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14
15 **UNITED STATES DISTRICT COURT**
16 **NORTHERN DISTRICT OF CALIFORNIA**
17

18 MARIN ALLIANCE FOR MEDICAL)
MARIJUANA, a not-for-profit association;)
19 JOHN D'AMATO, an individual,)

20 Plaintiffs/Petitioners,)

21 vs.)

22 ERIC HOLDER, Attorney General of the United)
States; MICHELLE LEONHART, Administrator)
23 of the Drug Enforcement Administration; HON.)
MELINDA HAAG, U.S. Attorney for the)
24 Northern District of California; and DOES 1)
through 10, inclusive,)

25 Defendants/Respondents.)
26
27

Case No. CV-11-005349-DMR

**DECLARATION OF RICK DOBLIN IN
SUPPORT OF PLAINTIFF'S PETITION
FOR TEMPORARY RESTRAINING
ORDER/ PRELIMINARY INJUNCTION**

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1
2 I, RICK DOBLIN, hereby declare

- 3 1. I am an adult, over the age of 18 years, and am fully competent to make this
4 declaration. I have personal knowledge of the matters set forth in this declaration, except for
5 those stated on information and belief. As to those facts, I believe them to be true. If called
6 upon to testify, I could and would testify competently to the truth of each matter stated in this
7 declaration.
- 8 2. I obtained a psychology degree from New College of Florida in 1987 and earned a
9 doctorate in public policy from the Kennedy School of Government, Harvard University in
10 2001. My dissertation (Public Policy, Harvard's Kennedy School of Government) was on
11 "The Regulation of the Medical Use of Psychedelics and Marijuana," and my 1990 master's
12 thesis (Public Policy, Harvard's Kennedy School of Government) focused on the attitudes and
13 experiences of oncologists concerning the medical use of marijuana. I am also the executive
14 director and founder of the Multidisciplinary Association for Psychedelic Studies ("MAPS"),
15 a non-profit organization sponsoring medical cannabis research to develop the cannabis plant
16 into an FDA-approved prescription medicine, smoked or vaporized.
- 17 3. The federal government regulates studies on medical cannabis with lengthy and
18 expensive requirements not applied to any other controlled substance.
- 19 4. All clinical research utilizing controlled substances on human patients under an
20 Investigational New Drug ("IND") application must be approved by the Drug Enforcement
21 Administration ("DEA"), the US Food and Drug Administration ("FDA"), and an
22 Institutional Review Board ("IRB").
- 23 5. Since 1999, however, cannabis research protocols, unlike any other protocols, must
24 additionally receive scientific merit approval from the Public Health Service ("PHS"). No
25 other controlled substance research protocol requires PHS review. The policy underlying
26 PHS review purports to facilitate further research.
27

- 1 6. Before a researcher can seek DEA, FDA, and PHS approval of a new study, the
2 National Institute on Drug Abuse (“NIDA”) must decide whether it has sufficient cannabis
3 available to provide, at cost, to the study. NIDA is the monopoly provider of cannabis, but no
4 other controlled substance, for medical research in the United States.
- 5 7. DEA permits only a single provider to produce cannabis for clinical research. Since
6 1968 the sole grantee of the contract has been the National Center for Natural Products
7 Research (“NCNPR”) at the University of Mississippi which provides cannabis under contract
8 to NIDA.
- 9 8. The cannabis provided by NIDA is often of substandard quality and in some cases is
10 not representative of medical cannabis. Cannabis provided by NIDA can be a crude mixture
11 of leaf, stem, and seed components which are undesirable for medical studies.
- 12 9. NIDA on two occasions has denied applications from MAPS-sponsored researchers
13 seeking to purchase medical cannabis, even after researchers obtained FDA approval and the
14 consent of IRBs for their protocols. Between June 2003 and August 2009, when it gave up, a
15 DEA-licensed analytical laboratory working for the pharmaceutical industry was repeatedly
16 rejected by NIDA in its attempts to purchase 10 grams of cannabis for MAPS-sponsored
17 research with vaporized cannabis. Most recently, on September 16, 2011, NIDA rejected an
18 application to purchase cannabis for a MAPS-sponsored FDA-approved study seeking to treat
19 fifty veterans with chronic treatment-resistant post-traumatic stress disorder.
- 20 10. Intending to provide an adequate and reliable supply of research-grade cannabis
21 without having to undergo the obstructionist NIDA review process, University of
22 Massachusetts at Amherst professor of plant and soil sciences Lyle E. Craker, PhD, applied to
23 the DEA in 2001 to be a private cultivator of cannabis for medical research, under contract to
24 MAPS. Professor Craker’s application was based on the Controlled Substances Act provision
25 that that DEA shall register manufacturers of Schedule I substances if it is in the public
26 interest and in accordance with international treaties.
27

