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"Working for Justice in Health"

Information on Federal Agencies' Positions on Medical Properties of Cannabis and Medical Cannabis Research since 1970

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OVERVIEW

Only recently did we learn that the intoxicating effects of marijuana do not occur in the same way as alcohol.[1] While alcohol destroys brain cells, the effects of marijuana are quite different. In the mid-1990's, scientists discovered receptors throughout the body which bind to ***cannabinoids,*** compounds in cannabis. When the receptors were first discovered, there were no known internal molecules to bind them. It seemed they would bind only to compounds from the cannabis plant. We later discovered that our bodies produce their own cannabinoids. These internal cannabinoids and their receptors combine to form our ***endocannabinoid system***. Since its discovery, the endocannabinoid system has been linked to a growing number of bodily functions.[2] Affecting the system holds therapeutic promise in a wide range of diseases and conditions, ranging from mood and anxiety disorders, movement disorders such as Parkinson's and Huntington's disease, neuropathic pain, multiple sclerosis and spinal cord injury, to cancer, atherosclerosis, myocardial infarction, stroke, hypertension, glaucoma, obesity/ metabolic syndrome, and osteoporosis, just to name just a few.[3]

Cannabinoids and their roles in body functions are now the focus of much research. However, the social taboo of the cannabis plant, the only known cannabinoid source outside our bodies, has led to a volatile and passionate social debate on how research should continue into ways that cannabinoids and the cannabis plant can be used to treat various conditions and illnesses. Modern science is just beginning to scratch the surface of how and why the cannabis plant can treat so many different conditions. As research continues, it will undoubtedly continue to yield some very exciting results.

Federal agencies, such as DEA, NIDA, and FDA, claim the issue of medical cannabis should be decided by "sound scientific research."[4] Advocates agree, but with an important distinction: there is an enormous body of anecdotal evidence on use of the cannabis plant to treat serious and life-threatening illnesses, and the amount of scientific data to explain this is large and growing. Because it has become a matter of cultural common knowledge, the use of cannabis by patients is inevitable; we can't stop it. The debate is over whether penalties should be removed for legitimate patients who use it under a doctor's recommendation, and whether patients should be forced into the illegal drug market to obtain this treatment.

While federal agencies recognize the medical benefits of cannabinoids, they are hostile to the use of the plant itself to treat medical conditions. While in some ways supporting research into producing pharmaceutical products derived from the plant, these agencies continue to arrest and support arresting patients who benefit from its effects. They claim (as the FDA did most recently in April, 2006) that cannabis has no medical use. The *implication* is that patients with serious illnesses are either *faking* the effectiveness of cannabis, or that "getting high" is making them think it helps when it actually it does not. This is absurd. For many, this position makes it seem as though federal agencies have little respect for democratic processes, scientific evidence, or public health.

Federal agencies have established a clear pattern of hostility toward the effort to prove the medical benefits of cannabis. They have reacted to public inquiry with arrogance and disdain by ignoring administrative protocol on petitions to review the matter. They have refused to follow the rulings of their own administrative courts with contempt for the democratic process. They have established procedural guidelines on research that have allowed them to systematically control and inhibit certain types of research that may conclusively establish the effectiveness of the cannabis plant in treating a multitude of illnesses and conditions. All of this is very evident with a review of the facts.

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[1] Goodman, Neil. PhD, BSc (Hons). *An Overview of the Endogenous Cannabinoid System: Its Components and Possible Roles of this Recently Discovered Regulatory System.* erowid.org. v1.1 May 2003.
[2] Pacher, Batkai, and Kunos. *The Endocannabinoid System as an Emerging Target of Pharmacotherapy.* Pharmacological Reviews. 58:389-462. 2006.
[3] Ibid.
[4] Dr. Nora Volkow, Director National Institute on Drug Abuse (NIDA) National Institutes of Health (NIH) US Department of Health and Human Services (HHS). *Testimony before the House Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources, US House of Representatives.* April 1, 2004.

Background on First Attempt to Reschedule Cannabis (1972 – 1988)

In 1970, Congress passed the Controlled Substances Act (CSA), which placed in "schedules" substances for which Congress sought to control the manufacture and distribution. Schedules were labeled I - V, with their schedule designating the extent of regulation by the Food and Drug Administration (FDA). Schedule I substances, such as "marijuana", are under the strictest control. However, the corresponding guidelines created by congress outlined conditions and stipulations for research, distribution, or prescription of substances in all schedules, cannabis ("marijuana") included.

