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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 **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT OR SUMMARY ADJUDICATION OF ISSUES** Date: August 16, 2007 Time: 8:00 a.m. Place: Courtroom of the Honorable William Alsup

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INTRODUCTION

Some falsehoods are harmless. Others ruin people's lives. Despite numerous scientific studies demonstrating that marijuana is effective in treating AIDS wasting syndrome, muscle spasticity and chronic pain, the Department of Health and Human Services ("HHS") tells the public that marijuana "has no currently accepted medical use in treatment in the United States." This falsehood causes unnecessary suffering by deterring sick and dying persons who might benefit from marijuana from obtaining and using the medicine that could provide them needed, and often life-saving, relief.

Fortunately, in 2000, Congress recognized a problem with the accuracy of information disseminated to the public by federal agencies, and it enacted the Information Quality Act ("IQA") to ensure the "quality, objectivity, utility, and integrity of [such] information. . . ." Under the IQA, federal agencies have an obligation to develop guidelines to ensure the quality of information they disseminate to the public and give aggrieved persons a mechanism to enforce those guidelines. As a result, Americans for Safe Access ("ASA") filed a Petition with HHS for the correction of information under the IQA to make the agency tell the truth about the medical benefits of marijuana. After more than twenty months of stalling, HHS finally rejected this Petition, which triggered ASA's right to seek review in this Court. The evidence cited in ASA's Petition demonstrates that marijuana is effective in treating various illnesses, and the IQA requires HHS to correct its statements to acknowledge this.

LEGAL STANDARDS

I. Standards for Summary Judgment

Summary judgment is proper where the pleadings, discovery and affidavits show that there is "no genuine issue as to any material fact and that the moving party is entitled to

judgment as a matter of law." Fed.R.Civ.P. 56(c); *Nissan Fire & Marine Insurance Co. v. Fritz Cos., Inc.*, 210 F.3d 1099, 1103 (9th Cir. 2000). Because reviews of administrative decisions are based solely on the administrative record and, for this reason, involve questions of law and legal questions of factual sufficiency, they are particularly well suited for resolution by way of summary judgment. *See McCall v. Andrus*, 628 F.2d 1185, 1189-90 (9th Cir. 1980); *Kuper v. Mulrean*, 209 F.Supp.2d 1079, 1085 (S.D. Cal. 2002); *Beard v. Glickman*, 189 F.Supp.2d 994, 998 (C.D. Cal. 2001); *Brower v. Daley*, 93 F.Supp.2d 1071, 1083 n.13 (N.D. Cal. 2000).

II. The Information Quality Act and Its Implementing Guidelines

Recognizing serious defects in the quality of information disseminated by federal agencies, Congress enacted the Information Quality Act ("IQA") in December of 2000 as an amendment to the Paperwork Reduction Act ("PRA"), 44 U.S.C. § 3502 *et seq.* Codified in the Statutory and Historical Notes to the PRA as Pub. L. No. 106-554 § 1(a), Title V, Sec. 515, 114 Stat. 2763, codified at 44 U.S.C. § 3516 (2000) (hereinafter "Section 515"), the IQA requires each federal agency to "issue guidelines ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by the agency. . . ." Section 515, § (b)(2)(A). In furtherance of this goal, Congress required each agency to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines. . . ." Section 515, § (b)(2)(B).

In compliance with the IQA mandate, HHS promulgated Guidelines for seeking and obtaining corrections of information it disseminates.[1] The HHS Guidelines define "quality" as

[1] Copies of the HHS Guidelines are filed herewith in the Declaration of Joseph D. Elford in Support of Plaintiff's Motion for Summary Judgment or Summary Adjudication of Issues as Exhibit 1. They are also codified at 67 Fed.Reg. 61343 (Sept. 30, 2002) and can be found at

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

To allow public participation in ensuring these goals, HHS Guideline E provides for: (1) an initial "request for correction" of information disseminated by HHS and (2) 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.

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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).

