

United States District Court
NORTHERN DISTRICT OF CALIFORNIA

ADR

AMERICANS FOR SAFE ACCESS

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SUMMONS IN A CIVIL CASE

CASE NUMBER:

C07-01049

WHA

v.

DEPARTMENT OF HEALTH AND HUMAN
SERVICES and FOOD AND DRUG
ADMINISTRATION

TO: (Name and address of defendant)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Federal Office Building
50 United Nations Plaza
San Francisco, CA 94102

FOOD AND DRUG ADMINISTRATION
1301 Clay Street, Suite 1180-N
Oakland, CA 94512-5217

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

Joseph D. Elford (S.B. No. 189934)
Americans for Safe Access
1322 Webster St., Suite 402
Oakland, CA 94612
Tel: (415) 573-7842

an answer to the complaint which is herewith served upon you, within **60** days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgement by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

Richard W. Wieking

CLERK

[Handwritten signature]

/s/

(BY) DEPUTY CLERK

DATE FEB 3 1 2007

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 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

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. 007-01049

**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

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

ADR

WHA

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.
6

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”).
18

19
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).
5

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

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

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.
7

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.
11

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.
4

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.
12

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.deaiversion.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.

17 14. To allow public participation in ensuring these goals, the HHS Guidelines provide
18 for both an initial petition to correct erroneous information that HHS has disseminated and an
19 administrative appeal (or “Information Quality Appeal”). With regard to an initial petition, the
20 Guidelines state that “[t]he agency will respond to all requests for correction within 60 calendar
21 days of receipt. If the request requires more than 60 calendar days to resolve, the agency will
22 inform the complainant that more time is required and indicate the reason why and an estimated
23 decision date.” HHS Guideline E. If the initial petition is denied by HHS, the HHS Guidelines
24 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
4 18. By letter dated December 20, 2004, ASA protested that HHS, by consulting with
5 DEA, was inexcusably expanding its review to include considerations outside the scope of
6 ASA's petition and that such expansion would unduly delay an administrative response to the
7 requested correction of information.

8
9 19. Nevertheless, HHS provided a series of interim responses over the next several
10 months stating that it needed additional time to coordinate agency review. On April 20, 2005,
11 HHS denied ASA's petition without presenting any evidence that its statements about the lack of
12 medical efficacy of marijuana are justified. HHS made no mention of its DQA Guideline
13 D.2.c.2, which requires it to ensure the "timely flow of vital information from agencies to
14 medical providers, patients, health agencies, and the public."

15
16 20. On May 19, 2005, ASA filed an appeal of the HHS rejection of its October 4,
17 2004, petition, pursuant to the HHS Guidelines. *See* HHS Guideline E.

18
19 21. ASA's May 19, 2005, appeal protested that: (a) HHS was evading its data quality
20 responsibilities and delaying a response in contravention of its Guidelines, especially by
21 referring the issues raised by the ASA Petition to a proceeding outside HHS; (b) the issues raised
22 by ASA's request for correction under the Data Quality Act are different and more limited than
23 those raised in the DEA rescheduling proceeding, so merging the proceedings would not allow
24 the consideration of data quality issues "on a timely basis," as required by the HHS Guidelines,
25 and (c) HHS had ignored its Guidelines stating that data quality complaints must be acted upon
26 in a timely fashion where there is a reasonable likelihood that persons were suffering actual harm
27 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].”

3
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.
14

15
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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2007 FEB 21 PM 2:51
U.S. DISTRICT COURT
OAKLAND, CALIFORNIA

/s/
SERVED ON [Signature]
USAO, OAKLAND
MANNER OF SERVICE:
 PERSONAL CERT MAIL
OTHER:
DATE 2/21/07 TIME 2:51 PM

E-filing

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8 Counsel for Plaintiff
9 AMERICANS FOR SAFE ACCESS

ORIGINAL
FILED
FEB 21 2007
RICHARD W. WIEKING
CLERK U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND

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

12 AMERICANS FOR SAFE ACCESS,)
13)
14 Plaintiff,)
15 v.)
16 DEPARTMENT OF HEALTH AND)
17 HUMAN SERVICES and FOOD AND)
18 DRUG ADMINISTRATION,)
19 Defendants.)

No. **07-01049**
**APPLICATION OF ALAN B.
MORRISON TO APPEAR
PRO HAC VICE**

ADR
WHA

No Hearing Scheduled

20 Pursuant to Local Rule 11-3, Plaintiff Americans for Safe Access ("ASA") moves this
21 Court for an order permitting Alan B. Morrison to appear *pro hac vice* as co-counsel representing
22 ASA in the above-captioned matter.

