Americans For Safe Access

AN ORGANIZATION OF MEDICAL PROFESSIONALS, SCIENTISTS, AND PATIENTS HELPING PATIENTS

THE OBSTRUCTION OF MEDICAL CANNABIS RESEARCH IN THE U.S.

A REVIEW OF THE GROWING CONTROVERSY REGARDING A FEDERAL MONOPOLY ON THE SUPPLY OF MEDICAL CANNABIS FOR RESEARCH

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INTRODUCTION

In the past three decades, there has been an explosion of international studies designed to investigate the therapeutic value of cannabis (marijuana). However, drastic restrictions on research in the U.S. have meant that few clinical trials are being conducted domestically and none are being conducted as part of a sponsor-funded drug development plan aimed at obtaining Food & Drug Administration (FDA) approval for the prescription use of the botanical plant itself. Meanwhile, research teams in Great Britain, Spain, Italy, Israel, and elsewhere have confirmed - through case studies, basic research, pre-clinical, and preliminary clinical investigations - the medical value of cannabis. Equally important, numerous studies have provided strong indications of the potential for more targeted drugs, whole-plant cannabis derivatives and synthetics. The current research challenge is to conduct large-scale human clinical trials that evaluate the remarkable range of potential applications for cannabis-based treatments to specific medical conditions.

That challenge was identified in the 1999 Institute of Medicine report Marijuana and Medicine, but the federal government has never undertaken any effort to review or fully implement its recommendations.[1] Moreover, the federal monopoly on the supply of cannabis has fundamentally limited FDA-approved clinical research to investigate its safety and efficacy in controlling symptoms of serious and chronic illnesses. In the United States, research is stalled, and in some cases blocked, by a complicated federal approval process, restricted access to research-grade cannabis, and the refusal of the Drug Enforcement Administration (DEA) to license private production of cannabis for use exclusively in federally approved research. These restrictions prevent sponsors from selecting the strain of cannabis they want to study and from having guaranteed access to that strain for potential sale as a prescription medicine.

Despite the fact that federal law clearly requires adequate competition in the manufacture of Schedule I and II substances, since 1968, first the National Institute of Mental Health (NIMH), then

PROBLEM QUOTE

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the National Institute on Drug Abuse (NIDA) has maintained a monopoly on the supply of cannabis used for legitimate research purposes.[2] The DEA helps to protect NIDA's monopoly by refusing to grant competitive licenses for the production of research-grade cannabis. Ordinarily, once the FDA has approved a protocol, sponsors of research produce the drug or plant strain they want to study and then proceed with the approved course of study. Unfortunately, in the case of cannabis, the DEA has continually obstructed research by protecting an unnecessary federal monopoly on the supply of cannabis available for FDA-approved research. In addition, some medical cannabis researchers who otherwise possess the appropriate licenses and requisite approval have been unable to initiate their FDA-approved protocols due to NIDA's refusal to provide research-grade cannabis.[3] On the rare occasion that the supply of research cannabis is approved, it is sold at a cost set by NIDA.

NIDA's mission is to support research on the causes, consequences, prevention and treatment of drug abuse and drug addiction. In fact, officials from the Institute have testified that it is not NIDA's mission to study medicinal uses of cannabis or to advocate for such research.[4] Consequently, research that aims to investigate or prove the therapeutic value of cannabis is often obstructed or otherwise altered to accommodate the limited scope and mission of NIDA. Moreover, NIDA's monopoly on the supply of cannabis available for research results in arbitrary and potentially harmful delays. Such delays make it financially prohibitive for sponsors to invest the millions of dollars needed to conduct research.

Since 2001, University of Massachusetts at Amherst Professor Lyle Craker has been struggling to obtain a DEA license for a privately funded facility to grow cannabis exclusively for FDA and DEA-approved studies designed to evaluate its potential medical value. In February 2007, after a lengthy hearing that included two weeks of testimony from twelve witnesses, DEA Administrative Law Judge Mary Ellen Bittner issued an 87-page opinion, which included findings of fact and recommendations urging an end to the federal monopoly on the supply of cannabis used in FDA-approved research. In her opinion, Judge Bittner concluded that the "respondent's registration to cultivate cannabis would be in the public interest,"[5] and recommended that the DEA grant Professor Craker a license.