STATEMENT OF FACTS

In response to a marijuana rescheduling petition filed in 1995, HHS made statements, which it codified in the *Federal Register* and disseminated on government websites, that marijuana has no accepted medical use. 66 Fed.Reg. 20037, 20039 (April 18, 2001) (Elford Decl., Exh. 2). DEA admitted that such statements were not raised by nor necessary to the adjudication of the marijuana rescheduling petition then pending before it, *see* 66 Fed.Reg. 20037, 20038 (April 18, 2001), yet it assigned HHS the task of determining the matter. After four full years, HHS concluded that marijuana had not met three of the five criteria it employs to determine whether a substance has a "currently accepted medical use." *See* 66 Fed.Reg. 20037, 20051 & 20053 (April 18, 2001).[2] Specifically, the HHS's Food and Drug Administration Controlled Substances Staff ("FDA") found:

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

66 Fed.Reg. 20037, 20051-52 (April 18, 2001) (emphasis added). Based on these findings, HHS concluded: "Indeed, the HHS scientific and medical evaluation reaffirms expressly that

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[2] 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)).

marijuana has no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision." 66 Fed.Reg. 20037, 20039 (April 18, 2001).

Notwithstanding the contrary evidence that ASA cited in its request for correction with HHS, which is more fully described below, many people believe these assertions by HHS. As a result, numerous seriously ill persons who might well have benefited from using marijuana have foregone the substance that would have dramatically improved their lives. For instance, ASA's founder and Executive Director, Steph Sherer ("Sherer"), suffers from a condition known as torticollis, which causes her to experience inflammation, muscle spasms, and pain throughout her body, and decreased mobility in her neck. *See* Declaration of Allayne Steph Sherer in Support of Plaintiff's Motion for Summary Judgment or Summary Adjudication of Issues ("Sherer Decl."), filed herewith, at ¶¶ 1 & 2. Until November of 2001, Sherer did not believe that marijuana had medical use because of statements by the government, including HHS, that it did not; however, after Sherer suffered kidney damage from the large amounts of conventional pain killers she was taking, her physician recommended that she try marijuana. Sherer Decl. ¶¶3 & 4. Sherer heeded her physician's advice and has successfully used marijuana since November of 2001 to reduce her inflammation, muscle spasms, and pain. Sherer Decl. ¶5. Sherer founded ASA several months later to share information about the medical benefits of marijuana with others. Sherer Decl. ¶6.

Since its formation in 2002, ASA's membership has grown to more than thirty-five thousand, including many seriously ill persons who would have benefited from the use of marijuana for medical purposes, but who were deterred from doing so, in part, by HHS's statement that marijuana "has no currently accepted medical use in treatment in the United States." Sherer Decl. ¶7. To combat this and the other harmful effects of HHS's false

statements, ASA implemented a campaign to educate the public about the true benefits of marijuana. Sherer Decl. ¶8. To this end, ASA has spent more than one hundred thousand dollars, plus 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. Sherer Decl. ¶¶9 & 10, Exhs. 10 & 11. ASA is making headway, but the task of combating HHS's false statements continues to drain its limited resources and impedes ASA's other efforts to increase the use of medical marijuana by seriously ill persons. Sherer Decl. ¶12.

Then, ASA discovered a legal remedy. Because the IQA requires federal agencies to disseminate truthful information and provides a mechanism to ensure this, ASA filed with HHS a "Request for Correction of Information Disseminated by HHS Regarding the Medical Use of Marijuana" (hereinafter "Petition") on October 4, 2004 (Elford Decl. Exh. 3).[3] ASA's Petition sought the correction of the four statements disseminated by HHS about medical marijuana quoted above. The Petition explained in detail why each statement is false and provided an extensive discussion of the numerous peer-reviewed scientific studies proving this so. In addition, the Petition details why these statements violate the objectivity and utility requirements of the IQA.

Over the next six months, HHS responded to the Petition with evasion and delay. On December 1, 2004, HHS sent ASA an interim response to its October 4, 2004, Petition. *See* Elford Decl. Exh. 4. The interim response stated that HHS had not yet completed its review of the ASA Petition "because of other agency priorities and the need to coordinate agency review of

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[3] Copies of the petition, the initial agency response, ASA's appeal, the final agency response to the appeal, and all agency interim responses, are filed with this motion as Elford Decl. Exhs. 3-15. They can also be accessed at http://aspe.hhs.gov/infoquality/requests.shtml, item 20.

the response." Elford Decl. Exh. 4 at 1. HHS contended that it needed to consult with the Drug Enforcement Administration ("DEA"), which was considering a petition to reschedule marijuana that was filed on October 9, 2002, and that it hoped to provide a response within the next 60 days. Elford Decl. Exh. 4 at 1. 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. *See* Elford Decl., Exh. 5. Nevertheless, HHS provided a series of interim responses over the next several months stating that it needed additional time to coordinate agency review. *See* Elford Decl., Exhs. 6 & 7. Finally, on April 20, 2005, HHS denied ASA's Petition without presenting any evidence that its statements about the lack of medical efficacy of marijuana are justified, or explaining how it was complying with its IQA Guideline D.2.c.2, which requires HHS to ensure the "timely flow of vital information from agencies to medical providers, patients, health agencies, and the public." *See* Elford Decl. Exh. 8.