21 U.S.C. § 812. Schedules of controlled substances.[5]

- **(a) Establishment**

  There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

- **(b) Placement on schedules; findings required**

  Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

- **(1) Schedule I. -**
  - (A) The drug or other substance has a high potential for abuse.
  - **(B) The drug or other substance has no currently accepted medical use in treatment in the United States.**
  - **(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.**
- (2) Schedule II. -
  - (A) The drug or other substance has a high potential for abuse.
  - (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
  - (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence. *(Schedules III, IV, and V omitted)*

The first modern attempt to persuade Congress of the medical value of cannabis began one year after the Act took effect, in 1972. The effort to move cannabis from a schedule I, with "**no accepted medical use**," to a schedule that would acknowledge the anecdotal and scientific data available lasted through 22 years of unnecessary delays and stalling by federal agencies. These delays represent a pattern of hostility by administrative agencies such as DEA and National Institute on Drug Abuse (NIDA) with regard to this issue.

The initial petition to reschedule cannabis, submitted by the National Organization for the Reform of Marijuana Laws (NORML), was not even filed by the Director of the Bureau of Narcotics and Dangerous Drugs (predecessor to DEA), who refused to do so. When the issue was brought to court, the US Court of Appeals for the Washington D.C. Circuit held that the director had rejected the petition "without reflective consideration and analysis," and that his refusal to file "*was not the kind of*

[5] **www.fda.gov**

agency action that promoted the kind of interchange and refinement of views that is the lifeblood of a sound administrative process" (NORML v. Ingersoll).[6] (emphasis added)

The court ordered DEA to hold hearings on rescheduling cannabis to allow for evidence of its medical properties to be presented, which it did in January 1975, four years after the petition was submitted. After the hearings, DEA Administrative Law Judge Lewis Parker ruled largely in NORML's favor and in favor of rescheduling. But in spite of and *directly contrary* to the ruling, the DEA Administrator denied the petition "in all respects".[7]

NORML again went to the courts (NORML v. DEA, 1977), which directed DEA to refer the petition to the Secretary of the Dept. of Health, Education, and Welfare (HEW – predecessor to Health and Human Services), and to comply with rule making procedures outlined in the CSA 811 (a) and (b) (*see Appendix: CSA Reclassification of Substances)*. Without any further hearings or evidence, HEW also defied the ruling of the DEA judge and recommended cannabis remain in Schedule I. DEA issued a final ruling denying NORML's petition.

NORML *again* went back to the Court of Appeals, which ruled that, "reconsideration of all the issues in this case would be appropriate," and remanded it to DEA, observing, "We regrettably find it necessary to remind respondents [DEA and HEW] of an agency's obligation on remand not to do anything which is contrary to either the letter or spirit of the mandate construed in the light of the opinion of [the] court deciding the case." (NORML v. DEA, et. al.1980)[8]. DEA was ordered to refer to the Dept. of Health and Human Services (HHS) for scientific and medical findings. After *six more years* of delay, HHS finally gave the matter back to DEA to hold further hearings.

Two more years of public hearings were held by DEA to garner testimony on the scientific discussion of medical properties of cannabis, which finally culminated in 1988, 16 years after proceedings had been initiated, with the decision of DEA Administrative Law Judge Francis L. Young, who held,

"The provisions of [CSA] permit and require the transfer of marijuana from Schedule I to Schedule II… It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record… the administrative law judge recommends that the Administrator conclude that the marijuana plant as a whole has a currently accepted medical use in treatment in the [US]…" (emphasis added)

Judge Young's ruling was, once again, ignored by the DEA and no action was ever taken to reschedule or to hold any further hearings. That decision went through five appeals before it was finally dead and considered dropped by federal agencies in 1994, 22 years after the petition had been filed.

The hostility by federal agencies is clear in this example. By DEA's refusal to acknowledge petitions, their consistent delays in a manor not respectful of the democratic process, and action directly contrary to the rulings of both U.S. and their own DEA Administrative Courts, it is easy to understand the skepticism felt by many on the federal government's good faith with regard to this issue. It should therefore be expected that citizens would seek action at the state level and through state legislation, which has been much more successful.

Throughout the DEA hearings over whether cannabis has at least *some* "accepted medical use in the US," 36 states (including Illinois) passed laws recognizing the medical benefits of cannabis, and the federal government created a program, which continues today, wherein it delivers cannabis directly to a number of patients throughout the US for medical use. This went ignored by DEA. If cannabis is moved to Schedule II, it would still be illegal in most circumstances, just like cocaine – also a Schedule II substance. But the difference would be that the thousands of patients who would hold a doctor's prescription would not daily risk arrest by local or state police, or the DEA.

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[6] Young, Francis L. *Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge*. Sept. 6, 1988. Docket No. 86-22.
[7] Ibid.
[8] Ibid.

2nd Attempt to Reschedule Cannabis, John Gettman 1995

On July 10, 1995 Dr. John Gettman of NORML again petitioned the DEA to initiate rulemaking procedures that would amend the scheduling of cannabis. No action was taken by DEA until December 17, 1997 – almost two and a half years after receipt of the petition, when DEA passed it to the Department of HHS. HHS conducted an evaluation and responded with their recommendation to deny the petition on March 20, 2001 – almost six years after the initial petition was submitted.

