in Washington, D.C. HHS claims on its website that it is the "government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves." *See* http://www.hhs.gov/. In April of 2000, in response to a request to reclassify marijuana, HHS stated its finding that marijuana "has no currently accepted medical use in treatment in the United States." *Federal Register*, 66 Fed.Reg. 20038, 20039 (April 18, 2001). HHS continues to disseminate this and related statements through testimony to Congress and on FDA and government websites, such as http://www.fda.gov/ola/2004/marijuana0401.html; http://www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html; http://www.access.gpo.gov/su_docs/fedreg/a010418c.html; and http://www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr0418/fr0418a.html.

10. Defendant FOOD AND DRUG ADMINISTRATION ("FDA") is a federal agency within the Department of Health and Human Services. FDA claims as its mission that it is "responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health." *See* http//www.fda.gov/opacom/morechoices/mission.html. The FDA was assigned the task of evaluating marijuana for medical use by HHS and, in 2001, concluded that marijuana did not have any medical use. HHS' statements to this effect are predicated on the FDA's findings.

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IV. THE INFORMATION QUALITY ACT AND HHS' IMPLEMENTING GUIDELINES

11. Passed in 2000 as an amendment to the Paperwork Reduction Act of 1995, 44 U.S.C § 3501 *et seq.*, the Information Quality Act ("IQA") requires administrative agencies to develop guidelines to ensure the "quality, objectivity, utility, and integrity of information" they disseminate to the American public. In furtherance of this goal, the IQA requires all federal agencies to "[e]stablish 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." 44 U.S.C. § 3516, Statutory and Historical Notes.

12. In compliance with the IQA mandate, HHS promulgated Guidelines for seeking and obtaining corrections of information it disseminates. The HHS Guidelines are codified at 67 Fed.Reg. 61343 (Sept. 30, 2002) and can also be found at http://www.hhs.gov/infoquality/part1.html. Similar Guidelines, which are also applicable to HHS, have been promulgated by the Office of Budget and Management ("OMB") and are codified at 67 Fed.Reg. 8452 (Feb. 22, 2002).

13. The HHS Guidelines recognize that "'[q]uality' is an encompassing term comprising utility, objectivity, and integrity." HHS Guideline D.2.a. The Guidelines define the term "utility" as referring to the "usefulness of the information to its intended users, including the public. . . ." HHS Guideline D.2.b. "Objectivity" requires that "disseminated information [be] presented in an accurate, clear, complete, and unbiased manner." HHS Guideline D.2.c. The Guidelines further recognize that agencies responsible for dissemination of "vital health and medical information" have additional responsibilities to "ensur[e] the timely flow of vital

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information from agencies to medical providers, patients, health agencies, and the public." HHS Guideline D.2.c.2.

14. To allow public participation in ensuring these goals, the HHS Guidelines provide for both an initial petition to correct erroneous information that HHS has disseminated and an administrative appeal (or "Information Quality Appeal"). 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. In cases where a petition to review information disseminated in connection with another pending HHS action, "requests for correction will be considered prior to the final agency action or information product [in the other proceeding] in those cases where in the agency's judgment issuing an earlier response would not unduly delay issuance of the [other] 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 [in the other proceeding]." HHS Guidelines, Section E.

V. FACTS

15. On October 4, 2004, ASA filed with HHS a "Request for Correction of Information Disseminated by HHS Regarding the Medical Use of Marijuana" (hereinafter

"petition"). 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.

16. ASA's petition alleges that HHS has disseminated to the public, and is continuing to disseminate to the public, the statement that marijuana "has no currently accepted medical use in treatment in the United States." The petition alleges that this HHS statement, and the findings underlying it, are inaccurate, in violation of the IQA and the OMB and HHS IQA Guidelines. The ASA petition alleges with specificity why the HHS information dissemination is inaccurate, and requests specific corrections. In particular, the ASA petition alleges that numerous peer-reviewed studies, including the 1999 Institute of Medicine ("IOM") study commissioned by the ONDCP establish that marijuana is accepted in the United States as effective in treating various illnesses.

17. On December 1, 2004, HHS sent ASA an interim response to its October 4, 2004, petition. The interim response stated that HHS had not yet completed its review of the ASA petition, due to other agency priorities and the need to coordinate agency review. HHS contended that it needed to consult with the Drug Enforcement Administration ("DEA"), which was considering a petition to reschedule marijuana, to prepare a response, and that it hoped to provide a response within the next 60 days.

18. 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.

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19. Nevertheless, HHS provided a series of interim responses over the next several months stating that it needed additional time to coordinate agency review. 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. 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."

20. 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.

21. ASA's May 19, 2005, appeal protested that: (a) HHS was evading its data quality responsibilities and delaying a response in contravention of its Guidelines, especially by referring the issues raised by the ASA Petition to a proceeding 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 merging the proceedings would not allow the consideration of data quality issues "on a timely basis," as required by the HHS Guidelines, and (c) HHS had ignored its Guidelines stating that data quality complaints must be acted upon in a timely fashion where there is a reasonable likelihood that persons were suffering actual harm from the inaccurate information being disseminated by the agency. ASA alleged that "seriously ill persons represented by ASA are suffering from being misled about the medical benefits of marijuana [by HHS]."

22. Again, commencing on July 28, 2005, HHS sent ASA a series of interim responses to its appeal over a period of more than eleven months, stating 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." Then, on July 12, 2006, HHS

sent ASA a nonsubstantive final denial of the appeal that does not meet the requirements of the IQA, the Guidelines issued by HHS and OMB, and the APA. HHS did not address any of the allegations of the petition, but merely noted that it anticipated providing a response to the Drug Enforcement Administration ("DEA") by September 2006, in connection with a marijuana rescheduling petition that had been pending before the DEA since October 9, 2002. This marks the conclusion of the administrative IQA petition process, as ASA has no additional administrative avenues of recourse.

23. HHS' failure to provide a substantive response to ASA's petition has a direct and immediate effect on the day-to-day operations of ASA. As a direct and proximate result of defendants' actions, ASA has suffered, and will continue to suffer, the loss of staff time, economic resources, and impairment of its mission. In particular, to combat HHS' dissemination of inaccurate statements that marijuana does not have any accepted medical use, ASA has spent more than one hundred thousand dollars and expended hundreds of hours of staff time producing and disseminating educational materials explaining that marijuana has medical use in the treatment of cancer, HIV/AIDS, multiple sclerosis, arthritis, gastrointestinal disorders, and chronic pain. This, in turn, causes ASA economic loss in staff pay and funds expended to produce educational materials, and it impedes ASA's mission of undertaking other efforts to improve the access of qualified patients to medical marijuana.

24. Furthermore, as a direct and proximate result of defendants' actions, ASA and its members and constituents -- which include seriously ill persons who would have benefited, or might benefit from the use of marijuana for medical purposes, but whose use of marijuana for health reasons has been impeded by HHS' flawed statement that marijuana does not have medical use -- have been irreparably harmed and continue to be harmed.

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25. If not enjoined by this Court, defendants will continue to disseminate inaccurate statements that marijuana "has no currently accepted medical use in treatment in the United States," in derogation of the rights of ASA, its constituents, and other similarly situated persons, and it will refuse to correct this false and misleading information, as legally required by the IQA.

VII. FIRST CAUSE OF ACTION

26. HHS' denial of the petition and appeal of ASA under the IQA constitutes final agency action that is arbitrary, capricious, an abuse of discretion, not in accordance with law, and in excess of statutory authority and limitations within the meaning of the APA (5 U.S.C. § 706(2)(A) & (C)).

VIII. SECOND CAUSE OF ACTION

27. HHS' denial of the ASA petition and appeal without providing a valid substantive response is arbitrary, capricious, an abuse of discretion, not in accordance with law, and in excess of statutory authority and limitations within the meaning of the APA (5 U.S.C. § 706(2)(A) & (C)).

IX. THIRD CAUSE OF ACTION

28. Alternatively, to the extent this Court does not consider HHS' denial of the ASA petition and appeal a final agency action, HHS has unlawfully withheld or unreasonably delayed providing a final agency action within the meaning of the APA (5 U.S.C. § 706(1)).

X. RELIEF SOUGHT

WHEREFORE, ASA, on behalf of itself, its constituents, and others similarly situated, seeks the following relief:

1. A declaration that the HHS' denial of ASA's petition and administrative appeal is arbitrary and capricious, an abuse of discretion, and not in accordance with law under the APA;

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2. A permanent injunction:

a. enjoining defendants from continuing to disseminate statements that marijuana "has no currently accepted medical use in treatment in the United States" or related statements, and

b. requiring HHS to make appropriate corrections to all statements that it has disseminated that marijuana "has no currently accepted medical use in treatment in the United States" and to all other related statements;

3. Alternatively to the relief sought in paragraphs 1 and 2, an order requiring HHS to provide a valid substantive response to the ASA petition that is in compliance with the IQA guidelines within 45 days, with the court to retain jurisdiction to review the agency's substantive response under the APA.

4. Costs and attorneys fees incurred in this action; and

5. Such other and further relief as may be just and proper.

DATED: August 17, 2007

Respectfully Submitted,

/s/ Joseph D. Elford
JOSEPH D. ELFORD
Attorney for Plaintiff
AMERICANS FOR SAFE ACCESS

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CERTIFICATION OF INTERESTED ENTITIES OR PERSONS

Pursuant to Civil L.R. 3-16, the undersigned certifies that as of this date, other than the named parties, there is no such interest to report.

DATED: August 17, 2007

Respectfully Submitted,

/s/ Joseph D. Elford
JOSEPH D. ELFORD
Attorney for Plaintiff
AMERICANS FOR SAFE ACCESS

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

AMERICANS FOR SAFE ACCESS,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and FOOD AND DRUG ADMINISTRATION,

Defendants.
_____/

No. C 07-01049 WHA

ORDER GRANTING MOTION TO DISMISS WITH LEAVE TO AMEND

INTRODUCTION

In this action under the Administrative Procedure Act, plaintiff Americans for Safe Access seeks to compel the US Department of Health and Human Service to correct statements that marijuana has no currently accepted medical use. Defendants' motion to dismiss plaintiff's claim pursuant to Rule 12(b)(6) is **GRANTED**. Plaintiff is granted leave to amend, however, with regard to whether defendants should be required to make a substantive response to plaintiff's information-correction petition.

STATEMENT

The Information Quality Act (IQA), also known as the Data Quality Act, provides that:

> The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504(d)(1) and 3516 [this section] of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for

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> 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 [this chapter], commonly referred to as the Paperwork Reduction Act.

Pub. L. No. 106–554, § 1(a)(3) [Title V, § 515](Dec. 21, 2000) (published at 44 U.S.C. 3516 note). In furtherance of the goals of the statute, the IQA requires 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 [of quality, objectivity, utility, and integrity of information]." *Ibid.*

Pursuant to the IQA, HHS has established administrative petition and review mechanisms by which parties can address their grievances. *See* United States Department of Health and Human Services, HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, *http://aspe.hhs.gov/infoquality/Guidelines/part1.shtml*.* The HHS guidelines provide for both an initial petition and an administrative appeal:

> Based on a review of the information provided, the agency will determine whether a correction is warranted and if, so what action to take. The agency will respond to the requestor by letter or e-mail. The agency's response will explain the findings of the review and the actions that the agency will take, if any. The response will consider the nature and timeliness 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. The response will describe how the complainant may request reconsideration. 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 . . . .
>
> If the individual submitting the complaint does not agree with the agency's decision (including the corrective action), the complainant may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal shall state the reasons why the agency response is insufficient or inadequate. Complainants shall attach a copy of their original request and the agency response to it,

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* These guidelines are only published on the HHS website; they do not appear in the Code of Federal Regulations.

> clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal to the specific agency appeals address.
>
> The agency official who handles the original complaint will not have responsibility for resolving the appeal. 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.

Ibid.

This action revolves around ongoing federal dissemination of information stating that marijuana lacks currently accepted medical use. Plaintiff Americans for Safe Access (ASA) is an advocacy organization, based in Oakland, which promotes increased access to medical marijuana. In October of 2004, ASA filed an IQA information-correction petition with HHS, asking that HHS revise and "correct" information it disseminated about medical marijuana. Specifically, ASA requested that four statements in a letter from the Surgeon General to the DEA Administrator, which were published in the Federal Register, be revised. These statements all generally suggested that marijuana "has no currently accepted medical use in the United States" (Compl. ¶ 16).

After some interim responses, in which HHS extended the time for review far longer than 60 days in order to consult with the Drug Enforcement Administration, HHS responded to plaintiff's petition on April 20, 2005. The response referred to the DEA's ongoing review of a separate marijuana-rescheduling petition under the Controlled Substances Act which had been pending since October 2002. This second petition was filed by the Coalition for Rescheduling Cannabis, an association of advocacy groups including plaintiff's organization. HHS said that "in the course of this [rescheduling] review, HHS will evaluate all the publicly available peer reviewed literature on the efficacy of marijuana" (Br. at 10). HHS therefore refused to either grant or deny plaintiff's petition.

Plaintiff filed a request for reconsideration with HHS on May 19, 2005, arguing that HHS was evading its data-quality responsibilities and delaying a response in contravention of its guidelines. HHS responded to this administrative appeal on July 12, 2006. The response did not

address plaintiff's purported scientific evidence and did not explicitly grant or deny plaintiff's petition. HHS did say, however, that it hoped to provide a response by September 2006 to the separate marijuana-rescheduling petition under the Controlled Substances Act. Although plaintiff had argued that "the CSA [rescheduling] process should not be utilized because of the length of time it involves," HHS responded that "a comprehensive review is essential to ensure that our recommendation [to DEA] is accurate" (Br. at 11). Plaintiff alleges in its complaint that HHS has still not responded to the separate marijuana-rescheduling petition. Plaintiff filed the present suit for declaratory and injunctive relief under the Administrative Procedure Act on February 21, 2007 (Compl. ¶ 15–22). This court has subject-matter jurisdiction because plaintiff presents a federal question pursuant to 28 U.S.C. 1331 and 1361.

ANALYSIS

The APA allows judicial review of federal agency action that is either "made reviewable by statute [or] final agency action for which there is no other adequate remedy in a court." 5 U.S.C. 704. This order holds that the IQA does not subject agency IQA decisions to judicial review. Nor is there any final agency action on the present record.

1. AGENCY FACT DETERMINATIONS ARE NOT JUDICIALLY REVIEWABLE UNDER THE IQA.

Although the Ninth Circuit has not addressed the issue, courts in other circuits have unanimously and persuasively rejected a right of judicial review under the Information Quality Act. True, the IQA directed the Office of Management and Budget to issue guidelines that provide "policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." Pub. L. No. 106–554, § 1(a)(3) [Title V, § 515]. The IQA, however, contained no provisions permitting judicial review of the information disseminated by agencies. Instead, the Act stated that the OMB must "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." *Ibid.* (emphasis added).

In the *Salt Institute* decision, a salt trade association brought suit under the IQA to correct and obtain data supporting the National Heart, Lung and Blood Institute's dissemination of data on the link between sodium intake and high blood pressure. The Fourth Circuit affirmed the district court's dismissal of the suit, stating that "the IQA . . . does not create any legal right to information or its correctness." *Salt Institute v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006). Without the existence of a legal right, the Fourth Circuit held that the plaintiff "failed to establish an injury in fact sufficient to satisfy Article III." *Ibid.* The only remedy for IQA claims, therefore, was held to be in the administrative process provided by the statute: "[t]he language of the IQA reflects Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts." *Salt Institute v. Thompson*, 345 F. Supp. 2d 589, 601 (E.D. Va. 2004) (Lee, J.).

The only other federal court to consider an IQA claim also dismissed the suit due to lack of a right to judicial review. *In re Operation of the Missouri River System Litigation*, 363 F. Supp. 2d 1145, 1174 (D. Minn. 2004) (Magnuson, J.), *vacated in part and aff'd in part on other grounds*, 421 F.3d 618 (8th Cir. 2005), held that the IQA provided no meaningful standard of review for APA claims. *Missouri River* held that although the IQA requires the OMB to issue guidelines that ensure the "quality, objectivity, utility, and integrity" of information disseminated by the government, "the plain language of the legislation fails to define these terms." *Id.* at 1174–75. Additionally, since "the history of the legislation fails to provide any indication of the scope of these terms," and "absent any 'meaningful standard' against which to evaluate the agency's discretion," the court held Congress did not intend to permit judicial review of IQA information correction requests. Instead, *Missouri River* concluded that since the IQA was "drawn in such broad terms," "there is no law to apply," and the "agency action is committed to agency discretion." *Ibid.*

The Ninth Circuit has not yet addressed the question. But the decisions from the Fourth Circuit and the District of Minnesota are persuasive. The IQA provided only an administrative remedy. Plaintiff would distinguish the *Salt Institute* decision as "decided the

way it was because the corporate plaintiff in that case was seeking to *obtain* information . . . under the IQA, not [to] *correct* erroneous information" (Opp. 24). A quick reading of the *Salt Institute* decision shows that the plaintiff there was attempting both to *obtain* and *correct* information. The *Salt Institute* plaintiff took issue with the government's publication of findings that *all* Americans, rather than just some subgroups, could reduce their blood pressure by lessening their sodium consumption. Seeking to show that this relationship only occurred in certain groups of Americans, the plaintiff in *Salt Institute* sought for the government to publicize the raw data that supported the government's findings.

2. FINAL AGENCY ACTION IS LACKING.

Plaintiff's other avenue for suit under the APA would be if defendants' denial of plaintiff's information quality appeals constituted final agency action. Agency action is defined under the APA as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. 551. In order for an agency action to be final, two conditions must be met. "First, the action must mark the consummation of the agency's decision-making process — it must not be of a merely tentative or interlocutory nature." *Nippon Miniature Bearing Corp. v. Weise*, 230 F.3d 1131, 1137 (9th Cir. 2000). Second, the agency action "must be one by which rights or obligations have been determined, or from which legal consequences flow." *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (internal citations and quotations omitted).

Neither requirement is satisfied. Plaintiff here challenges an alleged abuse of discretion in defendants' response to plaintiff's administrative appeals under the IQA. The agency, however, has not yet passed on the merits of the information-correction petition, so the agency process has not yet run its course. Plaintiff also fails to plead the second requirement of final agency action by failing to allege any facts that suggest that defendants' failure to correct their allegedly erroneous statements has any legal consequences, or that it determines any rights or obligations. Plaintiff argues that "the legal consequence of HHS's final decision denying ASA's [p]etition and appeal is that ASA has been deprived of its right under the IQA to seek and obtain the timely correction of incorrect information" (Opp. 20). As discussed, however, plaintiff has

failed to plead that the IQA grants any legal right to the correction of information. Plaintiff has identified no other legal consequences flowing from defendants' response to their IQA information correction request. Plaintiff has therefore failed to plead that defendants' response to their administrative appeal constituted final agency action. Since leave to amend shall be granted, perhaps the new pleadings will cure these shortfalls.

3. LEAVE TO AMEND IS WARRANTED.

At oral argument, plaintiff discussed a potential claim under 5 U.S.C. 706(1), for defendants' failure to respond in a timely manner and on the merits of their IQA petition. Plaintiff also raised this issue in a motion for summary judgment, arguing that "[defendants] cannot shrug off ASA's IQA Petition in this manner." Plaintiff suggested in the summary judgment brief that HHS neglected to follow its IQA guidelines, which require it to respond to information correction petitions in a substantive fashion within 60 days. In the summary judgment motion, plaintiff also alleges that HHS failed to meet its IQA responsibilities of making a substantive response by "lumping together ASA's narrow request for correction of information under the IQA with [the medical marijuana rescheduling petition,] a distinct, farther-reaching and much slower process."

Under the APA, a private party can bring suit to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. 706(1). Plaintiff, however, did not address the issue of defendants' "nonsubstantive" and delayed response to the IQA petition in the complaint. In the complaint, plaintiff raises a claim only under a different section of the APA, 5 U.S.C. 706(2)(A)&(C), alleging that defendants' response to their petition constituted final agency action in violation of the IQA. Plaintiff will be given leave to amend the complaint 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. Conceivably, a district court may order an agency to act on the merits of an information-correction petition within a specific time frame.

CONCLUSION

Plaintiff fails to identify a right to judicial review under the APA for denials of IQA information correction requests. Plaintiff therefore fails to state a claim upon which relief can be

granted. Defendants' motion to dismiss is hereby **GRANTED**. Plaintiff, however, will be given leave to amend to proceed on a theory that defendants unlawfully withheld or delayed agency action by not giving a substantive response to plaintiff's petition. Any amended complaint must be filed by **AUGUST 17, 2007**.

IT IS SO ORDERED.

Dated: July 24, 2007.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE

BEFORE THE UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
INFORMATION QUALITY GUIDELINES STAFF

Re: HHS Review of the 1995 Marijuana Rescheduling Petition: 66 Federal Register 20040 (April 18, 2001) at pages 20039 & 20051-52	)	**Docket No.**

REQUEST FOR CORRECTION OF INFORMATION DISSEMINATED BY HHS REGARDING THE MEDICAL USE OF MARIJUANA

AMERICANS FOR SAFE ACCESS
1700 SHATTUCK AVENUE #317
BERKELEY, CA 94709

Date: October 4, 2004

Request for Correction of Information Contained in
HHS Review of the Marijuana Rescheduling Petition of 1995

Filed by: Americans for Safe Access

ISSUE: The U.S. Department of Health and Human Services ("HHS") has blocked legal action to make marijuana available to *bona fide* medical patients under their physicians' supervision. In so doing, HHS repeatedly misstates the scientific evidence and ignores numerous reports and studies demonstrating the medical utility of marijuana and its constituent compounds. HHS disseminates these misstatements in correspondence and government websites. These disseminations violate the Data Quality Act requirement that information used and disseminated by federal agencies meet standards for "quality, objectivity, utility, and integrity of information." These standards have been defined as requiring lack of bias, consistency, and disclosure of the underlying rational basis for the agency's conclusion.

Specifically, in 2001, HHS issued statements in its review of the Marijuana Rescheduling Petition of 1995 that violate both government-wide data quality standards and the HHS guidelines implementing those standards. The conclusion of HHS that "marijuana has no currently accepted medical use in treatment in the United States" lacks objectivity, utility, transparency, peer review, and public participation. Thus, HHS has failed to ensure that the information it disseminates is based on sound science, as required by law.

Americans for Safe Access ("ASA") files this Request for Correction pursuant to the Data Quality Act amendments to the Paperwork Reduction Act, 44 U.S.C. § 3516 Statutory and Historical Notes, P.L. 106-554 ("Data Quality Act"), as implemented through the Office of Management and Budget's government-wide Data Quality Act guidelines, 67 Fed.Reg. 8452 (Feb. 22, 2002) ("OMB Guidelines"), and the HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, http:/www.hhs.gov/infoquality/part1.html ("HHS Guidelines").