On May 19, 2005, ASA filed an appeal of the HHS rejection of its October 4, 2004, Petition. *See* Information Quality Appeal, dated May 19, 2005 (Elford Decl. Exh. 9). In it, ASA protested that: (a) HHS was evading its information 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 Petition under the Information Quality Act are different and more limited than those raised in the DEA rescheduling proceeding, so that merging the proceedings would not allow the consideration of information quality issues "on a timely basis," as required by the HHS Guidelines, and (c) HHS had ignored its Guidelines stating that information 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 disseminated by the agency. Elford Decl. Exh. 9, at 3-4. ASA alleged that "seriously ill persons represented by ASA are suffering from being misled about the medical benefits of marijuana [by HHS]." Elford Decl. Exh. 9, at 4.

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." Elford Decl., Exh. 10. After four additional such letters, Elford Decl., Exhs. 11-14, on July 12, 2006, HHS sent ASA a final response effectively denying the appeal, again without ever addressing the scientific evidence. *See* Elford Decl. Exh. 15. Instead, HHS noted that it anticipated providing a response by September 2006 to the marijuana rescheduling petition pending before it since October 9, 2002. Elford Decl. Exh. 15 at 2. To date, that response has not been provided.

HHS's actions prompted ASA to file this action on February 21, 2007. To illustrate how HHS's refusal to correct its erroneous statements regarding the medical use of marijuana has affected the lives of countless Americans, it is submitting with this motion the Declarations of three individuals, in addition to ASA's founder Steph Sherer, who are identified in its Complaint and whose lives have been transformed by learning the truth about the medical efficacy of marijuana. Victoria Lansford ("Lansford"), for instance, suffers from fibromyalgia, which causes her to suffer severe chronic pain and muscle spasms. *See* Declaration of Victoria Lansford in Support of Plaintiff's Motion for Summary Judgment or Summary Adjudication of Issues ("Lansford Decl."), filed herewith, at ¶2. 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 to HHS's statements. *See* Lansford Decl. ¶¶3 & 4. In 2002, however, on the recommendation of her sister, Lansford started using marijuana to treat her chronic pain and muscle spasms, which significantly improved her health. *See* Lansford Decl. ¶5 & 6. Because of her transition to marijuana, Lansford has been able to discontinue her use of the highly addictive Oxycontin. *See* Lansford Decl. ¶6.

A similar story is told by Shayne Kintzel ("Kintzel"). Like Lansford, Kintzel experiences chronic pain and muscle spasms as a result of a serious back injury. *See* Declaration of Shayne Kintzel in Support of Plaintiff's Motion for Summary Judgment or Summary Adjudication of Issues ("Kintzel Decl."), filed herewith, at ¶2. Until 2002, Kintzel used conventional prescription pain medications, including morphine, to treat his chronic pain, since he was led to believe that marijuana would not be effective for this purpose from his review of federal government websites. *See* Kintzel Decl. ¶¶3 & 4. In approximately July of 2002, however, Kintzel began using marijuana in place of prescription medications. *See* Kintzel Decl. ¶5. Kintzel 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. *See* Kintzel Decl. ¶6.

Then, there is Jacqueline Patterson ("Patterson"). Patterson has cerebral palsy, which impairs her speech and causes her to suffer muscle spasticity and pain. *See* Declaration of Jacqueline Patterson in Support of Plaintiff's Motion for Summary Judgment or Summary Adjudication of Issues ("Patterson Decl."), filed herewith, at ¶2. Until June of 2001, 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. *See* Patterson Decl. ¶3. Patterson began using marijuana with great success and she is now able to speak more clearly, and she

rarely suffers the serious muscle spasms she used to experience in her right arm. *See* Patterson Decl. ¶¶4 & 5.

