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

17 AMERICANS FOR SAFE ACCESS,) No. C-07-01049 WHA
18)
19 Plaintiff,) **FIRST AMENDED COMPLAINT**
20) **FOR DECLARATORY AND**
21 v.) **INJUNCTIVE RELIEF**
22)
23 DEPARTMENT OF HEALTH AND)
24 HUMAN SERVICES and FOOD AND)
25 DRUG ADMINISTRATION,)
26)
27 Defendants.)
28)

I. INTRODUCTION

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

1 chronic pain, the Department of Health and Human Services (“HHS”) continues to tell the public
2 that marijuana “has no currently accepted medical use in treatment in the United States.” This
3 action is filed under the Information Quality Act, 44 U.S.C. § 3516, Statutory and Historical
4 Notes, P.L. 106-554 (“Information Quality Act” or “IQA”), and the Administrative Procedure
5 Act (“APA”), 5 U.S.C. § 701 *et seq.*, to correct this and related false and misleading statements,
6 as the Information Quality Act requires.
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8 2. In 1995 and again in 2000, Congress recognized a problem with the quality and
9 integrity of information disseminated by federal agencies, which prompted it to enact legislation
10 to ensure the “quality, objectivity, utility, and integrity of information” disseminated by federal
11 agencies. 44 U.S.C. § 3516, Statutory and Historical Notes, P.L. 106-554, Sec. 1(a)(3). Pursuant
12 to this Act, HHS has a legal duty to consider petitions from the public to correct erroneous
13 statements that it has disseminated and to correct information that does not comply with IQA
14 guidelines. Here, nearly three years ago, plaintiff Americans for Safe Access (“ASA”) submitted
15 such a petition to HHS with respect to particular HHS claims that marijuana has no medical use.
16 In support of its petition, ASA supplied citations to numerous scientific studies confirming the
17 medical efficacy of marijuana, including a report from the prestigious National Institute of
18 Medicine (“IOM”) that was commissioned by the White House’s Office of National Drug
19 Control Policy (“ONDCP”).
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22 3. HHS responded by engaging in inexcusable delay and, ultimately, on July 12,
23 2006, HHS issued a nonsubstantive final denial of ASA’s request, stating that it expected the
24 issue to be resolved by the Drug Enforcement Administration (“DEA”) in a different
25 administrative proceeding. Left with no other administrative recourse, ASA filed the instant suit
26 challenging HHS’ arbitrary and unlawful behavior, since the federal government’s false
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1 statements deter sick and dying persons from seeking to obtain medicine that could provide them
2 needed, and often life-saving, relief. When it comes to medical marijuana, HHS has failed in its
3 avowed mission of “protecting the health of all Americans and providing essential human
4 services, especially for those who are least able to help themselves.”

5 **II. JURISDICTION AND INTRADISTRICT ASSIGNMENT**

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

10 5. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and
11 1361.

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13 6. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) and Local Rule
14 3-5(b) because plaintiff ASA maintains its headquarters in Oakland, California, which is in this
15 judicial district, and a substantial portion of the events giving rise to the complaint occurred in
16 this judicial district.