Gettman's petition to DEA asserted that cannabis has less than a "high potential for abuse", and therefore should be transferred to schedule III, IV, or V of the CSA. As the most widely used illicit drug in the United States, it is clear that cannabis has sufficient abuse potential to warrant a status of schedule I or schedule II. The attempt by Dr. Gettman seems to have been a "last ditch" attempt for a new hearing in response to the impudent action of DEA after the much more legitimate 22-year attempt.

After an evaluation of Gettman's petition, and without further hearings, the Administrator determined that the evidence overwhelmingly led to the conclusion that marijuana has a "high potential for abuse" and that there "is no substantial evidence that marijuana should be removed from schedule I."[9]

While the evidence on the potential for abuse is clear, DEA again claimed in 2001 there was "no substantial evidence that marijuana should be removed from schedule I" in the face of glaring contradictions to its general medical acceptance: 36 symbolic state laws and resolutions, and a handful of effective laws, a federally commissioned report (the 1999 Institute of Medicine Report), and numerous studies about its medical efficacy that were available at the time.

These facts most certainly meet the schedule I criterion of "accepted medical use in the US" as held by DEA Administrative Law Judge Francis L. Young in 1988 and DEA Administrative Law Judge Lewis Parker in 1976. And, given the health risks of numerous FDA-approved drugs, cannabis's lack of toxicity and harms put forth by NIDA itself[10], cannabis does not "lack of acceptable safety for use under medical supervision," as required by schedule I.

Though the 1995 attempt to reschedule cannabis held little chance of success, it is important to note that federal response to the petition was once again consistent with well-documented patterns of dismissal and unnecessary delay not becoming of an institution charged with protection of the public interest, and, to quote the DC Circuit Court of Appeals when DEA was charged with inappropriate action in the past, "*was not the kind of agency action that promoted the kind of interchange and refinement of views that is the lifeblood of a sound administrative process*".

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[9] Gettman v. DEA, Government's Reply Brief, 3/19/2002 No. 01-1182

[10] In 2006, testifying in Craker v. DEA, et. al. on the harms of "marijuana," NIDA director Dr. Nora Volkow provided a list of the plant's harms which have been studied at great length for over 30 years, and which she reasoned was ample evidence for its restriction from medical use. The list she gave was: "possibility of addiction, disrupting short term memory, attention and judgment, impairment of coordination and balance, increasing heart rate, and overall dissatisfaction with mental and physical health for those who were lifetime abusers." (*DEA Proposed Findings of Fact 2006, Docket No. 05-16)* A comparison with "side effects" of FDA-approved medications currently prescribed for the same indications for which patients use cannabis is revealing. The "side effects" of drugs taken by cancer and HIV/AIDS patients alone can include: fever, fatigue, bone pain, muscle aches, constipation, loss of appetite, inflammation of the pancreas, changes in electrical activity of the heart, confusion, anxiety, facial swelling, vivid dreams, decreased breathing rate, increased heart rate, decrease in blood pressure, blurred vision, restlessness, involuntary muscle movements, tremors, rash, hives, dizziness, irritation of the stomach, euphoria, difficulty sleeping, mood changes, weakness, nausea and vomiting, dry mouth, diabetes, inflammation of the blood vessels, congestive heart failure, seizures, pneumonia, diarrhea, flatulence, heartburn, impotence, urinary frequency, urinary tract infection, vaginal bleeding and discharge, disease of the heart muscle, palpitation, chest pain, chest pressure, lung disorders, and many others. Claiming that cannabis is too "dangerous" to give to the patients who would otherwise be prescribed drugs that would subject them to these "side effects" is one of the most absurd arguments posed by federal agencies.

The 2002 Data Quality Act

> *"The process required by statute, a full and scientific medical review, is supposed to cover both the scientific evidence in the petition and everything else that's relevant.* [American's for Safe Access are] *arguing that HHS's review of this 1995 rescheduling petition was inadequate. One argument posed is how the FDA could have reviewed the 1999 Institute of Medicine study, commissioned by HHS, which found cannabis useful "for pain relief, control of nausea and vomiting, and appetite stimulation," and still denied accepted medical use?"*
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> - Data Quality Act Petition to Department of Health and Human Services, October 2004.

In 2004, the California-based patient advocacy group, Americans for Safe Access (ASA), filed a petition with the federal government under the 2002 Data Quality Act (DQA). The petition argued that cannabis is classified in Schedule I because the Department of Health and Human Services (HHS) has relied on inaccurate and incomplete information about its medical efficacy. ASA launched a legal challenge to HHS to correct published information under DQA.