ARGUMENT

I. PLAINTIFF IS ENTITLED TO SUMMARY JUDGMENT

This case is brought under the Administrative Procedure Act, 5 U.S.C. §§ 702-706 ("APA"), which provides for judicial review of a "final agency action for which there is no other adequate remedy in a court. . . ." 5 U.S.C. § 704. The APA's promise of judicial review is generous, liberally construed, and readily available in the absence of powerful authority to the contrary. *See Japan Whaling Ass'n v. American Cetacean Soc.*, 478 U.S. 221, 230 n.4 (1986); *Block v. Community Nutrition Institute*, 467 U.S. 340, 345 (1984); *Inova Alexandria Hospital v. Shalala*, 244 F.3d 342, 346 (4th Cir. 2001). "The APA 'creates a strong presumption of reviewability that can be rebutted only by a clear showing that judicial review would be inappropriate." *Animal Legal Defense Fund v. Veneman*, 469 F.3d 826, 836 (9th Cir. 2006) (quoting *Nat'l Res. Defense Council, Inc. v. S.E.C.*, 606 F.2d 1031, 1043 (D.C. Cir. 1979)); *see also Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 67, 670 (1986) (noting "strong presumption that Congress intends judicial review of administrative action"). Because this action is under the APA, review is based on the administrative record, which includes ASA's Petition and HHS's numerous, but non-substantive responses to the allegations in that Petition. Because the Petition contains more than enough evidence to support the corrections sought, and because HHS's refusal to respond was based on a legally inadequate reason – the desire to await the final results of a rescheduling petition being considered by another agency – ASA's motion for summary judgment should be granted.

II. HHS'S STATEMENTS ABOUT MARIJUANA AS MEDICINE VIOLATE THE IQA'S OBJECTIVITY REQUIREMENT BECAUSE THOSE STATEMENTS IGNORE OPPOSING PEER-REVIEWED SCIENTIFIC STUDIES AND HAVE BEEN CONTRADICTED BY ADDITIONAL DATA CITED IN ASA'S PETITION

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

Subject to judicial scrutiny, HHS's actions cannot stand. As is discussed more fully below, HHS's assertion that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition," 66 Fed.Reg. 20037, 20052 (April 18, 2001) (Elford Decl. Exh. 2), is patently false -- numerous peer-reviewed studies have assessed the efficacy of marijuana with respect to nausea, loss of appetite, muscle spasticity, and pain. ASA discussed more than two dozen such studies in its IQA Petition, yet HHS failed to address them in its response. *See* ASA Petition at 5-7 (Elford Decl. Exh. 3); Letter from John O. Agwunobi to Joseph D. Elford, dated July 12, 2006 (Elford Decl. Exh. 15).[4] HHS fails the objectivity requirement of the IQA by ignoring these studies and failing to present information in "an accurate, clear, complete, and unbiased manner." *See* HHS Guideline D.2.c.

For instance, not only does HHS ignore the more than 6,500 published scientific articles on medical applications for marijuana and its constituent components in the National Library of Medicine's database, http://www.pubmed.com, *see* Declaration of William Dolphin in Support of Plaintiff's Motion for Summary Judgment or Summary Adjudication of Issues, filed herewith, at ¶2, but one report it cites in its denial of the 1995 marijuana rescheduling petition -- *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

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[4] All scientific studies cited in this section were discussed in ASA's IQA Petition, except one neuropathy study expressly noted as not being included. *See infra* at 14 n.6.

House's Office of National Drug Control Policy -- found that marijuana does have accepted medical uses. *See* 66 Fed.Reg. 20037, 20047 (April 18, 2001); Remarks of IOM Principal Investigator Dr. John A. Benson, at March 17, 1999, News Conference (Elford Decl., Exh. 16) ("We concluded that there are some limited circumstances in which we recommend smoking marijuana for medical uses.").

Specifically, with respect to pain management, the IOM report 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. *Marijuana as Medicine: Assessing the Science Base* (1999) (hereinafter "IOM Report") at 142-43 (Elford Decl. Exh. 17) (citing Noyes et al. 1975a; Noyes et al. 1975b; Staquet et al. 1978); ASA Petition at 5 (Elford Decl. Exh. 3). The IOM also reports that an experimental study on pain showed that "cannabinoids were comparable with opiates in potency and efficacy. . . ." IOM Report at 54 (citing Borison et al. 1983 & Hanigan et al. 1986). "In conclusion, the available evidence from animal and human studies indicates that cannabinoids can have substantial analgesic effect." IOM Report at 145.