When it became apparent that the DEA was resisting action on the ruling, as it did in the case of the 1988 ruling on cannabis rescheduling, 45 Members of Congress wrote to DEA Administrator Karen Tandy in support of Judge Bittner's decision and urged her to approve the application.[6] In spite of this support, however, the DEA rejected the recommendations nearly two years after Judge

Bittner issued them, thereby continuing to maintain the monopoly on the production of research-grade cannabis.

This report reviews the way in which cannabis research in the U.S. is conducted, illustrating a double standard with regard to medical cannabis research and how the federal monopoly on cannabis production actively obstructs privately funded therapeutic research. This report also illustrates how Mahmoud A. ElSohly, PhD., a professor at the University of Mississippi and the Director of the National Institutes of Health Marijuana Project, is at the center of a growing controversy. Dr. ElSohly, who also owns ElSohly Laboratories, Inc., which grows cannabis under contract to NIDA,[7] holds the exclusive DEA contract to produce cannabis for the development of new forms of cannabis extracts. Dr. ElSohly benefits from such a monopoly by financially profiting from the research and sale of cannabis-based pharmaceuticals.

In particular, Dr. ElSohly is working with Mallinckrodt, a pharmaceutical subsidiary of Tyco International, to bring a whole-plant cannabis extract to market in the U.S.[8] And, because of the monopoly Dr. ElSohly holds on cannabis production in the U.S., the price for cannabis used to develop and market this product is determined either exclusively by Dr. ElSohly or in cooperation with the federal government.

HOT QUOTE

If cannabis were unknown, and bio-prospectors were suddenly to find it in some remote mountain crevice, its discovery would no doubt be hailed as a medical breakthrough.

THE ECONOMIST
April 27, 2006

CANNABIS ARBITRARILY ASSIGNED AS SCHEDULE I SUBSTANCE

In 1970, the U.S. Congress drafted legislation for what would become the Controlled Substances Act (CSA), and then-President Richard Nixon established the National Commission on Marijuana and Drug Abuse (or Shafer Commission, named after its Chair, Raymond Shafer) to study marijuana abuse in the U.S.[9] At the time, Congress temporarily labeled cannabis as a Schedule I substance with no medical value and a high potential for abuse.[10] In 1972, the Shafer report was presented to Congress recommending an end to the decades-long prohibition on cannabis. President Nixon failed to implement the Shafer report recommendations and never removed cannabis from its classification as a Schedule I substance.

Multiple attempts by doctors, researchers and advocates to reschedule cannabis have been met with strong resistance from federal agencies. However, in 1986, the DEA held public hearings concerning a petition to reschedule cannabis. After two years of hearings, Administrative Law Judge Francis L. Young concluded that cannabis should be reclassified, declaring it to be "one of the safest therapeutically active substances known to man."[11] However, the DEA refused to consider

any conclusions that justified the reclassification of cannabis, and instead required that the drug remain a Schedule I substance.

In the decades since the establishment of the CSA and the classification of cannabis as a Schedule I substance, significant research has been conducted on cannabis' medical efficacy.[12] As a result of the federal government's resistance to research, most scientific studies of cannabis have occurred outside of the U.S. The conclusions from years of research overwhelmingly show that cannabis has a therapeutic impact on a number of medical conditions including but not limited to, nausea or loss of appetite associated with cancer treatments, neuropathic pain associated with HIV/AIDS, movement disorders such as Multiple Sclerosis, arthritis, and gastrointestinal disorders.[13] Nonetheless, the federal government's position that "marijuana has no currently accepted medical use in treatment in the United States" is effectively kept in place by the obstruction of privately funded medical cannabis research.

