

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	) ) ) ) )	<b>Docket No.</b>
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**REQUEST FOR CORRECTION OF INFORMATION  
DISSEMINATED BY HHS REGARDING  
THE MEDICAL USE OF MARIJUANA**

AMERICANS FOR SAFE ACCESS  
1700 SHATTUCK AVENUE #317  
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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.access.gpo.gov/su_docs/fedreg/a010418c.html),  
[http://www.deadiversion.usdoj.gov/fed\\_regs/notices/2001/fr0418/fr0418a.htm](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).<sup>1</sup> 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.access.gpo.gov/su_docs/fedreg/a010418c.html), [http://www.deadiversion.usdoj.gov/fed\\_regs/notices/2001/fr0418/fr0418a.htm](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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<sup>1</sup> 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 MARIJUANA 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, neuropsychological 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**

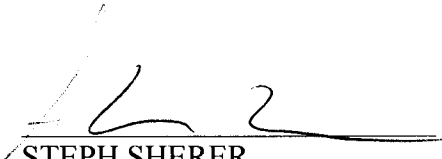
ASA represents seriously ill persons across the United States who are deeply and immediately affected by the controverted statements by HHS.<sup>2</sup> HHS’s statements about the lack of medical usefulness of marijuana harms these individuals in that it denies them access to medicine which will alleviate 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,

  
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JOSEPH D. ELFORD  
Attorney for Petitioner  
AMERICANS FOR SAFE ACCESS

  
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STEPH SHERER  
Executive Director for Petitioner  
AMERICANS FOR SAFE ACCESS

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<sup>2</sup> 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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