Other research on marijuana's efficacy for pain management that HHS failed to acknowledge includes a human study showing statistically significant increases in pain threshold after smoking marijuana, *see* Elford Decl. Exh. 18 (Milstein et al. 1975); ASA Petition at 5, 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, Elford Decl. Exh. 19, 20 & 21 (Grinspoon & Bakalar 1997) (Russo 2002) (Noyes & Baram 1974); ASA Petition at 5. 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*, "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." Elford Decl. Exh. 20, at 362 (Russo 2002); *see* Elford Decl., Exhs. 22 & 23 (Guyatt et al 1990) (Larson 1990); ASA Petition at 5. 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." Elford Decl. Exh. 24, at 5 (Hollister 2000); ASA Petition at 5.

On treating nausea, the IOM reported on numerous clinical studies – including "a carefully controlled double-blind study" and "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. *See* IOM Report at 148 (Elford Decl. Exh. 17) (citations omitted); ASA Petition at 6. Not only did the IOM report conclude that marijuana is 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." IOM Report at 177. Thus, "[i]t is possible that the harmful effects of smoking marijuana for a limited period of time might be outweighed by the antiemetic benefits of marijuana, at least for patients for whom standard antiemetic therapy is ineffective and who suffer from debilitating emesis." IOM Report at 154; *see also* IOM Report at 179 ("Until a nonsmoked rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from *chronic* conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting."). The IOM Report concluded:

"Nausea, appetite loss, pain, and anxiety are all afflictions of wasting, and all can be mitigated by marijuana." IOM Report at 159.[5]

Moreover, since the release of the IOM report and HHS's 2001 statements, additional clinical studies on the medical efficacy of marijuana were published in peer-reviewed journals and included in ASA's Petition. *See* ASA Petition at 6-7. 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. *See* Elford Decl Exh. 25 (Musty and Rossi 2001); ASA Petition at 6. Recent double-blind, placebo-controlled studies of HIV/AIDS patients showed that marijuana both reduced neuropathic pain and produced weight gain without immunological compromise. *See* Elford Decl. Exh. 26 (Abrams et al. 2003); ASA Petition at 6.[6] Clinical studies of multiple sclerosis, for which there are few effective treatments, have shown cannabis extracts to be effective for spasticity and other symptoms, Elford Decl. Exh. 27 (Zajicek et al. 2003); ASA Petition at 6, as well as chronic pain, Elford Decl. Exh. 28 (Notcutt and Rangappa 2004); ASA Petition at 6. As if this were not enough, three additional articles supporting the benefit of marijuana in treating MS patients for spasticity, pain, sleep and bladder function appear in the August 2004 issue of the journal *Multiple Sclerosis*. *See* Elford Decl. Exhs. 29-31 (Vaney et al. 2004) (Wade et al. 2004) (Brady et al. 2004); ASA Petition at 6. The non-psychoactive marijuana component cannibidiol has also been shown to have numerous medical applications as an anti-inflammatory and neuroprotective agent and as a treatment for

[5] The IOM report also noted: "Since 1996, five important reports pertaining to the medical uses of marijuana have been published, each prepared by deliberative groups of medical and scientific experts (Appendix E). . . . With the exception of the report by the Health Council of the Netherlands, each concluded that marijuana can be moderately effective in treating a variety of symptoms." IOM Report at 180.

[6] Although not part of the instant action, new research has emerged since ASA filed its petition, which demonstrates that marijuana is effective in treating neuropathy. *See* Elford Decl. Exh. 37 (Abrams et al. 2007).

rheumatoid arthritis. *See* Elford Decl. Exhs. 32 & 33 (Russo 2003) (Malfait et al. 2000); ASA Petition at 6.

In the face of these scientific studies, many of which are funded and approved by the federal government, it is not objective for HHS to continue to disseminate the statement that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition." 66 Fed.Reg. 20037, 20052 (April 18, 2001). There are, and the IQA requires HHS to acknowledge this.