FEDERAL FOCUS ON HARFMUL EFFECTS OF CANNABIS

As a result of its monopoly on the supply of cannabis that can be legally used in federally-approved research, NIDA, a subdivision of the National Institutes of Health (NIH), oversees all cannabis research in the U.S.[14] and funds the vast majority of approved studies involving cannabis. While a nominal number of studies in the U.S. are aimed at investigating the medical efficacy of cannabis, mainly funded by the State of California's Center for Medicinal Cannabis Research (CMCR), NIDA focuses exclusively on the supposed harmful effects of the plant. One consequence of this focus can be found in NIDA's policy of underwriting the cannabis supplied for "drug abuse" research that it funds, whereas researchers studying medical efficacy are required to pay for research-grade cannabis at a price set by NIDA.

At the time this report was issued, only 14 cannabis studies were under way, 13 of which were NIDA-funded drug abuse studies.[15] In 2006, during DEA Administrative Law Judge hearings on expanding the supply of research-grade cannabis, Dr. Steven Gust, Special Assistant to the Director of NIDA, who oversees NIDA's exclusive contract with the University of Mississippi, stated unequivocally that it was "not NIDA's mission to study medicinal uses of marijuana or to advocate for such research."[16]

SELECTIVE FEDERAL POLICY TO IMPEDE MEDICAL CANNABIS RESARCH

Even after the FDA approves medical cannabis research studies, those studies are still subject to additional approval that is not required for any other Schedule I substance.[17] Multiple researchers in the U.S. have been granted approval by the FDA to study medical cannabis, but have been significantly delayed or prevented from conducting their research at all as a result of NIDA's refusal to sell the cannabis.[18]

In 1999, the federal Department of Health & Human Services (HHS) established an exclusive process for medical cannabis research, directing the Public Health Service (PHS) to conduct an extraordinary review that does not exist for any other Schedule I substance made available through NIDA's Drug Supply Program or for controlled substances not provided by the federal government.[19] In contrast to the FDA's statutorily required 30-day limit for its review process, the PHS review has no time limitation. As a result, the PHS review has taken years to complete in some instances. In the event a NIDA/PHS review is unfavorable, researchers are granted a period designated for responses, but this NIDA/PHS response period also has no time limit and has resulted in similarly lengthy delays. Because of the PHS/NIDA resistance to advancing product development for whole-plant medical cannabis, research is substantially impeded. If a drug development plan can be arbitrarily delayed for years at a time by NIDA/PHS, despite the FDA approval of such a plan, privately funded sponsors become deterred from investing the requisite millions of dollars for research. The NIDA/PHS review process prevents cannabis from being adequately investigated or brought to market as a new drug.

HOT QUOTE

"The attorney general should heed calls to end the DEA's obstruction of serious research into the medicinal value of marijuana."

LOS ANGELES TIMES EDITORIAL
March 10, 2009

ARBITRARY AND LENGTHY DELAYS

In one extraordinary example of interference, not only did NIDA refuse to accept an FDA-approved protocol, but the institute also took nine months to provide an initial response and made no attempt at discussing the study or their concerns before denying the request for research-grade cannabis. In 1994, Dr. Donald Abrams, a longtime clinical faculty member at the University of California San Francisco, submitted to the FDA a pilot study protocol designed to evaluate high, medium and low potency smoked cannabis, or dronabinol, in stimulating appetite and reducing weight loss associated with HIV-related wasting syndrome.

Following approval by the FDA, Dr. Abrams submitted an application to NIDA for cannabis to be used in the study. Nine months later, NIDA rejected the application for cannabis despite the fact that the FDA had already approved the research protocol.[20] In June 1995,

Donald I. Abrams, MD, is Professor of Clinical Medicine at the University of California San Francisco, Chief of Hematology/Oncology at San Francisco General Hospital and Director of Clinical Programs at the Osher Center. Dr. Abrams was obstructed in his attempts to obtain research-grade cannabis for his studies related to HIV and cancer.