DQA requires federal agencies such as HHS to use reliable science when making regulations and disseminating information. The FDA has to set criteria to define "currently accepted medical use," and if it departs from them, it has abused its discretion, which is against the law. The petition filed by Americans for Safe Access invokes the DQA to charge that the FDA abused its discretion on three of its five criteria in denying Gettman's 1995 rescheduling petition. Wherever the FDA deviates from its own criteria, it seems they made an "arbitrary and capricious" decision.

If ASA is successful in their petition, HHS will be forced to admit that cannabis is used for medical treatment. If the FDA is shown to have abused its discretion, this should require the DEA to consider a new rescheduling procedure.

The Data Quality Act's key provision is that it is time-limited, so there's less foot-dragging allowed. In theory, this would limit federal agencies' ability to unnecessarily delay action on petitions. HHS has 60 days from the date of filing to give an answer, or at least file for a limited extension to make a decision.

However, as expected and consistent with federal agency stalling on all previous medical cannabis petitions, HHS has once again unnecessarily delayed. The original petition was filed on October 4, 2004. HHS was required to respond in 60 days or file for an extension, and indeed, approximately every 60 days since 2004 ASA had received a letter, 8 total, from HHS stating that the Department needed "additional time to coordinate Agency review." In May 2006, ASA finally threatened to sue if they did not receive a response. This prompted the anticipated denial of the DQA petition.

On July 12, 2006, over two months after ASA issued their final ultimatum and threat to sue and over almost 2 years after the initial petition, DEA finally replied stating that they had no obligation to rule on ASA's Data Quality Act petition because, in their view, it was the same as a completely separate 2002 rescheduling petition that had been submitted by different petitioners.

ASA's 2004 Data Quality Act petition made the following requests for corrections:

1. HHS states that "there have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition," which is disseminated on federal government websites (http://www.access.gpo.gov/su_docs/fedreg/a010418c.html, http://www.deadiversion.usdoj.gov/fed_regs/notices/2001/fr0418/fr0418a.htm) and in the *Federal Register*, 66 Fed.Reg. 20038, 20052 (April 18, 2001).

ASA requests that HHS replace this statement with the following statement: "**Adequate and well-recognized studies show the efficacy of marijuana in the treatment of nausea, loss of appetite, pain and spasticity.**"

2. HHS states that "a material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts" and "it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana," which are disseminated on the government websites and in the *Federal Register*, 66 Fed.Reg. 20038, 20052 (April 18, 2001).

   ASA requests that HHS replace this statement with the following statement: "**There is substantial consensus among experts in the relevant disciplines that marijuana is effective in treating nausea, loss of appetite, pain and spasticity. It is accepted as medicine by qualified experts.**"

3. HHS states that "a complete scientific analysis of all the chemical components found in marijuana has not been conducted," which is disseminated on the government websites and in the *Federal Register*, 66 Fed.Reg. 20038, 20051 (April 18, 2001).

   ASA requests that HHS replace this statement with the following statement: "**The chemistry of marijuana is known and reproducible.**"

4. HHS states that marijuana "has no currently accepted medical use in treatment in the United States," which is disseminated on the government websites and in the *Federal Register*, 66 Fed.Reg. 20038, 20039 (April 18, 2001).

   Based on the corrections above, ASA requests that HHS replace this statement with the following statement: "**Marijuana has a currently accepted use in treatment in the United States.**"

National Institute on Drug Abuse (NIDA) Monopoly on Cannabis Production; Barriers to and Obstruction of Research

The Controlled Substances Act (CSA) of 1970 specifically requires that Schedule I substances, such as cannabis, must be available for legitimate research, and there is much interest in conducting research on these substances. In 1999, the Institute of Medicine issued its report "*Marijuana and Medicine: Assessing the Science Base*," where they concluded:

> "*The accumulated data indicate a potential therapeutic value for cannabinoid drugs particularly for symptoms such as pain relief, control of nausea and vomiting, and appetite stimulation… cannabinoid-based drugs will only become available if public investment in cannabinoid drug research is sustained and if there is enough incentive for private enterprise to develop and market such drugs*."

No one should be opposed to researching cannabis and *all* of its compounds as much as possible through clinical or scientific studies. Learning through controlled research is the staple not only our of drug approval process, but also of our democratic culture and tradition. However, a review of the historic and current procedures exposes many unnecessary barriers and restrictions that, while overwhelmingly allowing for research looking for *harms* of cannabis, have actually inhibited research into identifying medical properties of the plant. These barriers are systematic and evident in three primary ways: **1) the approval process is different for researching cannabis than it is for any other drug, 2) NIDA has a monopoly on production, severely limiting the scope, quality, and therefore interest in research by private sources,** and **3) NIDA directly stops specific research from moving forward.**

<u>Cannabis Research Approval vs. Other Schedule I Substances</u>

The process of approving research on cannabis is unique from that of all other Schedule I drugs. To research Schedule I drugs, parties must obtain registration from FDA, and must be determined by the Department of Health and Human Services (HHS) to be qualified and competent. The proposed research must also be determined by HHS to have scientific merit.[11]

