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FILED

FEB 21 2007

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND

1 JOSEPH D. ELFORD (S.B. NO. 189934)
2 AMERICANS FOF SAFE ACCESS
3 1322 Webster St., Suite 402
4 Oakland, CA 94612
5 Telephone: (415) 573-7842
6 Fax: (510) 251-2036
7 joe@safeaccessnow.org

8 ALAN B. MORRISON
9 559 Nathan Abbott Way
10 Stanford CA 94305
11 Telephone: (650) 725 9648
12 Fax: (650) 725 0253
13 amorrisson@law.stanford.edu
14 (application to appear *pro hac vice* pending)

15 Counsel for Plaintiff
16 AMERICANS FOR SAFE ACCESS

17 IN THE UNITED STATES DISTRICT COURT
18 FOR THE NORTHERN DISTRICT OF CALIFORNIA

ADR

19 AMERICANS FOR SAFE ACCESS,)
20)
21 Plaintiff,)
22)
23 v.)
24)
25 DEPARTMENT OF HEALTH AND)
26 HUMAN SERVICES and FOOD AND)
27 DRUG ADMINISTRATION,)
28)
29 Defendants.)

No.

607-01049

WHA

**COMPLAINT FOR DECLARATORY
RELIEF AND PERMANENT
INJUNCTION**

I. INTRODUCTION

1. Despite numerous peer-reviewed scientific studies establishing that marijuana is effective in treating AIDS wasting syndrome, muscle spasticity and chronic pain, the Department

1 of Health and Human Services (“HHS”) continues to tell the public that marijuana “has no
2 currently accepted medical use in treatment in the United States.” This action is filed under the
3 Data Quality Act, 44 U.S.C. § 3516, Statutory and Historical Notes, P.L. 106-554 (“Data Quality
4 Act” or “DQA”), and the Administrative Procedure Act (“APA”), 5 U.S.C. § 701 *et seq.*, to
5 correct this false and misleading statement, as the Data Quality Act requires.
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7 2. In 2001, Congress recognized a problem with the quality and integrity of
8 information disseminated by federal agencies, which prompted it to enact legislation to ensure
9 the “quality, objectivity, utility, and integrity of information” disseminated by federal agencies.
10 44 U.S.C. § 3516, Statutory and Historical Notes, P.L. 106-554, Sec. 1(a)(3). Pursuant to this
11 Act, HHS has an obligation to consider requests from the public to correct erroneous statements
12 that it has disseminated. Here, more than two years ago, plaintiff Americans for Safe Access
13 (“ASA”) made such a request of HHS with respect to particular claims that marijuana has no
14 medical use. In support of its request, ASA supplied citations to numerous scientific studies
15 confirming the medical efficacy of marijuana, including a report from the prestigious National
16 Institute of Medicine (“IOM”) that was commissioned by the White House’s Office of National
17 Drug Control Policy (“ONDCP”).
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20 3. HHS responded by engaging in inexcusable delay and, ultimately, issuing a
21 nonsubstantive rejection of ASA’s request. Left with no other administrative recourse, ASA
22 filed the instant suit challenging HHS’ arbitrary and unlawful behavior, since the federal
23 government’s false statements deter sick and dying persons from seeking to obtain medicine that
24 could provide them needed, and often life-saving, relief. When it comes to medical marijuana,
25 HHS has failed in its avowed mission of “protecting the health of all Americans and providing
26 essential human services, especially for those who are least able to help themselves.”
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1 **II. JURISDICTION AND INTRADISTRICT ASSIGNMENT**

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

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6 5. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and
7 1361.

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9 6. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) and Local Rule
10 3-5(b) because plaintiff ASA maintains its headquarters in Oakland, California, which is in this
11 judicial district, and a substantial portion of the events giving rise to the complaint occurred in
12 this judicial district.