NIDA announced a new policy that required all medical cannabis protocols to be submitted to NIH for peer review in the context of a grant application, even if no federal funding was requested. One year later, Dr. Abrams resubmitted a revised protocol to evaluate the safety and efficacy of smoked cannabis as an appetite stimulant for HIV-associated anorexia and weight loss. In August 1996, NIH rejected the protocol.[21] After two more attempts, and numerous changes to the FDA-approved protocol to satisfy NIDA's restrictions, NIDA finally awarded Dr. Abrams a grant for a revised protocol. The results of his two-year clinical trial determined that using cannabis did not compromise the immune systems of people living with HIV/AIDS or increase viral load. Another privately sponsored study submitted by Dr. Ethan Russo, a cannabis researcher investigating the effects of cannabis on migraines, was approved by FDA but similarly obstructed by NIDA, which rejected the protocol and refused to sell the cannabis needed for the study.[22]

In another example, a DEA-licensed analytical group, Chemic Labs, has been trying unsuccessfully for more than five years to purchase 10 grams of cannabis for vaporizer research. Chemic was made to wait more than two years for a reply to its initial June 2003 request to purchase 10 grams of cannabis for a privately sponsored research protocol. The research was aimed at investigating the output of vaporizers, a low-heat, non-smoking way of inhaling medical cannabis, the development of which was recommended by the Institute of Medicine in 1999.[23] After two years of delay in processing the request, and a lawsuit filed against NIDA arguing unreasonable delay, the application was rejected in August 2005. Chemic then filed a response, disputing the reasons cited by NIDA/PHS for the rejection of the protocol. After two more years, and a refusal by NIDA to respond to Chemic's reply, Chemic filed a new protocol in January 2008 along with another request for 10 grams of cannabis. NIDA and PHS replied five months later, only to request a large amount of additional information. In November 2008, Chemic replied yet again to NIDA and supplied the information that had been requested.

Whereas FDA operates under a 30-day review process, NIDA and PHS are under no such time constraints. NIDA and PHS can indefinitely delay the approval of applications for research-grade cannabis as well as the applicants' appeals. This lack of timely review makes privately funded research so unpredictable and so financially risky that there are currently no privately funded medical cannabis research studies taking place anywhere in the U.S.

FEDERAL MONOPOLY ON RESEARCH CANNABIS

NIDA has held a monopoly on the production and distribution of research cannabis since 1968.[24] No other known Schedule I substance being researched in the U.S. is restricted to a sole-source supply as in the case of cannabis. Though the federal government has a bidding process for the exclusive license to cultivate research cannabis in the U.S., for nearly forty years that license has been repeatedly awarded to the University of Mississippi.

For many years, DEA's stated pretext for protecting NIDA's monopoly on research cannabis was based on the United Nations Single Convention on Narcotic Drugs, an international treaty adopted in 1961. Yet, while the treaty requires that signatory governments strictly regulate access to cannabis for research purposes, it does not require a sole-source supply. In fact, repeated use of the plural term "cultivators" in the treaty indicates that the Single Convention was never intended to limit the number of cannabis suppliers.[25] Evidence of this can be found in the research cannabis protocol established by the United Kingdom, a signatory to the Single Convention. The U.K. uses a single institution, the National Cannabis Agency, to regulate the production of research cannabis from multiple sources, including by importation. Refuting the government's claim that competitive licensing would violate international treaty obligations, Judge Bittner ruled that Professor Craker's application "would not be inconsistent with the Single Convention."[26]

Another pretext used by the federal government for instituting a sole-source supply of research cannabis is the purported need to control diversion. The lack of evidence of diversion in other countries employing a multi-source policy for cannabis notwithstanding, the federal government's own statistics show that diversion, even if it were to occur under tightly controlled protocols like in the U.K., is irrelevant given the enormously greater availability of cannabis from "street" sales in the U.S. For instance, according to a 2005 NIDA report, "marijuana is the most commonly used illicit drug in the [United States]."[27] In addition, according to the National Drug Intelligence Center's National Drug Threat Assessment published in 2005, "reporting from some areas has suggested that marijuana is easier for youths to obtain than alcohol and cigarettes."[28]

Affirming the improbability of diversion if multiple sources of research cannabis were to be used by the U.S. government, Administrative Law Judge Mary Ellen Bittner concluded that it would be "unlikely that the marijuana that [Professor Craker] would grow would be diverted from the University of Massachusetts' facility."[29]

HOT QUOTE

"...NIDA's system for evaluating requests for marijuana for research has resulted in some researchers who hold DEA registrations and requisite approval from the Department of Health and Human Services being unable to conduct their research because NIDA has refused to provide them with marijuana. I therefore find that the existing supply of marijuana is not adequate."