17 **III. THE PARTIES**

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19 7. Plaintiff AMERICANS FOR SAFE ACCESS (“ASA”) is a non-profit corporation
20 headquartered in Oakland, California that has as its primary purpose working to expand and
21 protect the rights of patients to use marijuana for medical purposes, including providing outreach
22 and education to the public regarding the use of marijuana for medical purposes. ASA’s
23 members and constituents include seriously ill persons who would have benefited from the use of
24 marijuana for medical purposes, but who were deterred from using marijuana to ease their
25 suffering, in part, by HHS’ statement that marijuana “has no currently accepted medical use in
26 treatment in the United States.” ASA has devoted significant resources to combat this and
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1 related false statements, including the expenditure of more than one hundred thousand dollars
2 and hundreds of hours of staff time producing and disseminating educational materials
3 explaining that scientific studies demonstrate that marijuana is effective in treating symptoms
4 associated with cancer, HIV/AIDS, multiple sclerosis, arthritis, gastrointestinal disorders, and
5 chronic pain. HHS' failure to correct its false statements that marijuana does not have any
6 currently accepted medical use in treatment in the United States adversely affects the
7 membership and constituency of ASA and causes ASA to suffer injury to its ability to carry out
8 its mission, as well as causing ASA to suffer economic loss in staff pay, funds expended to
9 produce educational materials, and in the inability to undertake other efforts to improve the
10 access of seriously ill persons to medical marijuana.
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13 8. Despite HHS' dissemination of false and misleading information about the
14 effectiveness of marijuana in relieving the pain of victims of certain diseases, four ASA
15 members obtained the correct information and it dramatically improved their lives.

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17 a. For instance, ASA's Executive Director, Steph Sherer, suffers from a
18 condition known as torticollis, which causes her to experience inflammation, muscle spasms,
19 pain throughout her body, and decreased mobility in her neck. Until November of 2001, Ms.
20 Sherer did not believe that marijuana had medical use, due to statements that it did not on federal
21 websites; however, after Ms. Sherer suffered kidney damage from the large amounts of
22 conventional pain killers she was taking, her physician recommended that she try marijuana.
23 Ms. Sherer heeded her physician's advice and has successfully used marijuana since November
24 of 2001 to reduce her inflammation, muscle spasms, and pain. Ms. Sherer founded ASA to share
25 medical information with others in April of 2002.
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1 b. Victoria Lansford (“Lansford”) is also an ASA constituent and member
2 who resides in Blackfoot, Idaho. Ms. Lansford suffers from fibromyalgia, which causes her to
3 suffer severe chronic pain and muscle spasms. Until 2002, Lansford used a regimen of pain
4 medications, including a morphine patch and Oxycontin, because she did not believe marijuana
5 had medical use, due in part to HHS’ statements. In 2002, on the recommendation of her sister,
6 Lansford started using medical marijuana to treat her chronic pain and muscle spasms. This use
7 of marijuana has significantly improved Ms. Lansford’s health and she has been able to stop
8 using the highly addictive Oxycontin.
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10 c. Jacqueline Patterson is an ASA member and constituent who resides in
11 Bolinas, California. Patterson has cerebral palsy, which among its other symptoms impairs
12 Patterson’s speech and causes her to suffer muscle spasticity and pain. Until June of 2001, Ms.
13 Patterson did not believe that marijuana was medicine because of the federal government’s
14 statements that it was not, but her husband eventually convinced her to try it. Since beginning to
15 use medical marijuana, Ms. Patterson has significantly improved her ability to speak and rarely
16 suffers the serious muscle spasms she experienced in her right arm.
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19 d. Shane Kintvel is an ASA member and constituent who experiences
20 chronic pain and muscle spasms as a result of a serious back injury. Until 2002, Mr. Kintvel, of
21 Golden, Colorado, used conventional prescription pain medications, including morphine, to treat
22 his chronic pain. He was led to believe that marijuana would not be effective for this purpose
23 from information he received from his doctors and his review of federal government websites.
24 In approximately July of 2002, however, Mr. Kintvel began using marijuana in place of
25 prescription medications. According to the progress measured by Dr. Michael McMillan, Mr.
26 Kintvel’s current treating physician, Kintvel is now completely mobile, has discontinued his use
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1 of morphine, and has lost more than fifty pounds that he had gained from taking large amounts of
2 morphine and being unable to exercise.