- 1 11. DEA initially claimed to have lost the application, and subsequently delayed in
2 responding Professor Craker's request for three and a half years.
- 3 12. Professor Craker sued DEA for its three-and-a-half-year delay and the Court of
4 Appeals in the District of Columbia ordered DEA to respond. DEA then issued an Order to
5 Show Cause rejecting Professor Craker's application. DEA based its rejection on several
6 points, claiming that an international treaty called the Single Convention on Narcotics of 1961
7 ("Single Convention") requires research cannabis to come only from a government-funded
8 source, that approval would not be in the public interest because cannabis is the most heavily
9 abused of all Schedule I substances, and that smoked cannabis is not an acceptable form of
10 delivery for any potential cannabis medication.
- 11 13. In August 2005 a DEA administrative hearing took place to review DEA's Order to
12 Show Cause. After a lengthy presentation of evidence, evaluation of testimony, and review of
13 applicable regulations, DEA Administrative Law Judge Mary Ellen Bittner issued a final
14 decision in February 2007. Judge Bittner recommended that it would be in the public interest
15 that Professor Craker be granted permission to grow and produce research-grade cannabis for
16 federally-regulated research.
- 17 14. Judge Bittner reasoned in her decision that registering Professor Craker would not
18 violate the Single Convention, that the cannabis grown by Professor Craker was not likely to
19 be diverted, and that the existing supply of cannabis is not adequate as some DEA- and FDA-
20 approved researchers are prevented from obtaining the cannabis needed for research. Judge
21 Bittner further stated that the NIDA contract does not provide adequate competition.
- 22 15. Should Professor Craker be licensed by DEA, NIDA would have no role to play in
23 reviewing FDA-, DEA-, and IRB-approved research protocols conducted using cannabis
24 produced by Professor Craker, similar to all other scheduled drugs produced by DEA-licensed
25 manufacturers.
- 26 16. DEA Deputy Administrator Michele Leonhart, after delaying for almost two years
27 after Judge Bittner's February 2007 recommendation, in January 2009, six days before

1 President Obama was inaugurated, rejected Judge Bittner's recommendations and ruled to
2 deny Professor Craker's request. The ruling was based in part on evidence not submitted or
3 heard at the administrative hearing. A motion for reconsideration was filed by Professor
4 Craker on the basis of this defect.

5 17. Despite rejecting Professor Craker's application to cultivate research-grade cannabis,
6 DEA granted NCNPR an additional license to grow cannabis for natural extraction of THC,
7 the primary active ingredient in the cannabis plant, for sale to Mallinckrodt, a division of
8 pharmaceutical company Coviden, for generic Marinol (the oral THC pill). NCNPR's
9 separate permit makes it the only legal grower of cannabis for commercial purposes.

10 18. NCNPR's contract as the sole producer of research cannabis, in conjunction with its
11 license to cultivate cannabis commercially for an inferior product that would compete
12 unsuccessfully with the cannabis plant, creates a conflict of interest. Dr. Mahmoud ElSohly,
13 principal investigator of the NCNPR cannabis program, was the only person to file an
14 objection to the licensing of Professor Craker. This monopoly on the provision of cannabis
15 allows NIDA to control the supply and Dr. ElSohly to control the price of cannabis, for
16 research as well as for potential prescription use.

17 19. DEA states that the federal government is open to cannabis research and claims that
18 the supply of research-grade cannabis is limited by the Single Convention. In May 1999
19 Health and Human Services issued guidance statement regarding the sale of its cannabis to
20 privately-funded researchers, stating "the purpose of clinical trials of smoked marijuana
21 would not be to develop marijuana as a licensed drug, but such trials could be a first step
22 towards the development of rapid-onset, nonsmoked cannabinoid delivery systems."


23 20. In late October 2011, Drug Czar R. Gil Kerlikowske stated the White House "ardently
24 support[s] ongoing research into determining what components of the marijuana plant can be
25 used as medicine." Once again the federal government is willing to provide the cannabis
26 plant only to researchers willing to study components of cannabis rather than the plant itself,
27 smoked or vaporized.

1 21. On August 15, 2011, DEA rejected Judge Bittner's recommendation to approve
2 Professor Craker's application to cultivate cannabis and opted instead to protect the NIDA
3 monopoly. In doing so, DEA rejected a statutory exemption for researchers in the Single
4 Convention, disregarded a judicial determination that the exemption was valid and applied to
5 Professor Craker, and ignored the fact that the National Cannabis Agency in the United
6 Kingdom (also a signatory to the Single Convention) licenses a privately-funded production
7 facility to produce, possess, and research cannabis and its components.

8 22. It is hypocritical that the federal government claims to be open to medical cannabis
9 research while simultaneously obstructing privately-funded FDA-approved research designed
10 to develop the marijuana plant into an FDA-approved prescription medication. The federal
11 government has fundamentally obstructed access to research cannabis for researchers seeking
12 to develop the plant itself into a prescription medicine and has subjected privately-funded
13 studies of cannabis to redundant and biased review not required of any other controlled or
14 uncontrolled substance. No sponsor of research can invest the many millions of dollars
15 required to develop cannabis as an FDA-approved medicine without an independent source
16 supplying the cannabis they seek to test and market for prescription use.

17 I declare under penalty of perjury that the foregoing is true and correct.

18
19 Executed: November 7, 2011

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Rick Doblin, PhD