DEA ADMINISTRATIVE LAW JUDGE MARY ELLEN BITTNER

FEDERAL MONOPOLY FAILS TO FULFILL REQUIREMENTS OF THE CONTROLLED SUBSTANCES ACT

HOT QUOTE

"Researchers hope to do more experiments with vaporizers, but they're stymied by the limited supply of marijuana available from the only legal source, a federal farm in Mississippi…They say that a new supply of better marijuana from Dr. Craker would be a boon to research."

JOHN TIERNEY,
NEW YORK TIMES
May 2007

The federal CSA directs the DEA to limit "the importation and bulk manufacture of [cannabis and other controlled substances] to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes."[30] Reviews of cannabis use by patients in states where such use is legal suggest that patients benefit from different strains of cannabis depending on the medical condition for which it's being used.[31] Given the large variety of cannabinoids in cannabis, and given the great variety of types of cannabis plants and thus types of available cannabinoids, these directives are not being satisfied by the current research cannabis monopoly sustained by DEA and NIDA.

Needless to say, with a sole-source provider of research cannabis, there is only one producer and not "a number of" producers. The adequacy of single-source cannabis cultivation, in terms of quality, quantity, and repeatability, has been disputed by a number of researchers in the field.[32] The competitive bidding process implemented by NIDA, in which a single license is granted every five years, is insufficient to meet the CSA requirement of "adequately competitive conditions."[33] In particular, there is nothing in the NIDA-ElSohly contract that keeps the price of cannabis competitive for researchers. For those researchers with FDA-approved studies, but for whom NIDA refuses to supply cannabis, competition as to cost is irrelevant inasmuch as there is no alternative supply. Other benefits to competition, such as improved product quality and reliability, are also unachievable under the current research cannabis monopoly.

DEA ADMINISTRATIVE LAW JUDGE: EXPANDED RESEARCH IS "IN THE PUBLIC INTEREST"

The DEA, NIDA, and Dr. ElSohly all vigorously defend the federal monopoly on research cannabis and actively prevent other potential suppliers from being awarded cultivation contracts. A clear example of this can be found in the case of Professor Lyle Craker, an experienced medicinal botanist at the University of Massachusetts at Amherst. In 2001, Professor Craker submitted an application to the DEA for a license to cultivate cannabis exclusively for federally approved research. After avoiding Prof. Craker's application for three and a half years, the DEA finally rejected his application in December 2004. In fact, DEA only responded after Prof. Craker filed a lawsuit against the DEA citing "unreasonable delay." The First Circuit Court of Appeals ruled that the DEA was obligated to explain itself. A review was then conducted on the DEA's rationale for rejecting his license, which resulted in extensive hearings and a recommendation by DEA Administrative Law Judge Mary Ellen Bittner.[34]

Among the expected proponents of maintaining a monopoly on the production of research cannabis were DEA and NIDA officials. However, Dr. ElSohly, at the center of the controversy as the government's only licensed manufacturer of research cannabis, also testified. Dr. ElSohly not only defended the availability and quality of the research cannabis cultivated at the University of Mississippi under his supervision, but he also testified against relinquishing control of his position as sole-source supplier.[35] Even if Dr. ElSohly did not have a financial stake in maintaining his monopoly, his testimony that "it is absolutely unnecessary to approve another manufacturer's registration to manufacture marijuana"[36] could be viewed as highly inappropriate given his interest in continuing to be the sole supplier.