23 As grounds for this motion, Alan B. Morrison, hereby declares as follows:

- 24 1. I am a Senior Lecturer at Stanford Law School, Stanford California. I specialize in the
25 area of administrative law and have expertise regarding the matters to be litigated in this
26 case.
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2. I am licensed to practice law in the District of Columbia, and have been admitted to practice in the United State Supreme Court, all of the United States Courts of Appeals, and the United States District Court for the District of Columbia and for the Eastern District of Michigan. I am active member in good standing and currently eligible to practice law in each of these courts. I was admitted to practice in the State of New York in 1967, but resigned from that bar in good standing when I moved to California in 2004. As a result, I am no longer a member of the bars of the United States District Courts for the Southern and Eastern Districts of New York.

3. I have not previously sought *pro hac vice* status in any other matter in California.

4. I agree to abide by the Standards of Professional Conduct set forth in Civil Local Rule 11-4, and to become familiar with the Local Rules and Alternative Dispute Resolution Programs of this Court

5. The undersigned California counsel making this motion is a member in good standing with the bar of this Court and the State Bar of California, and maintains his office in Oakland, California. The undersigned California counsel is associated as co-counsel with Mr. Morrison in representing ASA in this matter.

6. The interests of ASA would be best served and no prejudice would result to the Defendant by this Court permitting Mr. Morrison to appear *pro hac vice* in this matter.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on this 21st day of February, 2007, in Stanford California.

ALAN B. MORRISON

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CERTIFICATE OF SERVICE

I am a resident of the State of California, not a party to this action, and over the age of eighteen years. My business address is 1322 Webster St., Suite 402, Oakland, CA 94612. On February 21, I served the within document(s):

APPLICATION OF ALAN B. MORRISON TO APPEAR *PRO HAC VICE*

Via hand delivery to:

United States Attorney's Office
Northern District of California
Civil Division
Oakland Branch Office
1301 Clay Street, Suite 340S
Oakland, CA 94612

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on this 21st day of February, 2007, in Oakland, California.

/s/

Joseph D. Elford

RECEIVED

FEB 21 2007

IN THE UNITED STATES DISTRICT COURT

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

ADR
WHA

E-filing No. C07-01049

AMERICANS FOR SAFE ACCESS,

Plaintiff,

v.

DEPARTMENT OF HEALTH AND
HUMAN SERVICES and FOOD AND
DRUG ADMINISTRATION,

Defendants.

[PROPOSED] ORDER

Good cause appearing, IT IS HEREBY ORDERED, that Alan B. Morrison's Application
to Appear *Pro Hac Vice* is GRANTED.

DATED:

United States District Court Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ORIGINAL
FILED
FEB 21 2007
RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND

AMERICANS FOR SAFE ACCESS,

E-filing

No. C 07-01049 WHA

Plaintiff (s),

v.

**ORDER SETTING INITIAL CASE
MANAGEMENT CONFERENCE
AND ADR DEADLINES**

DEPARTMENT OF HEALTH AND
HUMAN SERVICES,

Defendant(s).

IT IS HEREBY ORDERED that this action is assigned to the Honorable William H. Alsup. When serving the complaint or notice of removal, the plaintiff or removing defendant must serve on all other parties a copy of this order, the handbook entitled "Dispute Resolution Procedures in the Northern District of California" and all other documents specified in Civil Local Rule 4-2. Counsel must comply with the case schedule listed below unless the Court otherwise orders.

IT IS FURTHER ORDERED that this action is assigned to the Alternative Dispute Resolution (ADR) Multi-Option Program governed by ADR Local Rule 3. Counsel and clients shall familiarize themselves with that rule and with the handbook entitled "Dispute Resolution Procedures in the Northern District of California."

CASE SCHEDULE -ADR MULTI-OPTION PROGRAM

Date	Event	Governing Rule
2/21/2007	Complaint filed	
5/10/2007	Last day to: <ul style="list-style-type: none"> meet and confer re: initial disclosures, early settlement, ADR process selection, and discovery plan file Joint ADR Certification with Stipulation to ADR Process or Notice of Need for ADR Phone Conference 	<u>FRCivP 26(f) & ADR L.R. 3-5</u> <u>Civil L.R. 16-8</u>
5/17/2007	Last day to complete initial disclosures or state objection in Rule 26(f) Report, file Case Management Statement and file/serve Rule 26(f) Report	<u>FRCivP 26(a) (1)</u> <u>Civil L.R. 16-9</u>
5/31/2007	CASE MANAGEMENT CONFERENCE (CMC) in Ctrm 9, 19th Fl,SF at 11:00 AM	<u>Civil L.R. 16-10</u>