13 **III. THE PARTIES**

14 7. Plaintiff AMERICANS FOR SAFE ACCESS (“ASA”) is a non-profit corporation
15 headquartered in Oakland, California that has as its primary purpose working to expand and
16 protect the rights of patients to use marijuana for medical purposes, including providing outreach
17 and education to the public regarding the use of marijuana for medical purposes. ASA’s
18 members and constituents include seriously ill persons who would have benefited from the use of
19 marijuana for medical purposes, but who were deterred from using marijuana to ease their
20 suffering, in part, by HHS’ statement that marijuana “has no currently accepted medical use in
21 treatment in the United States.” ASA has devoted significant resources to combat this false
22 statement, including the expenditure of more than one hundred thousand dollars and hundreds of
23 hours of staff time producing and disseminating educational materials explaining that scientific
24 studies demonstrate that marijuana is effective in treating symptoms associated with cancer,
25 HIV/AIDS, multiple sclerosis, arthritis, gastrointestinal disorders, and chronic pain. HHS’
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1 failure to correct its false statement that marijuana does not have any currently accepted medical
2 use in treatment in the United States adversely affects the membership and constituency of ASA
3 and causes ASA to suffer injury to its ability to carry out its mission, as well as causing ASA to
4 suffer economic loss in staff pay, funds expended to produce educational materials, and in the
5 inability to undertake other efforts to improve the access of seriously ill persons to medical
6 marijuana.
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8 8. Despite HHS' dissemination of false and misleading information about the
9 effectiveness of marijuana in relieving the pain of victims of certain diseases, four ASA
10 members obtained the correct information and it dramatically improved their lives.
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12 a. For instance, ASA's Executive Director, Steph Sherer, suffers from a
13 condition known as torticollis, which causes her to experience inflammation, muscle spasms,
14 pain throughout her body, and decreased mobility in her neck. Until November of 2001, Ms.
15 Sherer did not believe that marijuana had medical use, due to statements that it did not on federal
16 websites; however, after Ms. Sherer suffered kidney damage from the large amounts of
17 conventional pain killers she was taking, her physician recommended that she try marijuana.
18 Ms. Sherer heeded her physician's advice and has successfully used marijuana since November
19 of 2001 to reduce her inflammation, muscle spasms, and pain. Ms. Sherer founded ASA to share
20 medical information with others in April of 2002.
21

22 b. Victoria Lansford ("Lansford") is also an ASA constituent and member
23 who resides in Blackfoot, Idaho. Ms. Lansford suffers from fibromyalgia, which causes her to
24 suffer severe chronic pain and muscle spasms. Until 2002, Lansford used a regimen of pain
25 medications, including a morphine patch and Oxycontin, because she did not believe marijuana
26 had medical use, due in part to HHS' statements. In 2002, on the recommendation of her sister,
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1 Lansford started using medical marijuana to treat her chronic pain and muscle spasms. This use
2 of marijuana has significantly improved Ms. Lansford's health and she has been able to stop
3 using the highly addictive Oxycontin.
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5 c. Jacqueline Patterson is an ASA member and constituent who resides in
6 Marin, California. Patterson has cerebral palsy, which among its other symptoms impairs
7 Patterson's speech and causes her to suffer muscle spasticity and pain. Until June of 2001, Ms.
8 Patterson did not believe that marijuana was medicine because of the federal government's
9 statements that it was not, but her husband eventually convinced her to try it. Since beginning to
10 use medical marijuana, Ms. Patterson has significantly improved her ability to speak and rarely
11 suffers the serious muscle spasms she experienced in her right arm.
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13 d. Shane Kintvel is an ASA member and constituent who experiences
14 chronic pain and muscle spasms as a result of a serious back injury. Until 2002, Mr. Kintvel
15 used conventional prescription pain medications, including morphine, to treat his chronic pain.
16 He was led to believe that marijuana would not be effective for this purpose from information he
17 received from his doctors and his review of federal government websites. In approximately July
18 of 2002, however, Mr. Kintvel began using marijuana in place of prescription medications.
19 According to the progress measured by Dr. Michael McMillan, Mr. Kintvel's current treating
20 physician, Kintvel is now completely mobile, has discontinued his use of morphine, and has lost
21 more than fifty pounds that he had gained from taking large amounts of morphine and being
22 unable to exercise.
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25 9. Defendant DEPARTMENT OF HEALTH AND HUMAN SERVICES ("HHS")
26 is an administrative agency of the federal government with its headquarters in Washington, D.C.
27 HHS claims on its website that it is the "government's principal agency for protecting the health
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1 of all Americans and providing essential human services, especially for those who are least able
2 to help themselves.” See <http://www.hhs.gov/>. In April of 2000, in response to a request to
3 reclassify marijuana, HHS stated its finding that marijuana “has no currently accepted medical
4 use in treatment in the United States.” *Federal Register*, 66 Fed.Reg. 20038, 20039 (April 18,
5 2001). HHS continues to disseminate this and related statements in its publications and on
6 government websites. See http://www.access.gpo.gov/su_docs/fedreg/a010418c.html;
7 http://www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr0418/fr0418a.htm.