For requests to purchase all substances other than cannabis, including all other illegal drugs, National Institutes of Health (NIH) uses an "ad hoc" peer review that relies largely on outside (non-government) experts in the area of the proposed research. In contrast, requests to purchase cannabis for medical research are reviewed by a Public Health Service (PHS) Committee, which consists of *government employees*, including a NIDA representative.[12] Additionally, proposed studies to research cannabis must already be approved by FDA, which does a careful and comprehensive review of the scientific merit of all research. Why NIDA must then conduct its own redundant review after the review conducted by FDA, and why this distinct procedure is required only for cannabis and for no other drugs in Schedule I (such as "ecstasy," LSD, or heroin) is uncertain.

In addition, NIDA expressly states in its procedure for cannabis research approval that it will not approve all legitimate scientific studies, but only those it considers highest priority, or "most likely to yield usable, essential data."[13] This distinction for approval is also unique to cannabis research. NIDA's stated mission is to *"lead the Nation in bringing the power of science to bear on drug abuse and addiction."*[14] Nowhere is it in the stated interest or concern of NIDA to research the medical uses of any drug, including cannabis. In fact, according to former Assistant Deputy Director of the Office of

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[11] US Dept. of Health and Human Services, "*Guidance on Procedures for the Provision of Marijuana for Medical Research*". 1999.

[12] Julie Carpenter, Jenner and Block, LLP, *Proposed Findings of Fact, Lyle E. Craker Petition to DEA, Docket No. 05-16.* 2006

[13] US Dept. of Health and Human Services, "*Guidance on Procedures for the Provision of Marijuana for Medical Research*". 1999.

[14] *www.nida.nih.gov.*

National Drug Control Policy (ONDCP), Dr. Barbara Roberts, NIDA is and always has been opposed to medical use of cannabis.[15] Moreover, according to NIDA Director Dr. Nora Volkow, "… it is not NIDA's mission to study the medicinal use of marijuana or to advocate for the establishment of facilities to support this research."[16]

NIDA has free reign to decide and approve whatever research it considers highest priority, or "most likely" to yield usable data. Certainly research on the harms of cannabis would be of higher priority and more "likely to yield usable data" for an agency whose mission is to stop all cannabis use, than would research into its medical properties. An organization with a stated opposition to medical cannabis (NIDA) is in complete control over research that would explore and likely promote its medical use. This conflict is clearly inhibitive of honest scientific discovery, and reasons for NIDA's position as the deciding body on medical research of cannabis lacks justification.

NIDA Maintains a Monopoly on Cannabis Production

Despite the fact that there are many private facilities licensed by NIDA to produce and manufacture Schedule I drugs such as MDMA (ecstasy) and LSD for federally approved research, NIDA licenses *only one facility* to produce cannabis, which is at the University of Mississippi under direction of Dr. Mahmoud El Sohly. NIDA refuses to allow any other facility to grow cannabis, giving it a monopoly and thus full control over the supply that can be used in research.

Not only has this hindered the ability of research to move forward, but it also raises serious questions about Dr. El Sohly's financial interest as director of NIDA's sole licensed facility. As director of the University of Mississippi program, Dr. El Sohly is the only person in the country allowed to grow cannabis for his own research purposes and *without approval* from NIDA. In fact he does grow cannabis outside of that which NIDA controls, and uses it to extract THC which he and the University then sell to private commercial pharmaceutical manufacturers to develop the FDA-approved drug Marinol and all of its generic counterparts. As Dr. El Sohly is the only person in the country allowed by the government to sell cannabis extracts, he has a clear financial interest in maintaining the status quo.

This monopoly poses another problem, in that cannabis grown at the University of Mississippi and distributed for research is of notoriously low quality. The THC content of NIDA cannabis is both generally low and inaccurate, according to its labeling, and it is distributed in the form of pre-rolled cigarettes which can be contaminated with unusable seeds and stems. Also, the only cannabis available to researchers is at least 5 to 6 years old, while researchers acknowledge that fresh product is much better for research.[17] The implication is that the University of Mississippi program is either unable or not interested in performing the type of high quality and modern cultivation techniques that are ongoing by governments and private pharmaceuticals in Canada, UK, Netherlands, and other countries, and which is taking place in medical growing cooperatives in US states with medical cannabis laws.

The art of cultivating different strains (or breeds) of cannabis to obtain a yield of varying concentrations of medically active cannabinoids is an interesting and delicate practice, and one that is necessary for anyone serious about researching the medical benefits of the plant. "Potency," or concentration of the primary psychoactive compound THC, is not the only indicator for high quality cannabis. Dr. El Sohly has claimed that the adequacy of his facility is based on its ability to produce high-THC cannabis (if it were necessary) and does not even consider the importance of growing cannabis with different concentrations of other cannabinoids. It seems that Dr. El Sohly does not appreciate the more involved methods of cultivation, if he is even aware of them.