Despite testimony from Dr. ElSohly, federal government officials, and other opponents of allowing multiple sources of research cannabis, Judge Bittner ruled on February 12, 2007 that expanded research was "in the public interest."[37] Judge Bittner also determined that, since researchers with the requisite approval from HHS may still be unable to obtain research cannabis from NIDA, "the existing supply of marijuana is not adequate."[38] Finally, Judge Bittner recommended that Professor Craker be granted a license to cultivate research cannabis. Unfortunately, in spite of these strongly worded recommendations and support for Professor Craker's application from 45 Members of Congress,[39] the DEA rejected Judge Bittner's recommendations on January 9, 2009, refusing to issue any other licenses for the production of research-grade cannabis. The ACLU is currently challenging the DEA rejection and support continues to mount. On February 5, 2009, sixteen Members of Congress led by Rep. John Olver (D-MA) from Professor Craker's district sent a letter to newly seated U.S. Attorney General Eric Holder asking him to act "swiftly to amend or withdraw" the order rejecting Judge Bittner's recommendations.[40]

Lyle E. Craker, PhD, is a Professor with the Department of Plant, Soil and Insect Sciences at University of Massachusetts at Amherst. In 2001, Prof. Craker filed a petition to grow research cannabis, but DEA has refused in an attempt to uphold a federal monopoly on cannabis production for research.

FEDERAL POLICIES CREATE A DOUBLE STANDARD ON MEDICAL CANNABIS

The Food and Drug Administration's claim that "marijuana has no currently accepted medical use in treatment in the United States" is undermined by the ongoing supply of medical cannabis to four seriously ill patients under the federal Compassionate Investigational New Drug (IND) program.[41] These patients, having first proved medical necessity (often to the courts), have been supplied by NIDA with medicinal cannabis for the past several decades. Furthermore, a privately funded study of these patients confirmed that they benefited from their use of medical cannabis.[42]

The DEA has also rescheduled a synthetic form of tetrahydrocannabinol (THC), a psychoactive component and one of the chemical compounds (or cannabinoids) found in cannabis. Dronabinol, otherwise known by its brand name Marinol, is a pill of synthetic THC suspended in sesame oil produced by Solvay Pharmaceuticals, Inc.[43] A petition

before the DEA to reschedule naturally extracted THC currently has the support of several drug companies. Dr. ElSohly, who has a DEA license to grow cannabis for his own private purposes in order to extract THC from the plant, a process that is less expensive than synthetic manufacturing, also has a financial stake in the petition.[44]

Meanwhile, efforts to reschedule whole-plant cannabis have failed to gain traction. The first rescheduling petition was filed in 1972 and was subsequently denied. The most recent rescheduling petition was filed in 2002 and is still under review. In 2005, Americans for Safe Access (ASA) filed a petition with HHS under a little-known law called the Data Quality Act (DQA) in order to correct the government's public statement that "marijuana has no currently accepted medical use."[45] After refusing to answer the petition, ASA took HHS to federal court. The case is currently before the Ninth Circuit Court of Appeals.[46]

With each new published study lauding the therapeutic benefits of cannabis, whether in the U.S. or elsewhere, federal officials are losing ground in their arguments against its medical efficacy. Cracks in the edifice are becoming more and more visible. Deviating from the government's refusal to admit that cannabis has any medical efficacy, NIDA director Dr. Eric Voth testified in the Craker case that he "considers medical marijuana an excuse for legalization," however, he supposedly supports research and admits that "there is evidence on the potential medical use of various cannabinoids."[47] Assistant NIDA Director Dr. Steven Gust testified in the Craker case that "there is a strong endorsement of this concept within NIH and HHS that ultimately there's going to be pharmaceuticals developed based on the components of marijuana, that there will be purified pharmaceuticals. They won't be in a smoked product, and they'll probably develop to be administered through alternative devices."[48]

Further evidence of the government's double standard on medical cannabis can be seen in the U.S. patent (No. 6,630,507) filed by and awarded in 2003 to HHS, based on cannabinoid studies conducted by NIH.[49] The government's patent is for pharmaceutical compositions of cannabinoids that are useful in the "prevention and treatment" of disease, including stroke, trauma, autoimmune disorders, Parkinson's, Alzheimer's and HIV dementia. In addition, GW Pharmaceuticals, a company based in the U.K. that is licensed to sell its whole-plant derived medical cannabis spray, Sativex, in Canada, is engaged in clinical trials in the U.S. This non-synthetic, whole-plant drug, being developed by GW Pharmaceuticals for the U.S. market, provides even greater evidence of the federal double standard on medical cannabis.[50]