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

18 19 **IV. THE DATA QUALITY ACT AND HHS’ IMPLEMENTING GUIDELINES**

20 11. Passed in 2001 as an amendment to the Paperwork Reduction Act, 44 U.S.C §
21 3502(1), the Data Quality Act (“DQA”) requires administrative agencies to develop guidelines to
22 ensure the “quality, objectivity, utility, and integrity of information” they disseminate to the
23 American public. In furtherance of this goal, the DQA requires all federal agencies to
24 “[e]stablish administrative mechanisms allowing affected persons to seek and obtain correction
25 of information maintained and disseminated by the agency that does not comply with the
26 guidelines.” 44 U.S.C. § 3516, Statutory and Historical Notes.
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1 12. In compliance with the DQA mandate, HHS promulgated Guidelines for seeking
2 and obtaining corrections of information it disseminates. The HHS Guidelines are codified at 67
3 Fed.Reg. 61343 (Sept. 30, 2002) and can also be found at
4 <http://www.hhs.gov/infoquality/part1.html>. Similar Guidelines, which are also applicable to
5 HHS, have been promulgated by the Office of Budget and Management (“OMB”) and are
6 codified at 67 Fed.Reg. 8452 (Feb. 22, 2002).

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

19 14. To allow public participation in ensuring these goals, the HHS Guidelines provide
20 for both an initial petition to correct erroneous information that HHS has disseminated and an
21 administrative appeal (or “Information Quality Appeal”). With regard to an initial petition, the
22 Guidelines state that “[t]he agency will respond to all requests for correction within 60 calendar
23 days of receipt. If the request requires more than 60 calendar days to resolve, the agency will
24 inform the complainant that more time is required and indicate the reason why and an estimated
25 decision date.” HHS Guideline E. If the initial petition is denied by HHS, the HHS Guidelines
26 provide for an administrative appeal, and the “agency will respond to all requests for appeals
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1 within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve,
2 the agency will inform the complainant that more time is required and indicate the reason why
3 and an estimated decision date.” HHS Guideline E.
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5 V. FACTS

6 15. On October 4, 2004, ASA filed with HHS a “Request for Correction of
7 Information Disseminated by HHS Regarding the Medical Use of Marijuana” (hereinafter
8 “petition”). Copies of the petition, the initial agency response, ASA’s appeal, the final agency
9 response to the appeal, and all agency interim responses can be accessed at
10 <http://aspe.hhs.gov/infoquality/requests.shtml>, item 20.
11

12 16. ASA’s petition alleges that HHS has disseminated to the public, and is continuing
13 to disseminate to the public, the statement that marijuana “has no currently accepted medical use
14 in treatment in the United States.” The petition alleges that this HHS statement, and the findings
15 underlying it, are inaccurate, in violation of the DQA and the OMB and HHS DQA Guidelines.
16 The ASA petition alleges with specificity why the HHS information dissemination is inaccurate,
17 and requests specific corrections. In particular, the ASA petition alleges that numerous peer-
18 reviewed studies, including the 1999 Institute of Medicine (“IOM”) study commissioned by the
19 ONDCP establish that marijuana is accepted in the United States as effective in treating various
20 illnesses.
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23 17. On December 1, 2004, HHS sent ASA an interim response to its October 4, 2004,
24 petition. The interim response stated that HHS had not yet completed its review of the ASA
25 petition, due to other agency priorities and the need to coordinate agency review. HHS
26 contended that it needed to consult with the Drug Enforcement Administration (“DEA”), which
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1 was considering a petition to reschedule marijuana, to prepare a response, and that it hoped to
2 provide a response within the next 60 days.