A major inhibiting factor to research comes from the fact that no privately funded sponsor will invest the amount of money necessary for a drug development research program with the goal of obtaining FDA-approval for the prescription use of cannabis with NIDA cannabis from Mississippi. According to

[15] Julie Carpenter, Jenner and Block, LLP, *Proposed Findings of Fact, Lyle E. Craker Petition to DEA, Docket No. 05-16.* 2006
[16] ibid.
[17] ibid.

Dr. Irwin Martin, a former pharmaceutical executive and expert in new drug development, private sponsors are interested in obtaining their own independent source of supply of a drug whose quality, price and availability they control, as with any other drugs[18]. For developing new drugs, it is essential that research be done on the exact same product that will be brought to market. Studies done on a different product than what would eventually be sold would be scientifically useless and an enormous waste of money to a private sponsor or pharmaceutical company. NIDA cannabis is of such poor quality that no one would or will ever seek to market it as a treatment or medicine.

Attempt to License a More Capable Facility

Professor Lyle Craker, who is the Director of the Medicinal Plant Program at the University of Massachusetts, Amherst, Department of Plant and Soil Sciences, Chairman of the International Society for Horticultural Science (ISHS), founder of the International Council on Medicinal and Aromatic Plants, and editor of both *The Journal of Herbs, Spices, and Medicinal Plants*, and *The Herb, Spice, and Medicinal Plant Digest*, in association with the Multidiscleplinary Association for Psychedelic Studies (MAPS) are currently seeking DEA permission to establish a facility at UMASS Amherst to grow cannabis for FDA-approved research. NIDA has been hostile to this attempt. The petition to license Dr. Craker to grow cannabis for federally approved studies shows, once again, the very consistent pattern of federal agencies of ignoring and delaying requests and inquiries into gaining acceptance for cannabis as a legitimate medical treatment.

Dr. Craker originally submitted an application for a license to DEA in June 2001. In December 2001, DEA claimed it was either lost or never submitted. After resubmitting a photocopy, Dr. Craker was told in February 2002 that the photocopied application was invalid since it didn't have an original signature. In July 2002, the original application was returned to Dr. Craker, unprocessed, with a DEA date stamp showing it had in fact been received in June 2001. Dr. Craker resubmitted the original application to DEA on August 20, 2002, which DEA finally acknowledged receiving, over one year after it was initially sent.

One year later, on July 24, 2003, DEA finally filed a notice in the Federal Register about Dr. Craker's application, with a public comment period ending on September 23, 2003. DEA was expected to either approve or reject the application sometime before the end of 2003, but again DEA delayed its decision. On July 21, 2004, over 3 years after submitting the petition that DEA refused to acknowledge and act upon, MAPS and Dr. Craker filed lawsuits against DEA and also against HHS/NIH/NIDA for obstructing medical cannabis research.

On November 22, 2004, the Court required DEA to respond to the portion of the lawsuit against DEA about the UMass Amherst cannabis production facility. On December 3, MAPS mailed petitions for reconsideration to the DC Circuit Court of Appeals, asking also for the Court to pressure HHS and DEA for not responding in 17 ½ months to applications to purchase 10 grams and import 10 grams, respectively, in both cases for cannabis vaporizer research.[19]

On December 10, 2004, DEA finally rejected Dr. Craker's application seeking a license to establish a facility to produce cannabis for federally approved research, *3 and 1/2 years after the application was initially filed*. Dr. Craker and MAPS petitioned DEA for appeal.

On February 28, 2005, in DEA's prehearing statement, DEA explained its rationale, claiming it rejected Dr. Craker's application because it was "against the public interest" for it to issue the license and allow another facility. DEA also claimed that it was against international Single Convention of Narcotic Drugs Treaty, a dubious and highly refutable interpretation of the Treaty for many reasons, among them the fact that, even though the governments of Great Britain and Canada are also signers of the treaty, they license and oversee multiple cannabis producers and no action has ever been taken on the part of the US government to imply or accuse them of being in violation of this treaty.

[18] ibid.

[19] "Vaporizing" is a smokeless method of cannabis delivery that allows patients to inhale cannabis "vapor" by passing hot air over the cannabis at a specific temperature below the point of combustion. It has exciting potential as a safe method of delivery for patients.

These conditions established by NIDA and DEA have not only discouraged private researchers from looking into the potential of cannabis as an FDA approved drug, but NIDA has also actively refused to allow valuable research by legitimate researchers to proceed.

NIDA Prohibits Research

NIDA has denied proposals for research which had already been approved by the FDA and multiple review boards on at least three occasions: NIDA disallowed a study by Dr. Donald Abrams to look at the effectiveness of cannabis on HIV/AIDS wasting syndrome, it disallowed a study on cannabis on migraine headaches by Dr. Ethan Russo, and it disallowed a study by Chemic Labs to study the potential of vaporizers when compared to smoked cannabis.