PETITIONER: Americans for Safe Access ("ASA"), a non-profit advocacy group that represents the interests of medical marijuana patients, files this Request for Correction of HHS disseminations of information relating to the efficacy of marijuana for medical use. ASA brings this action on behalf of ill persons across the United States who are deeply and immediately affected by the controverted statements. HHS's statements about the lack of medical usefulness of marijuana harms these individuals in that it contributes to denying them access to medicine which will alleviate their suffering. The seriously ill persons ASA represents suffer variously from cancer and the side-effects of its treatments, Multiple Sclerosis, HIV/AIDS, spinal injury, and other medical conditions that produce chronic pain, nausea, loss of appetite and spasticity. Many of these persons who use marijuana to treat these symptoms cannot tolerate conventional medications or have serious health needs not treatable by pharmaceutical medicine.

RELIEF REQUESTED: ASA requests the following corrections:

1. HHS states that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition," which is disseminated on

federal government websites (http://www.access.gpo.gov/su_docs/fedreg/a010418c.html, http://www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr0418/fr0418a.htm) and in the *Federal Register*, 66 Fed.Reg. 20038, 20052 (April 18, 2001).

ASA requests that HHS replace this statement with the following statement: "**Adequate and well-recognized studies show the efficacy of marijuana in the treatment of nausea, loss of appetite, pain and spasticity.**"

2. HHS states that "a material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts" and "it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana," which are disseminated on the government websites and in the *Federal Register*, 66 Fed.Reg. 20038, 20052 (April 18, 2001).

   ASA requests that HHS replace this statement with the following statement: "**There is substantial consensus among experts in the relevant disciplines that marijuana is effective in treating nausea, loss of appetite, pain and spasticity. It is accepted as medicine by qualified experts.**"

3. HHS states that "a complete scientific analysis of all the chemical components found in marijuana has not been conducted," which is disseminated on the government websites and in the *Federal Register*, 66 Fed.Reg. 20038, 20051 (April 18, 2001).

   ASA requests that HHS replace this statement with the following statement: "**The chemistry of marijuana is known and reproducible.**"

4. HHS states that marijuana "has no currently accepted medical use in treatment in the United States," which is disseminated on the government websites and in the *Federal Register*, 66 Fed.Reg. 20038, 20039 (April 18, 2001).

   Based on the corrections above, ASA requests that HHS replace this statement with the following statement: "**Marijuana has a currently accepted use in treatment in the United States.**"

ASA files this Request for Correction pursuant to the Data Quality Act amendments to the Paperwork Reduction Act, 44 U.S.C. § 3516 Statutory and Historical Notes, P.L. 106-554 ("Data Quality Act"), as implemented through the Office of Management and Budget's government-wide Data Quality Act guidelines, 67 Fed.Reg. 8452 (Feb. 22, 2002) ("OMB Guidelines"), and the HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, http:/www.hhs.gov/infoquality/part1.html ("HHS Guidelines").

FACTUAL BACKGROUND: In 1995, Dr. Jon Gettman petitioned the Drug Enforcement Administration ("DEA") to initiate rulemaking proceedings to reschedule marijuana and other cannabinoids, pursuant to 21 U.S.C. § 811(a). In 1998, DEA requested that HHS conduct a scientific and medical evaluation of the available data and provide a scheduling recommendation for marijuana and the other cannabinoids. HHS's recommendations are binding on the DEA with respect to scientific and medical matters. 21 U.S.C. § 811(b).

HHS referred the matter to its Food and Drug Administration's ("FDA") Controlled Substances Staff, which found 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. 20038, 20051 (April 18, 2001).[1] Although the FDA recognized that FDA-approved safety studies had been carried out on marijuana and did not dispute that the scientific evidence is widely available (elements two and five), it found that marijuana had not satisfied the first, third and fourth requirements for accepted medical use. *Id.* at 20051-52. In particular, the agency 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. *Id.*
>
> [A] complete scientific analysis of all the chemical components found in marijuana has not been conducted. . . .

Based on these disputed findings, HHS determined that marijuana "has no currently accepted medical use in treatment in the United States," 66 Fed.Reg. 20038, 20039 (April 18, 2001), and recommended that marijuana continue to be subject to control under Schedule I of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA"). HHS continues to disseminate these disputed statements to the public through federal government websites, such as (http://www.access.gpo.gov/su_docs/fedreg/a010418c.html, http://www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr0418/fr0418a.htm). Consequently, these disputed statements are disseminations of information subject to the Data Quality Act Standards and Guidelines. *See* 67 Fed.Reg. 8452, 8460 (Feb. 22, 2002) (OMB Guidelines); HHS Guideline D.3.

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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).

ARGUMENT

I. LEGAL STANDARDS

Passed as an amendment to the Paperwork Reduction Act, 44 U.S.C. § 3502(1), the Data Quality Act requires administrative agencies to devise guidelines to ensure the "quality, objectivity, utility, and integrity of information" they disseminate and to "[e]stablish 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." (44 U.S.C. § 3516, Statutory and Historical Notes.) The HHS Guidelines recognize that "'[q]uality' is an encompassing term comprising utility, objectivity, and integrity." (HHS Guideline D.2.a.) The term "utility" refers to the "usefulness of the information to its intended users, including the public," so agency decisions must be transparent. (HHS Guideline D.2.b.) "Objectivity" refers to both presentation and substance, which requires that "disseminated information [be] presented in an accurate, clear, complete, and unbiased manner." (HHS Guideline D.2.c.) HHS must identify the supporting data and models in its scientific evaluations, so "the public can assess for itself whether there may be some reason to question the objectivity of the sources." (HHS Guideline D.2.c.) In short, the agency "must make their methods transparent by providing documentation, ensure quality by reviewing the underlying methods used, by consulting as needed with both experts and users, and by keeping users notified about corrections and revisions." 67 Fed.Reg. 8452, 8459 (Feb. 22, 2002).

Furthermore, where the agency is responsible for disseminating "influential" scientific, financial, or statistical information, it has heightened responsibilities under the Act to ensure that the data and methods employed in its decisionmaking is transparent. (HHS Guideline D.2.c.2.) "Influential" information "means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." (HHS Guideline D.2.i.) 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.) The HHS Guidelines recognize that "attention to information quality [is] a total and continuing process," which requires the agency to "stay informed of information needs and develop new data, and information products where appropriate." (HHS Guideline D.2.d & e.).

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II. HHS'S STATEMENTS ABOUT MARIJAUNA AS MEDICINE VIOLATE THE DATA QUALITY ACT'S UTILITY AND OBJECTIVITY STANDARDS BECAUSE THOSE STATEMENTS DO NOT REVEAL THE DATA ON WHICH THEY ARE BASED, IGNORE OPPOSING PEER-REVIEWED SCIENTIFIC STUDIES, AND HAVE BEEN CONTRADICTED BY NEW DATA

A. Numerous Peer-Reviewed Studies, Including the Institute of Medicine Study Commissioned by the Federal Government to Review the Medical Usefulness of Marijuana, Establish that Marijuana Is Effective in Treating Various Illnesses

Only by ignoring numerous peer-reviewed studies establishing that marijuana is effective in treating various illnesses can HHS assert that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition." 66 Fed.Reg. 20038, 20052 (April 18, 2001). Despite the federal government's refusal to either approve studies or make marijuana available to researchers, more than 6,500 published scientific articles on medical applications for marijuana are found in the National Library of Medicine's database (http:/pubmed.com). Of these, many are clinical studies that show marijuana's efficacy for treating pain, nausea, loss of appetite and spasticity. HHS's conclusion is even contradicted by data cited in a report to which HHS refers, *Marijuana as Medicine: Assessing the Science Base*, a comprehensive review of the therapeutic uses of marijuana prepared in 1999 by the Institute of Medicine ("IOM") commissioned by the White House's Office of National Drug Control Policy. That report found a medical basis for using marijuana as treatment for a variety of conditions.

Specifically, with respect to pain management, the IOM cited three double-blind, placebo-controlled studies on treating cancer pain, which found marijuana's primary psychoactive component to be comparable to codeine in effectiveness, but without the nausea and other debilitating side effects. (Noyes Jr R, Brunk SF, Baram DA, Canter A 1975a; Noyes R, Jr, Brunk SF, Avery DH, Canter A 1975b; Staquet M, Gantt C, Machin D 1978). The IOM also reports that an experimental study on pain showed that "cannabinoids were comparable with opiates in potency and efficacy. . . ."

Other research on marijuana's efficacy for pain management that HHS either failed to adequately consider or acknowledge includes a human study showing statistically significant increases in pain threshold after smoking marijuana (Milstein, MacCannell, Karr & Clark 1975) as well as numerous case studies of patients who voluntarily employed marijuana to treat painful conditions, including a woman whose severe juvenile rheumatoid arthritis was resistant to standard medicine but responsive to marijuana therapy (Grinspoon & Bakalar 1997, Randall 1991, Noyes & Baram 1974). As noted in the chapter on "The Role of Cannabis and Cannabinoids in Pain Management" in the sixth edition of *Pain Management: A Guide for Clinicians* (Russo 2003), "these accounts fulfill criteria of 'N-of-1 studies' and have been accepted by epidemiologists as proof of efficacy in rare conditions or ones in which blinded controlled trials are technically difficult (Guyatt, et al 1990, Larson 1990)." On the basis of these studies and other research published before the HHS response, a review of indications for medical treatment with marijuana concluded "any patient with pain unrelieved by conventional analgesics should have access to smoked marijuana" (Hollister 2000).

On treating nausea, the IOM reported on numerous clinical studies – including "a carefully controlled double-blind study" and a "a double-blind, cross-over, placebo-controlled study" – showing that both marijuana and select cannabinoids are effective antiemetics for patients suffering nausea and lack of appetite related to both cancer treatment and HIV/AIDS. In fact, the IOM concluded that marijuana is not only effective, but "[f]or patients such as those with AIDS or who are undergoing chemotherapy and who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad-spectrum relief not found in any other single medication."

Indeed, HHS ignores not only the data used but the conclusions reached by the IOM. Although the IOM report contains, as noted, information contradicting HHS's assertions, HHS refers only to the report's conclusions that "smoked marijuana is a crude drug delivery system that exposes patients to a significant number of harmful substances" and that additional studies are needed to assess its full medical efficacy. 66 Fed.Reg. 20038, 20047 (April 18, 2001). In doing this, HHS ignores the overall sense of the report's conclusions, which Principal Investigator Dr. John Benson, at the news conference releasing the IOM report, characterized as: "We concluded that there are some limited circumstances in which we recommend smoking marijuana for medical uses." HHS fails the objectivity standard of the Data Quality Act and its own Guidelines when it fails to consider the pertinent data used and conclusions reached by a study it cites. *See* HHS Guideline D.2.c ("in disseminating certain types of information to the public, other information must also be presented in order to ensure an accurate, clear, complete, and unbiased presentation").

Moreover, since the release of the IOM report and the HHS response, additional clinical studies on the medical efficacy of marijuana have been published in peer-reviewed journals. A review of clinical studies conducted in several states during the past two decades has shown that, in 768 patients, marijuana was a highly effective antiemetic in chemotherapy (Musty and Rossi 2001). Recent double-blind, placebo-controlled studies of HIV/AIDS patients showed that marijuana both reduced neuropathic pain and produced weight gain without immunological compromise (Abrams et al. 2003). Clinical studies of Multiple Sclerosis, for which there are few effective treatments, have shown cannabis extracts to be effective for spasticity and other symptoms (Wade et al. 2003; Zajicek et al. 2003), as well as chronic pain (Notcutt and Rangappa 2004). Three additional articles supporting the benefit of marijuana in treating MS patients for spasticity (Vaney), pain, sleep and spasticity (Wade) and bladder function (Brady) appear in the August 2004 issue of the journal *Multiple Sclerosis.* The non-psychoactive marijuana component cannibidol (CBD) has also been shown to have numerous medical applications as an anti-inflammatory and neuroprotective agent (Mechoulam, Parker, and Gallily 2002; Pertwee 2004; Russo 2003) (Mechoulam, Parker, and Gallily 2002; Pertwee 2004; Russo 2003) and as a treatment for rheumatoid arthritis (Malfait et al. 2000).