3 9. Defendant DEPARTMENT OF HEALTH AND HUMAN SERVICES (“HHS”)
4 is an administrative agency of the federal government with its headquarters in Washington, D.C.
5 HHS claims on its website that it is the “government’s principal agency for protecting the health
6 of all Americans and providing essential human services, especially for those who are least able
7 to help themselves.” *See* <http://www.hhs.gov/>. In April of 2000, in response to a request to
8 reclassify marijuana, HHS stated its finding that marijuana “has no currently accepted medical
9 use in treatment in the United States.” *Federal Register*, 66 Fed.Reg. 20038, 20039 (April 18,
10 2001). HHS continues to disseminate this and related statements through testimony to Congress
11 and on FDA and government websites, such as
12 <http://www.fda.gov/ola/2004/marijuana0401.html>;
13 <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html>;
14 http://www.access.gpo.gov/su_docs/fedreg/a010418c.html; and
15 http://www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr0418/fr0418a.html.

16 10. Defendant FOOD AND DRUG ADMINISTRATION (“FDA”) is a federal
17 agency within the Department of Health and Human Services. FDA claims as its mission that it
18 is “responsible for advancing the public health by helping to speed innovations that make
19 medicines and foods more effective, safer, and more affordable; and helping the public get the
20 accurate, science-based information they need to use medicines and foods to improve their
21 health.” *See* <http://www.fda.gov/opacom/morechoices/mission.html>. The FDA was assigned the
22 task of evaluating marijuana for medical use by HHS and, in 2001, concluded that marijuana did
23 not have any medical use. HHS’ statements to this effect are predicated on the FDA’s findings.
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1 information from agencies to medical providers, patients, health agencies, and the public.” HHS
2 Guideline D.2.c.2.

3 14. To allow public participation in ensuring these goals, the HHS Guidelines provide
4 for both an initial petition to correct erroneous information that HHS has disseminated and an
5 administrative appeal (or “Information Quality Appeal”). With regard to an initial petition, the
6 Guidelines state that “[t]he agency will respond to all requests for correction within 60 calendar
7 days of receipt. If the request requires more than 60 calendar days to resolve, the agency will
8 inform the complainant that more time is required and indicate the reason why and an estimated
9 decision date.” HHS Guideline E. If the initial petition is denied by HHS, the HHS Guidelines
10 provide for an administrative appeal, and the “agency will respond to all requests for appeals
11 within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve,
12 the agency will inform the complainant that more time is required and indicate the reason why
13 and an estimated decision date.” HHS Guideline E. In cases where a petition to review
14 information disseminated in connection with another pending HHS action, “requests for
15 correction will be considered prior to the final agency action or information product [in the other
16 proceeding] in those cases where in the agency’s judgment issuing an earlier response would not
17 unduly delay issuance of the [other] agency action or information product and the complainant
18 has shown a reasonable likelihood of suffering actual harm from the agency’s dissemination if
19 the agency does not resolve the complaint prior to the final agency action or information product
20 [in the other proceeding].” HHS Guidelines, Section E.

21 **V. FACTS**

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

4 16. ASA’s petition alleges that HHS has disseminated to the public, and is continuing
5 to disseminate to the public, the statement that marijuana “has no currently accepted medical use
6 in treatment in the United States.” The petition alleges that this HHS statement, and the findings
7 underlying it, are inaccurate, in violation of the IQA and the OMB and HHS IQA Guidelines.
8 The ASA petition alleges with specificity why the HHS information dissemination is inaccurate,
9 and requests specific corrections. In particular, the ASA petition alleges that numerous peer-
10 reviewed studies, including the 1999 Institute of Medicine (“IOM”) study commissioned by the
11 ONDCP establish that marijuana is accepted in the United States as effective in treating various
12 illnesses.
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15 17. On December 1, 2004, HHS sent ASA an interim response to its October 4, 2004,
16 petition. The interim response stated that HHS had not yet completed its review of the ASA
17 petition, due to other agency priorities and the need to coordinate agency review. HHS
18 contended that it needed to consult with the Drug Enforcement Administration (“DEA”), which
19 was considering a petition to reschedule marijuana, to prepare a response, and that it hoped to
20 provide a response within the next 60 days.
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22 18. By letter dated December 20, 2004, ASA protested that HHS, by consulting with
23 DEA, was inexcusably expanding its review to include considerations outside the scope of
24 ASA’s petition and that such expansion would unduly delay an administrative response to the
25 requested correction of information.
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1 19. Nevertheless, HHS provided a series of interim responses over the next several
2 months stating that it needed additional time to coordinate agency review. On April 20, 2005,
3 HHS denied ASA’s petition without presenting any evidence that its statements about the lack of
4 medical efficacy of marijuana are justified. HHS made no mention of its IQA Guideline D.2.c.2,
5 which requires it to ensure the “timely flow of vital information from agencies to medical
6 providers, patients, health agencies, and the public.”