Dr. Donald Abrams, of the University of California at San Francisco, is one of the leading AIDS researchers in the country. In a study to investigate whether cannabis could assist patients suffering with AIDS wasting syndrome, he developed a proposal that was: 1) approved by the Committee on Human Research at University of California at San Francisco, where it would be conducted, 2) approved by the Scientific Advisory Committee and Community Advisory Forum (San Francisco area review panel for AIDS research), 3) approved by the California Research Advisory Panel, and 4) approved by the FDA *after the FDA had been involved in developing the study and strongly influencing its design.*

Dr. Abrams then applied to NIDA, the only legal source in the US, to obtain the cannabis necessary to do the research. In yet another instance of unnecessary delay, NIDA did not respond to Dr. Abram's request at all for nine months before denying the *FDA approved proposal* and refusing to supply the cannabis. In a telling example of NIDA's priorities on research, Dr. Abrams later sought funding for a very similar study that sought to evaluate the *risks* of using cannabis in AIDS patients (rather than looking for benefits). The study was approved by NIDA under the condition that Dr. Abrams not use any of the individuals he was planning to use for the original study.

Dr. Ethan Russo is a neurologist and specialist in migraine headaches at the University of Montana. After receiving indications that cannabis may be efficacious in treating migraines, Dr. Russo developed a proposal for research that was, just like the study proposed by Dr. Abrams, approved by the facility where the research would be conducted *and the FDA.* Once again, NIDA refused to supply the cannabis necessary for the study to take place, and so it never did.

As previously stated, developing alternative routes of delivery other than smoking is an important area of research. "Vaporizing" has shown significant promise in mitigating the harms and carcinogens associated with smoking. Chemic Labs was looking to conduct a laboratory study testing a vaporizer with different kinds of cannabis to determine what constituents would exist in the vapor and at what levels. Chemic is a DEA-licensed contract research lab that works with many companies in the pharmaceutical industry. Chemic applied to receive and pay for 10 grams of cannabis on June 24, 2003. It also applied for a permit to import 10 grams of cannabis from the Netherlands, where the government makes available a type of cannabis that NIDA does not. The results of the research were to be submitted to the FDA about how the vaporizer device works and how substances used in it can be measured, as preliminary information necessary to conduct further testing with the vaporizer.

Again, NIDA delayed response for over *two and a half years* before informing Chemic Labs that it would not supply the cannabis, nor would it permit the research laboratory to import 10 grams from the Netherlands. NIDA claimed the study did not present "clinical potential," which is absurd because, not only did Chemic openly state the study was not intended for clinical reasons, but for reasons stated above, it is nearly impossible for clinical studies to be conducted with NIDA's cannabis, given its poor quality.

The state of California funded 15 separate studies for research to evaluate the efficacy of cannabis and cannabis compounds on specific medical conditions. The studies were to be conducted by the Center for Medicinal Cannabis Research (CMCR). After review, NIDA provided cannabis to CMCR for researchers conducting these studies. These were the first studies to be sponsored and funded by any state, and therefore refusal by NIDA to provide cannabis for the study would have raised major alarms about the motives of NIDA with regard to this type of research. On one hand, they may

have felt significant pressure to approve these CMCR studies. However, the evidence also established that CMCR had no intention of seeking FDA approval of cannabis as a prescription product.

This raises an interesting point: the studies denied by NIDA were intended to be privately funded by the nonprofit organization MAPS, which openly declares its intention to obtain FDA approval to allow botanical cannabis as a prescription drug. Studies that have been approved by NIDA have been consistently interested in evaluating the effectiveness of compounds found in cannabis, rather than the whole plant itself. This suggests a bias on the part of NIDA to disallow research that may show that the cannabis plant itself is therapeutic.

Why they would rather not learn this information is unclear, though there is speculation. The presumption is that NIDA intends to keep this plant from patients who need it, and to support arrest for those who use it, despite the enormous and growing amount of scientific and anecdotal data on the often miraculous medical effects and relative safety of the plant. Rather, NIDA would have patients wait for years for the testing and release of synthetic cannabinoid pharmaceutical drugs which may have similar effects as the cannabis plant (though possibly not as effective – as data on the effectiveness of Marinol compared with whole plant cannabis consistently show). Why this is so is uncertain.

NIDA continues to claim that another production facility at UMASS, Amherst that will cultivate different varieties of high quality cannabis is not in the public interest. They claim that doing so will increase the possibility of illegal diversion of cannabis onto the black market; an unconvincing argument. Why they make no such claims for production of other illegal drugs by privately licensed facilities is uncertain. Why the University of Mississippi, which grows at a large outdoor farm, has adequate security measures while UMASS, which will grow entirely indoors in locked research facilities, will not, is also uncertain. It is uncertain why NIDA and other federal agencies feel it necessary to consistently delay acting on inquiries and petitions on research, sometimes for years at a time. And it is most uncertain, given the history and available facts, why NIDA feels more research with a higher quality product that will undoubtedly yield much more useful data is contrary to the best interest of the public.