B. Qualified Experts Accept Marijuana for Medical Use

Also requiring correction are HHS's statements that "[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. 20037, 20052 (April 18, 2001). HHS does not identify the experts claiming that marijuana does not have medical efficacy, which fails the utility requirement of the IQA. *See* HHS Guidelines D.2.b ("when transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information"). Worse still, these statements fail the objectivity requirement, since they represent a departure from the plain language of the criteria HHS employs to assess medical use, which requires only that "[t]he drug is accepted by qualified experts." *See* 66 Fed.Reg. 20037, 20052 (April 18, 2001); *cf. United States v. Articles of Drug Consisting of Following: 5,906 Boxes*, 745 F.2d 105, 120 n.22 (1st Cir. 1984) ("It is by now clear that unanimity among experts is not required to demonstrate 'general' recognition" in the scientific community" (citing *United States v. Articles of Food and Drug Consisting of Coli-Trol 80,* 618 F.2d 743, 746 (5th Cir. 1975); *United States v. Articles of Drag*

Labeled "Quick-O-Ver", 274 F.Supp. 443, 448 n.7 (D. Md. 1967)); *see also 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"); *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"). At best, HHS's contrary assertion is a half truth, which requires correction or at least supplementation, in order to meet the standards of the IQA and HHS's own guidelines.

In any event, there is widespread agreement in the scientific community that marijuana has medical use. No less an authority than the IOM Report cited by HHS states "there is substantial consensus among experts in the relevant disciplines on the scientific evidence about potential medical uses of marijuana." IOM Report at 2 (Elford Decl. Exh. 17); *see also* IOM Report at 14 ("the study team found substantial consensus, among experts in the relevant disciplines, on the scientific evidence bearing on potential medical use")**.** The IOM Report, then, goes on to describe these experts and their findings. *See supra* at Part II.A. HHS is not objective when it relies on unidentified experts to deny, categorically and for all uses, the widespread opinion of experts that marijuana has medical uses.

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. 20037, 20051 (April

18, 2001).[7] Marijuana easily meets the published criterion. The active components of marijuana are well known and well described, as are the mechanisms of biologic action in humans. Research on marijuana chemistry published between the time of the original Petition and HHS's response seemingly was overlooked, Elford Decl. 34 (Mechoulam & Ben-Shabat 1999), while additional research published since the HHS response further describes the chemistry of marijuana, Elford Decl. Exhs. 35 & 36 (McPartland & Russo 2001) (ElSohly 2002); ASA Petition at 9. 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. 20037, 20051 (April 18, 2001). Both reveal bias on HHS's part and violate the objectivity requirement of the Information Quality Act and its Guidelines.

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. 20037, 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. 20037, 20051-52 (April 18, 2001). The corrections sought by plaintiff, however, would reverse these findings, and necessitate the conclusion that marijuana does, in fact, have currently accepted medical uses in treatment in the United States.

[7] If it were otherwise, no botanical could qualify as having an "accepted medical use." Congress has implicitly rejected this view by placing cocoa leaves, the opium poppy, and poppy straw in Schedule II, which means that these botanicals have "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." *See* 21 U.S.C. §§ 812(b)(2)(B) & (c), Schedule II(a)(3) & (4).

III. HHS CLEARLY ERRED IN PROVIDING A NONSUBSTANTIVE RESPONSE TO ASA'S PETITION

To avoid confronting the voluminous evidence of marijuana's medical efficacy, which cast grave doubt on its statements to the contrary, HHS stated that it need not provide a substantive response because "HHS is currently in the process of concluding its comprehensive review of the publicly available peer reviewed literature on marijuana in order to make a recommendation to the DEA as to whether marijuana should continue to be controlled under the CSA." *See* Letter from John O. Agwunobi to Joseph D. Elford, dated July 12, 2006 (Elford Decl. Exh. 15). The agency cannot shrug off ASA's IQA Petition in this manner. Under HHS's own IQA Guidelines, it has a responsibility to respond to requests for correction of information in a 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." HHS Guideline E (Elford Decl. Exh. 1). 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. If the rules were otherwise, HHS could render the IQA a nullity simply by delaying responses to IQA petitions indefinitely.