Lastly, a study of patients who have used standardized, heat-sterilized, quality-controlled medical marijuana as part of the federal government's Compassionate Investigational New Drug Program demonstrated the long-term clinical effectiveness of marijuana in treating chronic musculoskeletal pain, spasm and nausea, and spasticity of Multiple Sclerosis (Russo 2002). After using medical marijuana supplied by the federal government for periods ranging from 11 to 27 years, these patients showed no functionally significant problems in their physiological

systems, as determined by MRI scans of the brain, pulmonary function tests, chest X-ray, neuro-psychological tests, hormone and immunological assays, electroencephalography, P300 testing, and neurological clinical examination.

In the face of these carefully controlled scientific studies, many of which are funded and approved by the federal government, as well as the IOM report HHS cites, it is hardly accurate, or objective, to conclude that the efficacy of marijuana has not been scientifically assessed for any medical condition. Therefore, ASA requests that HHS withdraw its statement that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition," which is disseminated on federal government websites and in the *Federal Register*, 66 Fed.Reg. 20038, 20052 (April 18, 2001), and HHS replace it with the following statement: "Adequate and well-recognized studies show the efficacy of marijuana in the treatment of nausea, loss of appetite, pain and spasticity."

B. Qualified Experts Accept Marijuana for Medical Use

Without citing the basis for its finding, HHS states: "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." 66 Fed.Reg. 20038, 20052 (April 18, 2001). Because HHS does not reveal the data on which it relies in reaching this conclusion, it fails the utility and objectivity standards of the Data Quality Act, as the Act requires that agency decision-making be transparent. *See* HHS Guideline D.2.b & D.2.c.

Moreover, even if some unidentified experts still opine that marijuana is not appropriate for medical use, the majority opinion is to the contrary -- numerous experts agree that marijuana is effective in treating a variety of illnesses. As noted above, the IOM's Principal Investigator stated that the panel of experts convened by the IOM "concluded that there are some limited circumstances in which we recommend smoking marijuana for medical uses." And they are not alone. Before the enactment of any state laws legalizing the use of marijuana as medicine, a Harvard study found that 44% of oncologists were already recommending marijuana to their cancer patients (Doblin 1991). Even more indicated that they would advise their patients to use it if it were legal to do so. That widespread acceptance is also reflected in the numerous professional health organizations which have endorsed the medical use of marijuana. They include the American Public Health Association, the American Academy of Family Physicians, the American Nurses Association, the California Medical Association, the American Preventive Medical Association, the American Society of Addiction Medicine, and many more.

The current acceptance of marijuana as medicine in the United States is further evidenced by the thousands of American doctors who have recommended it to their patients, the tens of thousands of patients who are using it safely and effectively, and millions of American voters and two state legislatures that have approved its legal use as medicine. Furthermore, while the actions of other nations do not bear on the question of whether a practice is accepted in the United States, on the question of acceptance by experts, it is fair to note that marijuana is available by prescription in pharmacies in the Netherlands, and Health Canada is growing and distributing marijuana to patients there.

In any event, HHS's statement regarding consensus is doubly in error. First, no less an authority than the IOM Report cited by HHS states "there is substantial consensus among experts in the relevant disciplines" that marijuana is effective in treating pain, nausea, loss of appetite and anxiety. Secondly, even if there was not such agreement, universal agreement is not a reasonable standard for assessing medical practice, nor is it one of the five published requirements for an established medical use. In his 1988 ruling in favor of an earlier marijuana rescheduling petition, the DEA's Chief Administrative Law Judge Francis L. Young noted the standard for accepted medical use includes acceptance among patients and the public, which is incontrovertible for medical marijuana (Young 1988). That some experts might disagree does not deprive marijuana of its medical efficacy, if considered objectively. HHS's published criteria for accepted medical use requires only that "[t]he drug is accepted by qualified experts," 66 Fed.Reg. 20038, 20052 (April 18, 2001), not "a consensus of medical opinion," as HHS demands for marijuana. HHS fails the objectivity requirement of the Data Quality Act when it deviates from its published criteria in order to reach a decision. *See D&F Afonso Realty Trust v. Garvey*, 216 F.3d 1191, 1195 (D.C. Cir. 2000) ("we conclude that the FAA acted arbitrarily by issuing a hazard determination inconsistent with established standards"); *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C.Cir.1996) ("A long line of precedent has established that an agency action is arbitrary when the agency offer[s] insufficient reasons for treating similar situations differently"); *Airmark Corp. v. FAA*, 758 F.2d 685, 691 & 692 (D.C. Cir. 1985) ("Deference to agency authority or expertise . . . 'is not a license to . . . treat like cases differently.'" "At the very least, 'an agency . . . must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored'") (quotation omitted); *see also United States v. Diapulse Corporation of America*, 748 F.2d 56, 62 (D.C. Cir. 1984) ("we must insist that the FDA apply its scientific conclusions evenhandedly").

ASA requests that HHS retract its statements that "a material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts" and "[a]t this time, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana," which is disseminated on the federal government website and in the *Federal Register*, 66 Fed.Reg. 20038, 20052 (April 18, 2001). ASA requests that HHS replace it with the following statement: "There is substantial consensus among experts in the relevant disciplines that marijuana is effective in treating nausea, loss of appetite, pain and spasticity."

C. Peer-Reviewed Studies Establish that Marijuana's Chemistry Is Known and Reproducible

HHS fails the objectivity requirement for similar reasons in its treatment of the "known chemistry" requirement for accepted medical use. Whereas HHS has adopted and disseminated the FDA's finding that "a complete scientific analysis of all the chemical components found in marijuana has not been conducted," the known chemistry requirement published in the *Federal Register* requires only that the "drug's chemistry is known and reproducible," not that every one of its components be scientifically evaluated and analyzed. *See* 66 Fed.Reg. 20038, 20051 (April 18, 2001). Marijuana easily meets the published criterion. Numerous peer-reviewed studies characterize in detail the chemistry of marijuana. Its active components of marijuana are well known and well described, as are the mechanisms of biologic action in humans. The primary

psychoactive component, delta-9 tetrahydrocannabinol, was synthesized in the 1960s and is currently available in the United States as the Schedule III drug Dronabinol. Since the 1960s, researchers have isolated, synthesized and stereochemically defined 66 cannabinoid components, as well as scores of inactive metabolites. HHS makes clear, of those 66 cannabinoids, most are closely related, falling into only 10 groups, many of which differ by only a single chemical moiety, suggesting they are merely midpoints along biochemical pathways, such as degradation products, precursors, or byproducts. (Ross, Elsohly 1995; Turner, Elsohly, Boeren 1980.)

As the HHS report details, the biologic pathways of action are also well described, as are the CB1 and CB2 receptor sites of the endogenous cannabinoid system, with which marijuana interacts. Research on marijuana chemistry published between the time of the original petition and HHS's response seemingly was overlooked (Mechoulam and Ben-Shabat 1999), while additional research published since the HHS response further describes the chemistry of marijuana (Russo 2003; McPartland and Russo 2001; Elsohly 2002).

Only by ignoring these peer-reviewed studies and deviating from its announced criteria can HHS continue to disseminate to the public the statement that "a complete scientific analysis of all the chemical components found in marijuana has not been conducted." 66 Fed.Reg. 20038, 20051 (April 18, 2001). Both reveal bias on HHS's part and violate the objectivity requirement of the Data Quality Act and its Guidelines. *Cf.* HHS Guideline D.2.c. ("in disseminating certain types of information to the public, other information must also be presented in order to ensure an accurate, clear, complete, and unbiased presentation"); *D&F Afonso Realty Trust v. Garvey*, 216 F.3d 1191, 1195 (D.C. Cir. 2000) ("FAA acted arbitrarily by issuing a hazard determination inconsistent with established standards"); *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C.Cir.1996) ("agency action is arbitrary when the agency offer[s] insufficient reasons for treating similar situations differently"); *Airmark Corp. v. FAA*, 758 F.2d 685, 691 & 692 (D.C. Cir. 1985) ("At the very least, 'an agency . . . must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored'") (quotation omitted).

ASA requests that HHS withdraw its statement that "a complete scientific analysis of all the chemical components found in marijuana has not been conducted," which is disseminated on federal government websites and in the *Federal Register*, 66 Fed.Reg. 20038, 20051 (April 18, 2001), and replace it with the following statement: "The chemistry of marijuana is known and reproducible."

D. Marijuana Has A Currently Accepted Medical Use

Once HHS corrects the disputed statements described above, it must also correct its conclusion that marijuana "has no currently accepted medical use in treatment in the United States." 66 Fed.Reg. 20038, 20039 (April 18, 2001). This conclusion is based on the FDA's finding that marijuana fails the first, third and fifth requirements for accepted medical use. 66 Fed.Reg. 20038, 20051-52 (April 18, 2001). The corrections sought by petitioner, however, would reverse these findings, and necessitate the conclusion that marijuana does, in fact, have a currently accepted medical use in treatment in the United States.

ASA, therefore, requests that, if HHS makes the other three requested corrections, it withdraw its statement that marijuana "has no currently accepted medical use in treatment in the United States, which is disseminated on federal government websites and in the *Federal Register*," 66 Fed.Reg. 20038, 20039 (April 18, 2001). ASA requests that HHS replace it with the following statement: "Marijuana has a currently accepted use in treatment in the United States."

III. ASA REPRESENTS SERIOUSLY ILL PERSONS WHO ARE DEEPLY AND IMMEDIATELY AFFECTED BY THE CONTROVERTED STATEMENTS BY HHS

ASA represents seriously ill persons across the United States who are deeply and immediately affected by the controverted statements by HHS.[2] HHS's statements about the lack of medical usefulness of marijuana harms these individuals in that it denies them access to medicine which will alleviate their suffering because these statements deter doctors from discussing and recommending marijuana to their patients. ASA seeks to ensure that doctors not be chilled in this manner by requesting that HHS's review of the medical efficacy of marijuana be based on sound science. Several HHS Guidelines recognize that application of the requirements of the Data Quality Act is especially appropriate to correct scientifically flawed statements about important public health and policy issues, of which this is one. *See* HHS Guidelines D.2.c.2, D.2.i & D.2.c.2; *see also* HHS Guideline D.2.h (noting that "[s]everal HHS agencies are responsible for dissemination of authoritative health, medical and safety information on a real time basis in order to protect the health of the public against urgent and emerging threats").

More importantly, HHS's statements play a crucial role in the DEA's marijuana rescheduling determination, as HHS's scientific and medical recommendations are binding on the DEA. 21 U.S.C. § 811(b). Should marijuana be rescheduled, its availability for medical use and additional research would increase tremendously, thereby alleviating the suffering of numerous medical marijuana patients throughout the United States represented by ASA, as well as the millions of Americans with conditions for which marijuana has been shown to be effective but who are unwilling to violate federal law to act on their doctors' considered expert advice.

DATED: October 4, 2004

Respectfully submitted,

JOSEPH D. ELFORD
Attorney for Petitioner
AMERICANS FOR SAFE ACCESS

STEPH SHERER
Executive Director for Petitioner
AMERICANS FOR SAFE ACCESS

[2] Steph Sherer, the Executive Director for ASA, is a medical marijuana patient who uses marijuana to treat chronic pain in her neck, upper back, and jaw, after conventional pain treatments proved harmful to her internal organs.