3 18. By letter dated December 20, 2004, ASA protested that HHS, by consulting with
4 DEA, was inexcusably expanding its review to include considerations outside the scope of
5 ASA's petition and that such expansion would unduly delay an administrative response to the
6 requested correction of information.
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8 19. Nevertheless, HHS provided a series of interim responses over the next several
9 months stating that it needed additional time to coordinate agency review. On April 20, 2005,
10 HHS denied ASA's petition without presenting any evidence that its statements about the lack of
11 medical efficacy of marijuana are justified. HHS made no mention of its DQA Guideline
12 D.2.c.2, which requires it to ensure the "timely flow of vital information from agencies to
13 medical providers, patients, health agencies, and the public."
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15 20. On May 19, 2005, ASA filed an appeal of the HHS rejection of its October 4,
16 2004, petition, pursuant to the HHS Guidelines. *See* HHS Guideline E.
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18 21. ASA's May 19, 2005, appeal protested that: (a) HHS was evading its data quality
19 responsibilities and delaying a response in contravention of its Guidelines, especially by
20 referring the issues raised by the ASA Petition to a proceeding outside HHS; (b) the issues raised
21 by ASA's request for correction under the Data Quality Act are different and more limited than
22 those raised in the DEA rescheduling proceeding, so merging the proceedings would not allow
23 the consideration of data quality issues "on a timely basis," as required by the HHS Guidelines,
24 and (c) HHS had ignored its Guidelines stating that data quality complaints must be acted upon
25 in a timely fashion where there is a reasonable likelihood that persons were suffering actual harm
26 from the inaccurate information being disseminated by the agency. ASA alleged that "seriously
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1 ill persons represented by ASA are suffering from being misled about the medical benefits of
2 marijuana [by HHS].”

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4 22. Again, commencing on July 28, 2005, HHS sent ASA a series of interim
5 responses to its appeal over a period of more than eleven months, stating that the agency required
6 additional time to coordinate agency review to prepare a response and that its “goal is to have a
7 response to your appeal within 60 days of the date of this letter.” Then, on July 12, 2006, HHS
8 sent ASA a response effectively denying the appeal without addressing the scientific evidence.
9 HHS merely noted that it anticipated providing a response by September 2006 to a marijuana
10 rescheduling petition that has been pending before the DEA since October 9, 2002. HHS has not
11 provided such response to the rescheduling petition as of the filing of this Complaint and its
12 pattern of delay and evasion demonstrate that it cannot be expected to provide a substantive
13 public response to the rescheduling petition within any reasonable time.
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16 23. As a direct and proximate result of defendants’ actions, ASA has suffered, and
17 will continue to suffer, the loss of staff time, economic resources, and impairment of its mission.
18 In particular, to combat HHS’ dissemination of scientifically flawed statements that marijuana
19 does not have any accepted medical use, ASA has spent more than one hundred thousand dollars
20 and expended hundreds of hours of staff time producing and disseminating educational materials
21 explaining that marijuana has medical use in the treatment of cancer, HIV/AIDS, multiple
22 sclerosis, arthritis, gastrointestinal disorders, and chronic pain. This, in turn, causes ASA
23 economic loss in staff pay and funds expended to produce educational materials, and it impedes
24 ASA’s mission of undertaking other efforts to improve the access of qualified patients to medical
25 marijuana.
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1 **CERTIFICATION OF INTERESTED ENTITIES OR PERSONS**

2 Pursuant to Civil L.R. 3-16, the undersigned certifies that as of this date, other than the
3 named parties, there is no such interest to report.
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6 DATED: February 21, 2007

Respectfully Submitted,

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10 JOSEPH D. ELFORI
11 Attorney for Plaintiff
12 AMERICANS FOR SAFE ACCESS
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