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,

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JOSEPH D. ELFORD

Attorney for Petitioner
AMERICANS FOR SAFE ACCESS

EXHIBIT A

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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EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 1[illegible] 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
Acting Director, Center for Drug Evaluation
and Research

EXHIBIT C

P.O. Box 427112
San Francisco, CA 94142
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Americans for Safe Access

Joseph D. Elford
Staff Attorney
Americans for Safe Access
P.O. Box 427112
San Francisco, CA 94142
(415) 573-7842

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

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Ombudsman
5600 Fishers Lane, (HF-7)
Room 14-72
Rockville, MD 20857-0001

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

EXHIBIT E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Ombudsman
5600 Fishers Lane, HF-7
Room 14-72
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

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

EXHIBIT F

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary

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.