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(*Note:* Legal citations are included in the body of the petition)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 1 2004

Mr. Joseph D. Elford
Staff Attorney
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

Dear Mr. Elford:

This letter is an interim response to your October 4, 2004, complaint and request for correction pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, 114 Stat. 2763A-153 (2000), hereinafter referred to as the "Federal Data Quality Act," concerning the Department of Health and Human Services (HHS) Review of the Marijuana Rescheduling Petition of 1995. Your complaint has been referred to the Food and Drug Administration (FDA) for response. We will be consulting with the National Institute on Drug Abuse and the Drug Enforcement Administration in preparing our response.

Your complaint alleges that statements made by HHS in its review of the 1995 Marijuana Rescheduling Petition, which is published on federal government websites (http://www.access.gpo.gov/su docs/fedreg/a010418c.html, http://www.deadiversion.usdoj. gov/fed regs/notices/2001/fr0418/fr0418a.htm) and in the Federal Register, 66 Fed.Reg. 20038, 20052 (April 18, 2001) lack "objectivity, utility, transparency, peer review, and public participation" and need to be corrected. Your complaint requests that HHS replace each of the statement(s) within the HHS review with alternative statements.

FDA's data quality guidance, which is part of the Department of Health and Human Services *Guidelines for Ensuring the Quality of Information Disseminated to the Public*, September 30, 2002, states that FDA will respond to a data quality complaint within 60 days, either by issuing a decision or by informing you that more time is required to respond to the complaint, and providing you with an estimated decision date.

We have not yet completed our response to your complaint because of other agency priorities and the need to coordinate agency review of the response. We hope to provide you with a response within 60 days from the date of this letter.

If you have any questions, you may contact Terry Martin, Regulatory Health Project Manager, at 301-443-5591.

Sincerely,

Steven Galson, M.D., M.P.H
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Americans for Safe Access

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December 20, 2004

Terry Martin
Regulatory Health Project Manager
Department of Health and Human Services
Food and Drug Administration
Rockville, MD 20857

Re: Re: HHS Review of the 1995 Marijuana Rescheduling Petition: 66 Federal Register 20040 (April 18, 2001) at pages 20039 & 20051-52

Dear Ms. Martin:

I have received the letter of Dr. Steven Galson, dated December 1, 2004, regarding our request for correction of information pursuant to the Federal Data Quality Act. I write to express my concerns about your anticipated treatment of our request.

The Data Quality Act requires a prompt response by a government agency to a request for correction of information it disseminates, ordinarily within 60 days. Your agency has already requested 60 more days to respond to our request and has stated that it "hopes to provide [us] with a response within 60 days." *See* Letter from Steven Galson to Joseph D. Elford, dated December 1, 2004. Based on my conversations with Hillary McQuie at our office, I am not confident that your agency will meet that estimate.

Whereas our request for correction is aimed solely at findings regarding whether marijuana has a "currently accepted medical use in treatment in the United States," *see* 21 U.S.C. § 812(B)(1)(b), your agency has stated its intention to expand its inquiry to include

consideration of whether marijuana presents a "risk to public health," and given your intention to include input from NIDA, appear to intend to assess whether marijuana has a "high potential for abuse" under 21 U.S.C. § 812(B)(1)(a). This latter inquiry may be relevant to the marijuana rescheduling petition pending before you, but it is outside the scope of our Data Quality Act request. To ensure that our Data Quality Act request is given the expeditious treatment it deserves under the Data Quality Act Guidelines, I would request that you consider only our specific request for corrections regarding medical use and not delay your response because of a perceived need to address relative abuse potential. While I appreciate that you may wish to coordinate the various agency responses to our Data Quality Act request and the pending marijuana rescheduling petition, I believe that the procedures to be employed for the evaluation of these petitions are distinct and the Data Quality Act Guidelines have prescribed time limitations, which ought to be followed.

Sincerely,

Joseph D. Elford
Staff Attorney
Americans for Safe Access
(415) 573-7842

cc: Tommy Thompson; Lester M. Crawford; Representative Maurice Hinchey; Representative Sam Farr; Representative Barney Frank; Representative Dana Rohrbacher; Senator Richard Durbin; Senator Patrick Leahy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Ombudsman
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Food and Drug Administration
Rockville MD 20857

February 2, 2005

Joseph D. Elford, Esq.
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

RE: Request for Correction of Information Submitted by HHS Regarding the Medical Use of Marijuana

Dear Mr. Elford:

Your October 4, 2004, request for correction of information disseminated by the Department of Health and Human Services regarding the medical use of marijuana is still under review. While the goal of the Food and Drug Administration is to respond within 60 days to such requests, we are unable to do so in this case. We anticipate that a response will be forwarded to you by April 1, 2005.

Thank you for your interest in the quality of information disseminated by HHS. Should you have any questions, please contact Terry Martin, Regulatory Health Project Manager, at 301-443-5591.

Sincerely,

Laurie Lenkel

Laurie Lenkel
Office of the Ombudsman
Office of the Commissioner

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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April 5, 2005

Joseph D. Elford, Esq.
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

RE: Request for Correction of Information submitted by HHS
Regarding the Medical Use of Marijuana

Dear Mr. Elford:

Your request for correction of information submitted by the Department of Health and Human Services (DHHS) regarding the medical use of marijuana is still under review. Under FDA Guidelines for Ensuring the Quality of Information Disseminated to the Public" the goal is to respond to each request for correction within 60 days of receipt either by providing a decision on the request or, if the request will require more than 60 days to complete, informing the complainant that more time is required.

We wrote to you on February 2, 2005, indicating that we would need additional time to complete our response to your request and expected to reply by April 1, 2005. At this time we are continuing to prepare our response but require additional time to coordinate Agency review. We anticipate that a response will be forwarded to you by April 15, 2005.

Should you have any questions, please contact Terry Martin, Regulatory Project Manager, at 301-443-5591.

Sincerely,

Laurie Lenkel

Laurie Lenkel
Office of the Ombudsman

00051

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

APR 20 2005

Mr. Joseph D. Elford
Staff Attorney
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

Dear Mr. Elford:

This letter is in response to your October 4, 2004 request for correction concerning the Department of Health and Human Services (HHS) response to the Marijuana Rescheduling Petition of 1995,[1] pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, 114 Stat. 2763A-153 (2000), (Federal Data Quality Act). In your request, you ask the HHS to "correct" several statements made in its response to the 1995 petition.

Your request alleges that the HHS review of the 1995 Marijuana Rescheduling Petition violates the Data Quality Act requirement that information used and disseminated by federal agencies meet standards for "quality, objectivity, utility, and integrity of information" because it lacks "objectivity, utility, transparency, peer review, and public participation." You request that HHS replace "each of the following statement(s)" within the HHS response to the 1995 Marijuana Rescheduling Petition with alternative statements, as described below:

(a) The HHS statement that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition," should be replaced by:

"Adequate and well-recognized studies show the efficacy of marijuana in the treatment of nausea, loss of appetite, pain and spasticity."

(b) The HHS statements that "a material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts" and "it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana," should be replaced by:

"There is substantial consensus among experts in the relevant disciplines that marijuana is effective in treating nausea, loss of appetite, pain and spasticity. It is accepted as medicine by qualified experts."

[1] The HHS review of the 1995 Marijuana Rescheduling Petition was published by the United States Drug Enforcement Administration (DEA) in the Federal Register, Vol. 66, p. 20038, April 18, 2001, and at http://www.access.gpo.gov/su_docs/fedreg/a010418c.html and http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_register&docid=01-9306-filed.pdf.

(c) The HHS statement that "a complete scientific analysis of all the chemical components found in marijuana has not been conducted" should be replaced by:

"The chemistry of marijuana is known and reproducible."

(d) The HHS statement that marijuana "has no currently accepted medical use in treatment in the United States," should be replaced by:

"Marijuana has a currently accepted use in treatment in the United States."

The 1995 Marijuana Rescheduling Petition in the Federal Register, Vol. 66, p. 20038, April 18, 2001, was published by the Department of Justice/Drug Enforcement Administration (DEA), based in part on input from HHS. The Controlled Substances Act (CSA) establishes a mechanism by which any interested party may petition the DEA to change the schedule of a given substance (section 201(a)). Under the CSA, the Secretary of HHS has the responsibility to make a recommendation to DEA as to whether a specific drug or substance should be controlled under the CSA. We have consulted with DEA on your information quality request and we are providing them with a copy of our response.

Both the Office of Management and Budget (OMB) and the HHS Information Quality Guidelines provide that federal government agencies may use existing processes that are in place to address correction requests from the public. In the case of marijuana, HHS currently is in the process of conducting a review in response to the petition for change that was submitted to DEA in October 2002 by the Coalition for Rescheduling Cannabis (CRC), an association of public-interest groups and medical cannabis patients that includes the ASA.[2] In the course of the review, HHS will evaluate all the publicly available peer reviewed literature on the efficacy of marijuana.

In accord with HHS's implementing guidelines, if you do not agree with this decision on your request, you may send a request for reconsideration within 30 days of receipt of this decision. Your request for reconsideration should be designated as an "Information Quality Appeal" and should include a copy of your original request as well as this decision. Your appeal should state the reasons why you believe this response to your complaint is inadequate.

Sincerely,

RADM Arthur J. Lawrence
Assistant Surgeon General
Acting Principal Deputy Assistant Secretary
for Health

cc: Karen P. Tandy, Administrator
Drug Enforcement Administration

[2] You may wish to consider submitting the new data you cite in you data quality complaint to the DEA as an addendum to this petition.

INFORMATION QUALITY APPEAL

Re: HHS Review of the 1995 Marijuana Rescheduling Petition: 66 Federal Register 20040 (April 18, 2001) at pages 20039 & 20051-52

AMERICANS FOR SAFE ACCESS, ON BEHALF OF ITS INDIVIDUAL MEMBERS', APPEAL REQUESTING CORRECTION OF HHS RESPONSE TO 1995 MARIJUANA RESCHEDULING PETITION

May 19, 2005

VIA ELECTRONIC TRANSMISSION AND OVERNIGHT MAIL

Department of Health and Human Services
Food and Drug Administration
Office of the Ombudsman
5600 Fishers Lane
Room 14B03, HF-7
Rockville, MD 20857
informationquality@oc.fda.gov

Dear Sir or Madam:

In the interest of protecting the health and well-being of seriously ill persons who are suffering pain and other deleterious effects from following the Department of Health and Human Services' ("HHS") statements that marijuana does not have any medical use, Americans for Safe Access ("ASA") seeks reconsideration of your response to our October 4, 2004, Data Quality Act Request for Correction. That Request was constructively denied by HHS by letter, dated April 20, 2005. HHS's failure to correct its inaccurate statements that marijuana lacks medical use violates the goal of the Data Quality Act, Paperwork Reduction Act, 44 U.S.C. § 3516 Statutory and Historical Notes, P.L. 106-554, as well as its own implementing Guidelines, of ensuring the timely flow of vital health and safety information to the members of the public. As a result, many of ASA's members will continue to suffer.

I. PROCEDURAL HISTORY

On October 4, 2004, ASA submitted a Request for Correction of the specified portions of the HHS review HHS Review of the 1995 Marijuana Rescheduling Petition, 66 Federal Register

20040 (April 18, 2001) at pages 20039 & 20051-52. (*See* Exhibit A) As required by the HHS and FDA Guidelines, ASA's Request provided all the necessary information:

> (1) a detailed description of the specific material to be corrected;
> (2) the specific reasons and supporting documentation for believing that the information does not comply with OMB, HHS and FDA guidelines and is in error;
> (3) the specific recommendations for correcting the information;
> (4) a description of how ASA and its membership is affected by the information error, and
> (5) contact information for the individual submitting the request on ASA's behalf.