Nor can HHS evade its responsibilities under these temporal requirements by lumping together ASA's narrow request for correction of information under the IQA with a distinct, farther-reaching and much slower process. Although the HHS Guidelines allow the agency to use existing procedures to respond to IQA complaints that arise in "rule-making and other formal agency actions [that] already provide well established procedural safeguards that allow affected persons to raise information quality issues on a timely basis," HHS Guideline E, the marijuana rescheduling process is far too slow to qualify as providing a timely alternative. One marijuana

rescheduling petition was pending for more than twenty-two years before it was denied. *See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994). Another was pending for more than six. *See Gettman v. DEA*, 290 F.3d 430 (D.C. Cir. 2002). The current rescheduling petition has been pending since October 9, 2002, with no end in sight, which prompted Senator Jim Jeffords, in January of 2005, to inquire of the Secretary of the Department of Health and Human Services, Michael Leavitt, when the agency would respond to that petition. *See* Letter from James M. Jeffords to Michael O. Leavitt, dated October 10, 2005 (Elford Decl. Exh. 38). Leavitt initially responded that all efforts would be made to complete the medical evaluation by August of 2005, but when this date came and went without a response, Senator Jeffords wrote Leavitt a letter requesting an explanation for the delay and a new anticipated date. *See* Elford Decl. 28. Leavitt does not appear to have provided an answer, but HHS has responded to ASA's Petition by stating that it anticipated a conclusion to its review by September of 2006. *See* Letter from John O. Agwunobi to Joseph D. Elford, dated July 12, 2006, at 2 (Elford Decl. Exh. 15).[8] HHS has a history of ignoring timelines and delaying indefinitely when it comes to marijuana rescheduling petitions. This process does not provide the prompt and timely response to requests for correction of information, as the IQA demands.

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[8] Another judge of this Court has expressed its frustration with the pace of this process this way:

> The Court doubts whether a rescheduling petition is a reasonable alternative for all seriously ill patients whose physicians have recommended marijuana for therapeutic purposes. For example, such a petition was filed in 1972 and did not receive a final ruling from the Administrator of the Drug Enforcement Agency until 1992, and a final decision on appeal until 1994. *See Alliance for Cannabis Therapeutics v. Drug Enforcement Administrator*, 15 F.3d 1131 (D.C. Cir. 1994). Needless to say, it hardly seems reasonable to require an AIDS, glaucoma, or cancer patient to wait twenty years if the patient requires marijuana to alleviate a current medical problem.

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

One reason the marijuana rescheduling process is so comparatively slow, as ASA has repeatedly explained to HHS in its protests to the agency, *see* Elford Decl. Exh. 5, is that it involves considerations other than whether marijuana has an accepted medical use, such as whether it has a "high potential for abuse." *See* 21 U.S.C. § 812(b)(1)(A). This latter consideration involves complex sociological questions about the type of people who use marijuana, their number, and its addictiveness. *See* 66 Fed.Reg. 20037, 20039-51 (April 18, 2001). These considerations are outside the scope of ASA's discrete and specific requests for correction of information, and their resolution will significantly delay a response to which ASA is entitled.

Meanwhile, putative medical marijuana patients and ASA will pay a steep price, as the experiences of Lansford, Kintzel, Patterson and Sherer demonstrate. In a provision ignored by HHS, its Guidelines require it to act on ASA's Petition before the final resolution of the marijuana rescheduling petition 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 Petition would expedite, rather than delay, the DEA's consideration of the pending marijuana rescheduling petition and, in the meantime, seriously ill persons represented by ASA are suffering unnecessarily from being misled about the medical benefits of marijuana. HHS has no credible explanation why it cannot at least respond to ASA's request on the merits, instead of hiding behind the long pending (and irrelevant) DEA rescheduling proceeding.

CONCLUSION

The federal government has been misleading the public about the medical efficacy of marijuana for decades. As far back as 1988, a DEA administrative law judge held lengthy hearings on the subject and, at their conclusion, found that the federal government had acted arbitrarily and capriciously in denying marijuana's medical use.[9] Even this, however, did not persuade the federal government to be truthful. Since then, Congress has enacted the IQA, which demands that federal agencies consider the input of the public and, where it is shown that information they disseminate is inaccurate, correct it. As shown by ASA's Petition, this is precisely the case here. The IQA requires the federal government to disseminate the truth -- that marijuana is medicine. No more seriously ill persons should endure unnecessary suffering from HHS's false statements.

DATED: May 24, 2007

Respectfully Submitted,

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[9] *Marijuana Rescheduling Petition*, No. 86-22 (DEA Sept. 6, 1988) (available at http://www.druglibrary.org/olsen/MEDICAL/YOUNG/young.html) at 26, 34, 54 & 68.