DR. MAHMOUD A. ELSOHLY, PHD.: AT THE CENTER OF THE MEDICAL CANNABIS STORM

Dr. Mahmoud A. ElSohly is at the center of government obstruction to research and is mired in a conflict-of-interest over his exclusive right to provide cannabis to pharmaceutical corporations for research and product development. Dr. ElSohly is a research Professor and Director of the National Institutes of Health Marijuana Project at the University of Mississippi, which has held an exclusive contract since 1968 with the federal government to cultivate cannabis and process its extracts for research purposes.[51] The NIDA contract also includes cultivation of medial cannabis and distribution to four patients under the federal government's IND program.

Dr. ElSohly has established a career in the field of cannabis research. He is the president of ElSohly Laboratories, Inc. (ELI), which according to its website "is a privately held Mississippi Corporation…offering analytical and advisory services to the drug testing community since 1985."[52] Dr. ElSohly has used ELI and his role as a sole-source provider of research cannabis to NIDA to obtain several cannabis-related patents. Dr. ElSohly's patents in the field of cannabis include a cannabis patch, multiple sprays, a suppository and various cannabis preparation methods.[53] Worth noting in particular are Dr. ElSohly's patents that contain dozens of methods for the extraction of cannabinoids from whole-plant cannabis.[54]

Because of Dr. ElSohly's exclusive arrangement with the federal government in the field of cannabis production for research, his position has afforded him the ability to not only patent certain methods and processes unavailable to other researchers, but also to obtain contracts worth millions of dollars. For example, according to OMB Watch, between 2000 and 2007 ElSohly Laboratories, Inc. received more than $1.3 million for cannabis production through NIDA contracts alone.[55] With scores of articles related to cannabis printed in scientific publications and a flourishing consultancy business, Dr. ElSohly has gained an enviable position among peers, attained primarily due to his exclusive relationship with the U.S. government.[56]

This information by itself may not be cause for alarm. However, under another exclusive license with the federal government, Dr. ElSohly cultivates cannabis for Mallinckrodt, a pharmaceutical subsidiary of Tyco International, for the purpose of product development.[57] Dr. ElSohly's role puts him at the center of a proverbial and very tangible storm around medical cannabis at the federal level. No other single person better exemplifies the federal government's efforts to suppress meaningful cannabis research and the widespread use of whole-plant medical cannabis for those that benefit from it.

Mahmoud A. ElSohly, Ph.D., is the director of the Marijuana Project at the University of Mississippi, which is funded by the National Institute on Drug Abuse. Dr. ElSohly is at the center of government obstruction to research and is mired in a conflict-of-interest over his exclusive right to provide cannabis to pharmaceutical corporations for research and product

DR. ELSOHLY'S CONFLICT OF INTEREST

It's bad enough to obstruct meaningful research into the medical efficacy of whole-plant cannabis, but it becomes an unjust conflict of interest when the government and corporations work together to bring to market a more palatable, socially acceptable, higher cost form of cannabis while simultaneously ensuring the suffering of hundreds of thousands of patients who could benefit from cannabis by actively denying them an otherwise available medicine. The fact that such an arrangement will enrich only Dr. ElSohly and the pharmaceutical industry simply adds insult to injury. Preventing hundreds of thousands of people from gaining access to medical cannabis so that a pharmaceutical pill can be developed and exclusively produced is indefensible, if not potentially contrary to anti-trust laws, and certainly contrary to the current demand for medical cannabis and the promise that it holds through open, diversified research and nationwide access.

The Marinol pill, also known by its chemical name "Dronabinol," is due to go off patent in February of 2011.[58] Marinol is currently produced using synthetically derived THC, yet it is much easier and less expensive to produce naturally extracted THC from whole-plant cannabis. However, in 1986, when THC was reclassified as a Schedule II substance, which allowed Marinol to be prescribed and produced for medical use, the DEA only reclassified synthetically derived THC.[59] Now, with pharmaceutical companies poised to produce cheaper generic Marinol in two years, there is a significant effort afoot to reclassify natural forms of THC.