Without objection to the format, and without seeking further information from ASA, Dr. Steven Galston, Acting Director, Center for Drug Evaluation and Research, Food and Drug Administration, HHS, responded by letter, dated December 1, 2004, which stated that HHS would be consulting with the National Institute on Drug Abuse and the Drug Enforcement Administration in preparing its response and that it hoped to provide such response within an additional 60 days. Dr. Galston further stated that the delay was occasioned by "other agency priorities and the need to coordinate agency review of the response." (*See* Exhibit B)

In response, by letter dated December 20, 2004, ASA protested that HHS was inexcusably expanding its inquiry to include considerations outside the scope of ASA's Request for Correction and that such expansion would unduly delay an administrative response to ASA's Request. (*See* Exhibit C) HHS did not respond to this letter and, instead, by letter dated February 2, 2005, responded that it would be unable to respond to ASA's Request for Correction within the additional 60 days and that it anticipated that it would do so by April 1, 2005. (*See* Exhibit D)

On April 5, 2005, Laurie Lenkel from the Office of the Ombudsman, Office of the Commissioner, HHS, sent ASA another letter delaying the agency response, yet again, to April 15, 2005. (*See* Exhibit E) Then, by letter dated April 20, 2005, RADM Arthur L. Lawrence, Assistant Surgeon General, informed ASA that HHS would not act on its Data Quality Act Request, but would instead considered the information presented thereby in connection with a petition to reschedule marijuana, which has been pending since 2002. (*See* Exhibit F) This denial of ASA's Request for Correction states as follows:

> Both the Office of Management and Budget (OMB) and the HHS Information Quality Guidelines provide that federal government agencies may use existing processes that are in place to address correction requests from the public. In the case of marijuana, HHS currently is in the process of conducting a review in response to the petition for change that was submitted to DEA in October 2002 by the Coalition for Rescheduling Cannabis (CRC), an association of public-interest groups and medical cannabis patients that includes ASA. [footnote omitted] In the course of the review, HHS will evaluate all the publicly available peer reviewed literature on the efficacy of marijuana.

(Exhibit F at 2)

II. SPECIFIC REASONS WHY HHS'S RESPONSE IS INADEQUATE

Under HHS's own Information Quality Act Guidelines, the agency has a responsibility to respond to requests for correction of information in a prompt and timely manner. To this end, the HHS Guidelines state in the section entitled "Responsibility of the Agency" that "[t]he agency will respond to all requests for correction within 60 calendar days of receipt." Furthermore, 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.) In short, the Data Quality Act and the HHS Guidelines require prompt consideration of a request for correction of information, especially where vital health and medical information is at issue.

Nor can HHS evade its responsibilities under these temporal requirements by lumping a request for correction of information under the Data Quality Act together with a distinct, farther-reaching and much slower process. While the HHS Guidelines provide that the agency may use existing procedures to respond to information quality 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," no such procedures exist for a marijuana rescheduling petition. That process is slow. One such petition was pending for more than twenty-two years. (*See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994)) Another for more than six. (*See Gettman v. DEA*, 290 F.3d 430 (D.C. Cir. 2002)) And the current petition has been pending for nearly three years, with no end in sight. Unlike the discrete and specific requests for correction of information by ASA regarding the efficacy of marijuana for medical use (*see* Exhibit A), the pending marijuana rescheduling petition involves additional considerations, such as whether marijuana presents a "risk to public health" and whether it has a "high potential for abuse" under 21 U.S.C. § 812(B)(1)(a). HHS is violating both the letter and the spirit of the Data Quality Act, as well as its own Guidelines, by delaying indefinitely its review of ASA's Request for Correction by transferring the substance of that request to another agency.[1]

Meanwhile, medical marijuana patients and putative medical marijuana patients will be paying a steep price. As was stated in ASA's Request for Correction, medical marijuana patients suffer reduced access to medical marijuana, and doctors are chilled from discussing it with their patients, by the HHS's dissemination of scientifically flawed information that marijuana lacks currently accepted medical use. In particular, persons who would otherwise become medical marijuana patients to alleviate their suffering are deterred from doing so by the false information disseminated by HHS. Exacerbating this, doctors are unwilling to discuss the medical benefits of marijuana with their patients because of HHS's statements. (*See* Doblin, Richard and Kleiman, Mark, "Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes," *Journal of Clinical Oncology* 9(7), at pp. 1314-1319 (1991) (reporting that 48% of oncologists would recommend marijuana to at least some of their patients if it were legal).

[1] Even if the marijuana rescheduling petition resulted in the rescheduling of marijuana ,HHS would still have to act on ASA's Request for Correction, since such decision would not change the inaccurate statements made by HHS in 1995, which continue to be disseminated.

Even in cases where a request for correction is made to review information disseminated in connection with another pending HHS action, the HHS Guidelines require -- in a provision ignored by the agency's response -- that the agency consider the request for correction prior to the final agency action where 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, Section E) Here, a prompt response to ASA's Request would expedite, rather than delay, the DEA's consideration of the pending marijuana rescheduling petition and, in the interim, seriously ill persons represented by ASA are suffering from being misled about the medical benefits of marijuana. HHS should act on ASA's Request for Correction.

DATED: May 18, 2005

Respectfully submitted,

_____

JOSEPH D. ELFORD

Attorney for Petitioner
AMERICANS FOR SAFE ACCESS

Assistant Secretary for Health
Washington, D.C. 20201

July 28, 2005

Joseph D. Elford, Esq.
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

Dear Mr. Elford:

Your appeal of the denial of your Request for Corrections under the Office of Public Health and Science (OPHS) Guidelines for Ensuring the Quality of Information Disseminated to the Public, received by OPHS on May 20, is still under review. We could not respond within the 60 day guideline. At this time we are continuing to prepare our response but require additional time to coordinate Agency review. Our goal is to have a response to your appeal within 60 days of the date of this letter.

Sincerely yours,

Executive Officer,
Office of Public Health and Science,
Office of the Secretary,
Department of Health and Human Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Assistant Secretary for Health
Washington, D.C. 20201

October 5, 2005

Joseph D. Elford, Esq.
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

Dear Mr. Elford:

Your appeal of the denial of your Request for Corrections under the Office of Public Health and Science (OPHS) Guidelines for Ensuring the Quality of Information Disseminated to the Public, received by OPHS on May 20, is still under review.

We wrote to you on July 28, 2005 indicating that we would need additional time to complete our response to your appeal. At this time we are continuing to prepare our response but require additional time to coordinate Agency review. Our goal is to have a response to your appeal within 60 days of the date of this letter.

Sincerely,

John S. Jarman
Executive Officer,
Office of Public Health and Science,
Office of the Secretary,
Department of Health and Human Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Assistant Secretary for Health
Washington, D.C. 20201

December 8, 2005

Joseph D. Elford, Esq.
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

Dear Mr. Elford:

Your appeal of the denial of your Request for Corrections under the Office of Public Health and Science (OPHS) Guidelines for Ensuring the Quality of Information Disseminated to the Public, received by OPHS on May 20, is still under review.

We wrote to you on October 05, 2005 indicating that we would need additional time to complete our response to your appeal. At this time we are continuing to prepare our response but require additional time to coordinate Agency review. Our goal is to have a response to your appeal within 60 days of the date of this letter.

Sincerely,

John S. Jarman
Executive Officer,
Office of Public Health and Science,
Office of the Secretary,
Department of Health and Human Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Assistant Secretary for Health
Washington, D.C. 20201

February 7, 2006

Joseph D. Elford, Esq.
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

Dear Mr. Elford:

Your appeal of the denial of your Request for Corrections under the Office of Public Health and Science (OPHS) Guidelines for Ensuring the Quality of Information Disseminated to the Public, received by OPHS on May 20, 2005 is still under review.

We wrote to you on December 08, 2005 indicating that we would need additional time to complete our response to your appeal. At this time we are continuing to prepare our response but require additional time to coordinate Agency review. Our goal is to have a response to your appeal within 60 days of the date of this letter.

Sincerely,

John S. Jarman
Executive Officer,
Office of Public Health and Science,
Office of the Secretary,
Department of Health and Human Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Assistant Secretary for Health
Washington, D.C. 20201

April 12, 2006

Joseph D. Elford, Esq.
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

Dear Mr. Elford:

Your appeal of the denial of your Request for Corrections under the Office of Public Health and Science (OPHS) Guidelines for Ensuring the Quality of Information Disseminated to the Public, received by OPHS on May 20, 2005 is still under review.

We wrote to you on February 07, 2006 indicating that we would need additional time to complete our response to your appeal. At this time we are continuing to prepare our response but require additional time to coordinate Agency review. Our goal is to have a response to your appeal within 60 days of the date of this letter.

Sincerely,

John S. Jarman
Executive Officer,
Office of Public Health and Science,
Office of the Secretary,
Department of Health and Human Services

Americans for Safe Access

1322 Webster St., Ste. 208
Oakland, CA 94612
Phone: 510-251-1856
Fax: 510-251-2036
www.SafeAccessNow.org

Joseph D. Elford
Chief Counsel
Americans for Safe Access
1322 Webster St., Suite 208
Oakland, CA 94612
(415) 573-7842

May 2, 2006

John S. Jarman
Executive Officer
Office of Public Health and Science
Office of the Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Request for Correction of Information re 1995 Marijuana Rescheduling Petition

Dear Mr. Jarman:

I write to request an immediate response to our appeal of your denial of our Request for Correction of Information under the Data Quality Act, 44 U.S.C. § 3516, Statutory and Historical Notes, P.L. 106-554 ("The Act"). Although that appeal was received by the Office of Public Health and Science ("OPHS") on May 20, 2005, your office has repeatedly delayed in issuing a definitive response, claiming a need for "additional time to coordinate Agency review." *See* Letter from John S. Jarmin to Joseph D. Elford, dated April 12, 2006. Just eight days after the latest such letter, however, on April 20, 2006, the Food and Drug Administration ("FDA") publicly announced the results of this coordinated agency review in an Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is a Medicine. *See* Exhibit A. Now that these agencies -- the FDA, Drug Enforcement Administration and Office of National Drug Control Policy -- have already publicly announced that they "do not support the use of smoked marijuana for medical purposes," *id.*, there is no reason your office needs additional time to respond to our pending appeal for the reason you stated on April 12th.

As I explained previously, time is of the essence in a public health issue such as this one. The Data Quality Act is an amendment to the Paperwork Reduction Act of 1995, which requires administrative agencies to (1) develop guidelines to ensure the "quality, objectivity, utility, and integrity of information" they disseminate to the public and (2) "[e]stablish 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." 44 U.S.C. § 3516, Statutory and Historical Notes. Because the Act is intended to "ensur[e] the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public," the Department of Health and Human Services ("HHS") Guidelines require the agency to respond to such requests within 60 calendar days. *See* HHS Guideline D.2.c.2.

Pursuant to this law, on October 4, 2004, Americans for Safe Access ("ASA") filed a Request for Correction of information disseminated by HHS regarding the Marijuana Rescheduling Petition filed by Dr. Jon Gettman in 1995. More than eighteen months have elapsed since ASA filed this request and nearly a year has elapsed since ASA appealed the initial denial of this request. Coordinated agency review which caused this delay was unnecessary, *see* Letter from Joseph D. Elford to Dr. Steven Galston, dated December 20, 2004, but, now that it has been completed, this cannot possibly serve to justify an even greater delay. I hope and expect that HHS will issue a final determination of our appeal in the 60 days you anticipate. If not, ASA will file suit in federal district court to compel this.