8 20. On May 19, 2005, ASA filed an appeal of the HHS rejection of its October 4,
9 2004, petition, pursuant to the HHS Guidelines. *See* HHS Guideline E.

10 21. ASA’s May 19, 2005, appeal protested that: (a) HHS was evading its data quality
11 responsibilities and delaying a response in contravention of its Guidelines, especially by
12 referring the issues raised by the ASA Petition to a proceeding outside HHS; (b) the issues raised
13 by ASA’s request for correction under the Information Quality Act are different and more
14 limited than those raised in the DEA rescheduling proceeding, so merging the proceedings would
15 not allow the consideration of data quality issues “on a timely basis,” as required by the HHS
16 Guidelines, and (c) HHS had ignored its Guidelines stating that data quality complaints must be
17 acted upon in a timely fashion where there is a reasonable likelihood that persons were suffering
18 actual harm from the inaccurate information being disseminated by the agency. ASA alleged
19 that “seriously ill persons represented by ASA are suffering from being misled about the medical
20 benefits of marijuana [by HHS].”

21 22. Again, commencing on July 28, 2005, HHS sent ASA a series of interim
22 responses to its appeal over a period of more than eleven months, stating that the agency required
23 additional time to coordinate agency review to prepare a response and that its “goal is to have a
24 response to your appeal within 60 days of the date of this letter.” Then, on July 12, 2006, HHS
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1 sent ASA a nonsubstantive final denial of the appeal that does not meet the requirements of the
2 IQA, the Guidelines issued by HHS and OMB, and the APA. HHS did not address any of the
3 allegations of the petition, but merely noted that it anticipated providing a response to the Drug
4 Enforcement Administration (“DEA”) by September 2006, in connection with a marijuana
5 rescheduling petition that had been pending before the DEA since October 9, 2002. This marks
6 the conclusion of the administrative IQA petition process, as ASA has no additional
7 administrative avenues of recourse.
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9 23. HHS’ failure to provide a substantive response to ASA’s petition has a direct and
10 immediate effect on the day-to-day operations of ASA. As a direct and proximate result of
11 defendants’ actions, ASA has suffered, and will continue to suffer, the loss of staff time,
12 economic resources, and impairment of its mission. In particular, to combat HHS’ dissemination
13 of inaccurate statements that marijuana does not have any accepted medical use, ASA has spent
14 more than one hundred thousand dollars and expended hundreds of hours of staff time producing
15 and disseminating educational materials explaining that marijuana has medical use in the
16 treatment of cancer, HIV/AIDS, multiple sclerosis, arthritis, gastrointestinal disorders, and
17 chronic pain. This, in turn, causes ASA economic loss in staff pay and funds expended to
18 produce educational materials, and it impedes ASA’s mission of undertaking other efforts to
19 improve the access of qualified patients to medical marijuana.
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22 24. Furthermore, as a direct and proximate result of defendants’ actions, ASA and its
23 members and constituents -- which include seriously ill persons who would have benefited, or
24 might benefit from the use of marijuana for medical purposes, but whose use of marijuana for
25 health reasons has been impeded by HHS’ flawed statement that marijuana does not have
26 medical use -- have been irreparably harmed and continue to be harmed.
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