On September 24, 2007 the DEA published a notice of proposed rulemaking that would expand the classification of dronabinol beyond soft gel capsules to also include tablets and other capsules. More importantly, it would place naturally derived THC in the category of a Schedule III substance.[60] According to the DEA, several companies are pursuing approval of Abbreviated New Drug Applications (ANDA) for generic versions of Marinol.[61] Multiple pharmaceutical companies have submitted comments regarding rescheduling, the identity of which are unknown due to a closed petition process.

If the DEA allows dronabinol (THC) to be produced in its natural form, which is expected, the obvious question becomes "how will the cannabis be supplied and extracted?" The answer becomes clear after reviewing the records of the DEA's Office of Diversion Control (ODC). Under the United Nations Single Convention on Narcotic Drugs, signatory countries can only produce a certain amount of cannabis annually.[62] In 2001, the U.S. production quota for cannabis was 500,000 grams.[63] Beginning in 2005, however, the

ODC lists an annual increase in the quota for cannabis production to the current 4,500,000 grams per year.[64] This is an unexplained 900% increase in federally sanctioned production of cannabis in the U.S. Another important aspect of the Single Convention on Narcotic Drugs is that while it requires government licensing for the private trade in cannabis it does not prohibit private trade in "cannabis preparations," including the extracts developed by Dr. ElSohly, the University of Mississippi, and ElSohly Laboratories, Inc.[65]

Between his role as one of the primary advocates for the perpetuation of NIDA's monopoly on the production of cannabis for research and as the exclusive cannabis cultivator for NIDA, Dr. ElSohly's conflict of interest is apparent. In addition, his personal, financially remunerative roles in product development on behalf of the for-profit pharmaceutical company Mallinckrodt and as a patent-holder of natural cannabis extraction processes also raise concerns. Not only does Dr. ElSohly have a personal commercial interest in generic Marinol worth millions of dollars, but equally disturbing is the exclusive nature by which Dr. ElSohly, in cooperation with the DEA and NIDA, sets the cost for cannabis cultivation and dronabinol (THC) extraction. Dr. ElSohly may also receive financial compensation from royalties if his patented extraction process is employed by another entity in the production of generic Marinol. Dr. ElSohly operates a federal monopoly on medical cannabis production that provides the means by which he can personally enrich himself in the process of bringing generic Marinol to market.

CONCLUSION

Federal policies in relation to medical cannabis research fundamentally obstruct privately funded drug development research, which prevents essential research on the medical efficacy of cannabis. These delays are harmful to those that might benefit from the therapeutic uses of cannabis. Furthermore, Dr. ElSohly's relationship with NIDA and DEA not only hampers scientific advancement, but also establishes a serious conflict of interest. As a result, efforts to provide patients with the medicines they need are diverted from scientific research into state-level reforms requiring millions of dollars for state initiatives and legislative action.

In order to reverse the political obstruction of medical cannabis research and to better facilitate such research, Congress and the Obama Administration should adopt the following recommendations:

1. **Advise the DEA to implement the February 2007 Opinion and Recommended Ruling of Administrative Law Judge Mary Ellen Bittner (Docket No. 05-16) to authorize multiple sources to cultivate cannabis for research and product development;**

2. **Streamline the approval process for access to government-supplied research-grade cannabis by eliminating the extraordinary and unnecessary NIDA/PHS review processes that do not apply to other Schedule I substances; and**

3. **Remove cannabis from the list of Schedule I controlled substances to facilitate drug development so that it may be made available to all who would benefit from its therapeutic properties.**

HOT QUOTE

"Now the Drug Enforcement Administration's chief administrative law judge is recommending that the federal drug police allow competition in growing marijuana for research purposes. The administration should follow her recommendation."

EDITORIAL,
LOS ANGELES TIMES
May 2007

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1 See "Marijuana and Medicine: Assessing the Science Base,"Institute of Medicine, 1999.

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