Sincerely,

Joseph D. Elford

Joseph D. Elford
Chief Counsel
Americans for Safe Access
(415) 573-7842

JUL 12 2006

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

Mr. Joseph D. Elford
Staff Attorney
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142

Dear Mr. Elford:

This letter constitutes a response to the May 19, 2005 Request for Reconsideration (RFR) that you submitted on behalf of the Americans for Safe Access (ASA). Your reconsideration request was filed pursuant to the Information Quality Act of 2000 (Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Public Law No. 106-554, 114 Stat. 2763A-153). The RFR concerns the review by the Department of Health and Human Services (HHS) of the 1995 Marijuana Rescheduling Petition that was published by the United States Drug Enforcement Administration (DEA) in the Federal Register, Vol. 66, p. 20038, April 18, 2001.[1]

Your RFR claims that the statements made in the response to the 1995 Marijuana Rescheduling Petition lack "objectivity, utility, transparency, peer review, and public participation and that a prompt HHS response would expedite DEA consideration of the October 2002 petition filed by the Coalition for Rescheduling Cannabis, an association of public interest groups and medical cannabis patients that includes the ASA. Your request urges HHS to respond in a prompt and timely manner.

We understand your concerns and would like to thank you for your comments on the marijuana rescheduling process. As HHS explained in the response to your Request for Correction, the United States Congress has established a process to address rescheduling issues. The congressionally mandated Controlled Substances Act (CSA) in section 201(a) establishes a mechanism by which interested parties may petition the DEA to change the schedule of a given substance. Under the CSA, the Secretary of HHS has the responsibility to make recommendations concerning whether a specific substance or drug should be controlled.

In the preamble to the Office of Management and Budget (OMB) Information Quality Guidelines, OMB recognizes that many agencies already have processes in place to respond to public concerns and states that it is not the intent of OMB to require these agencies to establish new processes (67 F.R. at 8458). Similarly the HHS Part I and (Part II agency-specific) FDA Information Quality Guidelines provide that federal agencies may use existing processes that are in place to address information quality requests.

[1] The HHS review of the 1995 Marijuana Rescheduling Petition also is at http://www.access.gpo.gov/su_docs/fedreg/a010418c.html and http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_register&docid=01-9306-filed.pdf

In response to the October 2002 Marijuana Petition, 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. Your appeal request states that the CSA process should not be utilized because of the length of time it involves.

However, a comprehensive review is essential to ensure that our recommendation is accurate. To 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. We estimate that we will complete the analysis and transmit it to DEA in September 2006. We plan to send the DEA a copy of this response to your Request for Reconsideration. We hope that the information that we are providing you helps to clarify both the HHS information quality guidelines and the role of the Department of Health and Human Services in the marijuana rescheduling process.

Sincerely yours,

John O. Agwunobi
Assistant Secretary for Health

cc: Karen P. Tandy, Administrator
Drug Enforcement Administration

ADRMOP, APPEAL, CLOSED, E-Filing

U.S. District Court
California Northern District (San Francisco)
CIVIL DOCKET FOR CASE #: 3:07-cv-01049-WHA

Americans for Safe Access v. Department of Health and Human Services et al
Assigned to: Hon. William H. Alsup
Cause: 28:1331 Fed. Question

Date Filed: 02/21/2007
Date Terminated: 11/20/2007
Jury Demand: None
Nature of Suit: 890 Other Statutory Actions
Jurisdiction: U.S. Government Defendant

Plaintiff

Americans for Safe Access

represented by **Joseph D. Elford**
Americans for Safe Access
1322 Webster Street
Suite 208
Oakland, CA 94612
415-573-7842
Fax: 510-251-2036
Email: joeelford@yahoo.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Alan B. Morrison
559 Nathan Ave Way
Standford, CA 94305
650-725-9648
TERMINATED: 10/29/2007
ATTORNEY TO BE NOTICED

V.

Defendant

Department of Health and Human Services

represented by **Steven Yale Bressler**
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Ave., NW
Washington, DC 20530
(202) 514-4781
Email: steven.bressler@usdoj.gov
LEAD ATTORNEY

00067

ATTORNEY TO BE NOTICED

Defendant

Food and Drug Administration represented by **Steven Yale Bressler**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
02/21/2007	1	COMPLAINT FOR DECLARATORY RELIEF AND PERMANENT INJUNCTION against Department of Health and Human Services, Food and Drug Administration (Filing fee $ 350, receipt number 44611000360.). Filed byAmericans for Safe Access. (sis, COURT STAFF) (Filed on 2/21/2007) Additional attachment(s) added on 3/21/2007 (sis, COURT STAFF). (Entered: 02/22/2007)
02/21/2007		Summons Issued as to Department of Health and Human Services, Food and Drug Administration, U.S. Attorney and U.S. Attorney General (sis, COURT STAFF) (Filed on 2/21/2007) (Entered: 02/22/2007)
02/21/2007	2	MOTION for leave to appear in Pro Hac Vice (Receipt No. 44611000360) filed by Americans for Safe Access. (sis, COURT STAFF) (Filed on 2/21/2007) (Entered: 02/22/2007)
02/21/2007		Received Order re 2 MOTION for leave to appear in Pro Hac Vice by Americans for Safe Access. (sis, COURT STAFF) (Filed on 2/21/2007) (Entered: 02/22/2007)
02/21/2007	3	ADR SCHEDULING ORDER: Case Management Statement due by 5/17/2007. Case Management Conference set for 5/31/2007 11:00 AM. (sis, COURT STAFF) (Filed on 2/21/2007) (Entered: 02/22/2007)
02/21/2007	4	SUPPLEMENTAL ORDER TO ORDER SETTING INITIAL CASE MANAGEMENT CONFERENCE re 3 ADR Scheduling Order (sis, COURT STAFF) (Filed on 2/21/2007) (Entered: 02/22/2007)
02/21/2007		CASE DESIGNATED for Electronic Filing. (sis, COURT STAFF) (Filed on 2/21/2007) (Entered: 02/22/2007)
03/01/2007	5	NOTICE of Appearance by Steven Yale Bressler *on Behalf of All Defendants* (Bressler, Steven) (Filed on 3/1/2007) (Entered: 03/01/2007)
03/19/2007	6	CLERK'S NOTICE re: Failure to E-File and/or Failure to Register as an E-Filer (Doc. 1) (sis, COURT STAFF) (Filed on 3/19/2007) (Entered: 03/19/2007)
03/20/2007	7	ORDER by Judge William Alsup granting 2 Motion for Pro Hac Vice of Alan B. Morrison. (dt, COURT STAFF) (Filed on 3/20/2007) (Entered: 03/20/2007)

03/20/2007	8	*** DUPLICATE FILING - SEE DOC. #1 *** COMPLAINT against all defendants (Filing fee $ 350.). Filed byAmericans for Safe Access. (Elford, Joseph) (Filed on 3/20/2007) Modified on 3/21/2007 (sis, COURT STAFF). (Entered: 03/20/2007)
03/20/2007	9	SUMMONS Returned Executed by Americans for Safe Access. Department of Health and Human Services served on 2/21/2007, answer due 4/23/2007. (Attachments: # 1)(Elford, Joseph) (Filed on 3/20/2007) (Entered: 03/20/2007)
03/20/2007	10	SUMMONS Returned Executed by Americans for Safe Access. Food and Drug Administration served on 2/21/2007, answer due 4/23/2007. (Attachments: # 1)(Elford, Joseph) (Filed on 3/20/2007) (Entered: 03/20/2007)
04/09/2007	11	STIPULATION re 1 Complaint,, 3 ADR Scheduling Order *Requesting an Order Extending Defendants' Time to Respond to the Complaint Until May 25, 2007* by Department of Health and Human Services, Food and Drug Administration, Americans for Safe Access. (Attachments: # 1 Civil L.R. 6.2 Declaration of Steven Y. Bressler)(Bressler, Steven) (Filed on 4/9/2007) Modified on 4/9/2007 (sis, COURT STAFF). (Entered: 04/09/2007)
04/12/2007	12	ORDER RE STIPULATED REQUEST TO EXTEND TIME TO RESPOND TO COMPLAINT. Signed by Judge Alsup on April 12, 2007. (whalc1, COURT STAFF) (Filed on 4/12/2007) (Entered: 04/12/2007)
04/13/2007	13	STIPULATION re 1 Complaint, *Extending Defendants' Time to Answer or Otherwise Plead in Response to the Complaint Until May 25, 2007* by Americans for Safe Access, Department of Health and Human Services, Food and Drug Administration. (Bressler, Steven) (Filed on 4/13/2007) (Entered: 04/13/2007)
05/16/2007	14	ADR Clerks Notice re: Non-Compliance with Court Order. (tjs, COURT STAFF) (Filed on 5/16/2007) (Entered: 05/16/2007)
05/18/2007	15	NOTICE of need for ADR Phone Conference (ADR L.R. 3-5 d) (Elford, Joseph) (Filed on 5/18/2007) (Entered: 05/18/2007)
05/18/2007	16	STIPULATION by Americans for Safe Access. (Elford, Joseph) (Filed on 5/18/2007) (Entered: 05/18/2007)
05/18/2007	17	ORDER EXTENDING TIME TO FILE JOINT CASE MANAGEMENT STATEMENT [re 16 Stipulation filed by Americans for Safe Access]. Signed by Judge William Alsup on 5/18/2007. (whasec, COURT STAFF) (Filed on 5/18/2007) (Entered: 05/18/2007)
05/18/2007		Set/Reset Deadlines: Case Management Statement due by 5/23/2007. (sis, COURT STAFF) (Filed on 5/18/2007) (Entered: 05/21/2007)
05/21/2007	18	ADR Clerks Notice Setting ADR Phone Conference on 5/29/07 at 10:30 a.m. Please take note that plaintiff's counsel initiates the call to all parties. (tjs, COURT STAFF) (Filed on 5/21/2007) (Entered: 05/21/2007)

05/22/2007	19	STIPULATION *Requesting Order Permitting the Parties to Exceed the Local Rule 7-4(b) Page Limit* by Americans for Safe Access, Department of Health and Human Services, Food and Drug Administration. (Bressler, Steven) (Filed on 5/22/2007) (Entered: 05/22/2007)
05/23/2007	20	STIPULATION AND ORDER PERMITTING THE PARTIES TO EXCEED PAGE LIMITATION. Signed by Judge Alsup on May 23, 2007. (whalc1, COURT STAFF) (Filed on 5/23/2007) (Entered: 05/23/2007)
05/23/2007	21	JOINT CASE MANAGEMENT STATEMENT filed by Americans for Safe Access. (Elford, Joseph) (Filed on 5/23/2007) (Entered: 05/23/2007)
05/24/2007	22	MOTION for Summary Judgment filed by Americans for Safe Access. Motion Hearing set for 8/16/2007 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Elford, Joseph) (Filed on 5/24/2007) (Entered: 05/24/2007)
05/24/2007	23	Memorandum of Points and Authorities in Support of 22 Motion to Summary Judgment filed by Americans for Safe Access. Motion Hearing set for 8/16/2007 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Elford, Joseph) (Filed on 5/24/2007) Modified on 5/25/2007 (sis, COURT STAFF). (Entered: 05/24/2007)
05/24/2007	24	Declaration of Allayne Steph Sherer 22 filed byAmericans for Safe Access. (Attachments: # 1 Exhibit Condition Based Booklet# 2 Exhibit Invoices)(Elford, Joseph) (Filed on 5/24/2007) Modified on 5/25/2007 (sis, COURT STAFF). (Entered: 05/24/2007)
05/24/2007	25	NOTICE by Americans for Safe Access *Manual Filing of Declaration of Joseph D. Elford* (Elford, Joseph) (Filed on 5/24/2007) (Entered: 05/24/2007)
05/24/2007	26	Declaration 22 *Victoria Lansford in Support of Motion for Summary Judgment* filed byAmericans for Safe Access. (Elford, Joseph) (Filed on 5/24/2007) Modified on 5/25/2007 (sis, COURT STAFF). (Entered: 05/24/2007)
05/24/2007	27	Declaration 22 *Joseph Shayne Kintzel in Support of Motion for Summary Judgment* filed byAmericans for Safe Access. (Elford, Joseph) (Filed on 5/24/2007) Modified on 5/25/2007 (sis, COURT STAFF). (Entered: 05/24/2007)
05/24/2007	28	Declaration 22 *Jacqueline Patterson in Support of Motion for Summary Judgment* filed byAmericans for Safe Access. (Elford, Joseph) (Filed on 5/24/2007) Modified on 5/25/2007 (sis, COURT STAFF). (Entered: 05/24/2007)
05/24/2007	29	Declaration 22 *William Dolphin in Support of Motion for Summary Judgment* filed byAmericans for Safe Access. (Elford, Joseph) (Filed on 5/24/2007) Modified on 5/25/2007 (sis, COURT STAFF). (Entered: 05/24/2007)

05/24/2007	30	Proposed Order re 22 MOTION for Summary Judgment by Americans for Safe Access. (Elford, Joseph) (Filed on 5/24/2007) (Entered: 05/24/2007)
05/25/2007	31	MOTION to Dismiss for Lack of Jurisdiction *and, in the Alternative, for Failure to State a Claim Upon Which Relief May Be Granted* filed by Department of Health and Human Services, Food and Drug Administration. Motion Hearing set for 8/9/2007 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Bressler, Steven) (Filed on 5/25/2007) (Entered: 05/25/2007)
05/25/2007	32	Declaration of Joseph D. Elford in Support of 25 Notice (Other), 22 MOTION for Summary Judgment filed byAmericans for Safe Access. (Related document(s) 25 , 22) (sis, COURT STAFF) (Filed on 5/25/2007) (Entered: 05/25/2007)
05/29/2007		ADR Remark: ADR Phone Conference conducted on 5/29/07 by DB. (tjs, COURT STAFF) (Filed on 5/29/2007) (Entered: 05/29/2007)
05/31/2007	33	ORDER SETTING BRIEFING SCHEDULE FOR MOTION TO DISMISS AND VACATING HEARING ON PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT. Signed by Judge Alsup on May 31, 2007. (whalc1, COURT STAFF) (Filed on 5/31/2007) (Entered: 05/31/2007)
05/31/2007	34	Minute Entry: Initial Case Management Conference held on 5/31/2007 before William Alsup (Date Filed: 5/31/2007), Set Deadlines/Hearing as to 31 MOTION to Dismiss for Lack of Jurisdiction *and, in the Alternative, for Failure to State a Claim Upon Which Relief May Be Granted*: (Date Filed: 5/31/2007), Responses due by 6/21/2007. Replies due by 6/28/2007. Motion to Dismiss Hearing set for 7/12/2007 08:00 AM. (Court Reporter Kathy Powell.) (be, COURT STAFF) (Date Filed: 5/31/2007) (Entered: 05/31/2007)
06/21/2007	35	Memorandum in Opposition *to Motion to Dismiss 31* filed by Americans for Safe Access. (Elford, Joseph) (Filed on 6/21/2007) Modified on 6/22/2007 (sv, COURT STAFF). (Entered: 06/21/2007)
06/21/2007	36	Proposed Order *Denying Motion to Dismiss 31* by Americans for Safe Access. (Elford, Joseph) (Filed on 6/21/2007) Modified on 6/22/2007 (sv, COURT STAFF). (Entered: 06/21/2007)
06/27/2007	37	STIPULATION *Requesting an Order Permitting Defendants to Exceed the Page Limitation* by Americans for Safe Access, Department of Health and Human Services, Food and Drug Administration. (Bressler, Steven) (Filed on 6/27/2007) (Entered: 06/27/2007)
06/28/2007	38	STIPULATED REQUEST FOR ORDER PERMITTING DEFENDANTS TO EXCEED PAGE LIMITATION. Signed by Judge Alsup on June 28, 2007. (whalc1, COURT STAFF) (Filed on 6/28/2007) (Entered: 06/28/2007)
06/28/2007	39	Reply Memorandum re 31 MOTION to Dismiss for Lack of Jurisdiction *and, in the Alternative, for Failure to State a Claim Upon Which Relief May Be Granted* filed byDepartment of Health and Human Services, Food and Drug Administration. (Bressler, Steven) (Filed on 6/28/2007) (Entered:

		06/28/2007)
07/12/2007	40	Minute Entry: Motion Hearing held on 7/12/2007 before William Alsup (Date Filed: 7/12/2007) re 31 MOTION to Dismiss for Lack of Jurisdiction *and, in the Alternative, for Failure to State a Claim Upon Which Relief May Be Granted* filed by Department of Health and Human Services, Food and Drug Administration. (Court Reporter Jim Yeomans.) (dt, COURT STAFF) (Date Filed: 7/12/2007) (Entered: 07/12/2007)
07/24/2007	41	ORDER GRANTING MOTION TO DISMISS WITH LEAVE TO AMEND by Judge William Alsup [granting 31 Motion to Dismiss for Lack of Jurisdiction]. (whasec, COURT STAFF) (Filed on 7/24/2007) Additional attachment(s) added on 7/24/2007 (rbe, COURT STAFF). (Entered: 07/24/2007)
08/17/2007	42	AMENDED COMPLAINT against all defendants. Filed byAmericans for Safe Access. (Elford, Joseph) (Filed on 8/17/2007) (Entered: 08/17/2007)
08/28/2007	43	STIPULATION re 42 Amended Complaint *Extending Defendants' Time to Respond to Plaintiff's Amended Complaint Until and Including October 11, 2007* by Americans for Safe Access, Department of Health and Human Services, Food and Drug Administration. (Bressler, Steven) (Filed on 8/28/2007) (Entered: 08/28/2007)
09/06/2007	44	CLERK'S NOTICE Scheduling Case Management Conference set for 10/25/2007 11:00 AM. Case Management Statement due by 10/18/2007. (dt, COURT STAFF) (Filed on 9/6/2007) (Entered: 09/06/2007)
10/11/2007	45	MOTION to Dismiss *Plaintiff's Amended Complaint* filed by Department of Health and Human Services, Food and Drug Administration. Motion Hearing set for 11/15/2007 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Bressler, Steven) (Filed on 10/11/2007) (Entered: 10/11/2007)
10/11/2007	46	Proposed Order re 45 MOTION to Dismiss *Plaintiff's Amended Complaint* by Department of Health and Human Services, Food and Drug Administration. (Bressler, Steven) (Filed on 10/11/2007) (Entered: 10/11/2007)
10/15/2007	47	STIPULATION re 44 Clerk's Notice *Requesting That the Court Continue the Case Management Conference to November 15, 2007* by Americans for Safe Access, Department of Health and Human Services, Food and Drug Administration. (Bressler, Steven) (Filed on 10/15/2007) (Entered: 10/15/2007)
10/16/2007	48	STIPULATION AND ORDER CONTINUING CASE MANAGEMENT CONFERENCE [re 47 Stipulation, filed by Americans for Safe Access, Department of Health and Human Services, Food and Drug Administration]. Signed by Judge William Alsup on 10/16/2007. (whasec, COURT STAFF) (Filed on 10/16/2007) (Entered: 10/16/2007)
10/16/2007		Set Deadlines/Hearings: Case Management Statement due by 11/8/2007. Case Management Conference set for 11/15/2007 11:00 AM. (sis, COURT

		STAFF) (Filed on 10/16/2007) (Entered: 10/17/2007)
10/25/2007	49	MOTION to Withdraw as Attorney *(Alan B. Morrison)* filed by Americans for Safe Access. (Elford, Joseph) (Filed on 10/25/2007) (Entered: 10/25/2007)
10/25/2007	50	Proposed Order re 49 MOTION to Withdraw as Attorney *(Alan B. Morrison)* by Americans for Safe Access. (Elford, Joseph) (Filed on 10/25/2007) (Entered: 10/25/2007)
10/25/2007	51	Memorandum in Opposition 45 *to Motion to Dismiss First Amended Complaint* filed byAmericans for Safe Access. (Elford, Joseph) (Filed on 10/25/2007) Modified on 10/26/2007 (sis, COURT STAFF). (Entered: 10/25/2007)
10/29/2007	52	ORDER by Judge Alsup granting 49 Motion to Withdraw as Attorney. Attorney Alan B. Morrison terminated (whalc1, COURT STAFF) (Filed on 10/29/2007) (Entered: 10/29/2007)
11/01/2007	53	Reply Memorandum re 45 MOTION to Dismiss *Plaintiff's Amended Complaint* filed byDepartment of Health and Human Services, Food and Drug Administration. (Bressler, Steven) (Filed on 11/1/2007) (Entered: 11/01/2007)
11/09/2007	54	JOINT CASE MANAGEMENT STATEMENT filed by Americans for Safe Access, Department of Health and Human Services, Food and Drug Administration. (Bressler, Steven) (Filed on 11/9/2007) (Entered: 11/09/2007)
11/15/2007	55	Minute Entry: Motion Hearing held on 11/15/2007 before William Alsup (Date Filed: 11/15/2007) re 45 MOTION to Dismiss *Plaintiff's Amended Complaint* filed by Department of Health and Human Services, Food and Drug Administration. (Court Reporter Joan Columbini.) (dt, COURT STAFF) (Date Filed: 11/15/2007) (Entered: 11/15/2007)
11/15/2007	56	Letter from Joseph D. Elford. (Elford, Joseph) (Filed on 11/15/2007) (Entered: 11/15/2007)
11/20/2007	57	ORDER GRANTING MOTION TO DISMISS by Judge William Alsup [granting 45 Motion to Dismiss]. (whasec, COURT STAFF) (Filed on 11/20/2007) (Entered: 11/20/2007)
11/20/2007	58	JUDGMENT in favor of defendants and against plaintiff. Signed by Judge William Alsup on 11/20/2007. (whasec, COURT STAFF) (Filed on 11/20/2007) (Entered: 11/20/2007)
12/20/2007	59	NOTICE OF APPEAL by Americans for Safe Access (Elford, Joseph) (Filed on 12/20/2007) Modified on 12/26/2007 (sis, COURT STAFF). Modified on 1/2/2008 (sis, COURT STAFF). USCA #07-17388. (Entered: 12/20/2007)
12/26/2007	60	Copy of Notice of Appeal and Docket sheet mailed to all counsel (sis, COURT STAFF) (Filed on 12/26/2007) (Entered: 12/26/2007)

12/26/2007		Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals 59 Notice of Appeal (sis, COURT STAFF) (Filed on 12/26/2007) (Entered: 12/26/2007)
12/31/2007		USCA Case Number 07-17388 Ninth Circuit 59 Notice of Appeal (sis, COURT STAFF) (Filed on 12/31/2007) (Entered: 01/02/2008)
01/22/2008	61	TRANSCRIPT DESIGNATION by Americans for Safe Access for proceedings held on 07/12/07, 11/15/07 before Judge William Alsup. (sis, COURT STAFF) (Filed on 1/22/2008) (Entered: 01/22/2008)
03/07/2008	62	TRANSCRIPT of Proceedings held on 08/12/07 before Judge William Alsup. Court Reporter: James Yeomans. (sis, COURT STAFF) (Filed on 3/7/2008) (Entered: 03/10/2008)
03/17/2008	63	TRANSCRIPT of Proceedings held on 11/15/07 before Judge William Alsup. Court Reporter: Joan Columbini. (sis, COURT STAFF) (Filed on 3/17/2008) (Entered: 03/18/2008)

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CERTIFICATE OF SERVICE

I hereby certify that one copy of the foregoing was 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 five 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