Conclusions and Comments

Federal, state, and private research should continue to work toward minimizing any potential risks that may be posed by compounds in the cannabis plant. However, it is indisputable that hundreds of millions of federal dollars have been poured into studying the negative effects of marijuana over the past 40 years. Research conducted since the 1960's were intended to produce useful information on the harms of marijuana, and that's exactly what we have. We know it can affect motor function, judgment, balance, and short-term memory. For those already predisposed to schizophrenia, there is some evidence that it may exacerbate those symptoms, and for patients who smoke it, it can have negative effects on the respiratory system, including contributing to bronchitis.[20] Of course research into harms should and will continue, but there is a tendency by government agencies (which have been openly opposed to medical cannabis) to say that we don't know enough about cannabis to know if it is safe enough for patients. That statement is not at all supported by the research.

What seems to irk federal agents charged with touting its dangers when it comes to medical use is that the research continues to show it just isn't as dangerous as they would like it to be. We know it is much less physically addictive than alcohol, tobacco, and numerous pharmaceutical products. We know that it does not destroy brain cells, though for years government programs told us it did. We know there is no biochemical component of the plant that leads to the use of more dangerous drugs, though official government positions stated the opposite. We know it is intoxicating, but much less so than alcohol, morphine, and many pharmaceuticals. There is absolutely no record, in over 5000 years of historic use as medicine in cultures throughout the world, of anyone ever dying from an overdose on cannabis, because it is almost impossible to do so. In fact, because of the lack of real data on long-term negative effects, federal officials often resort to dangers associated with general intoxication or impairment of judgment (such as increased car accidents or, teen pregnancy and accidentally shooting your friends, according to popular ONDCP ad campaigns[21]), rather than dangers associated with the plant specifically. These risks should be thoroughly discussed and guarded against, but should not preclude a terminal patient from using it as an effective medicine.

Even the concern over "sending the wrong message" does not hold up to scrutiny as an argument against its medical use. As held by DEA Judge Francis Young in his 1988 ruling:

> *"There are those who, in all sincerity, argue that the transfer of marijuana to Schedule II will 'send a signal' that marijuana is 'OK' generally or for recreational use. This argument is specious. It presents no valid reason for refraining from taking an action required by law in light of the evidence."* [i.e. rescheduling cannabis]

A review of the history of DEA, NIDA, and FDA positions on medical cannabis shows a pattern of ignoring scientific evidence, disregarding court rulings, and not responding to requests or petitions related to medical cannabis. And yet, these agencies have direct control over what research is allowed to move forward. Not only do these barriers to research exist, but they should come as no surprise to anyone; in fact they should be expected. As NIDA Director Dr. Nora Volkow herself states, NIDA is not interested in promoting medical cannabis research, nor is it in their mission. But if we are truly interested in promoting fact-based policies in the best interest of public health, we must ask important questions: why do these barriers exist? Why is NIDA in charge of medical research? What is the reason for all of these delays? Is there concern over what data from increased research into the therapeutic properties of cannabis may show?

[20] See Testimony of Dr. Nora Volkow, NIDA Director. Footnotes, p. 5

[21] Interestingly, recent studies done at the University of Michigan on the effectiveness of this advertisement campaign by the Office of National Drug Control Policy (ONDCP) showed that the ads were so laughable and absurd that teens were actually *more likely* to use drugs after viewing them. Congress later severely cut funding to this ad program, largely as a result of these studies.

If DEA, NIDA, and FDA were all to change their policies that inhibit research and open, honest debate today, we might be optimistic.[22] Unfortunately, this is unlikely. Altering the fundamental missions of these federal agencies will not happen without an explicit directive from the White House or from Congress. Medical cannabis advocates are not holding their breath for word from Pennsylvania Ave, no matter the governing party. Rather, the task has fallen on states and US Congress to take action to pressure the federal government, which they are doing. Between 1977 and 1996, 36 states passed symbolic laws acknowledging medical cannabis. Illinois was the second in 1978. Since 1996, 12 states have passed laws that have removed penalties for patients who use cannabis under recommendation from their doctor.

Illinois's bill will position our state to take the lead on this issue, nationally. As the first state in the Midwest with a medical cannabis law, and one that would be a model for other states to follow, Illinois would be sending a strong message to the federal government: that they can no longer ignore this issue and hope it will go away. Illinois cannot pass a research bill alone because the barriers to research, specifically with regard to quality from the University of Mississippi, from where the cannabis currently *must* come, still exist. Any attempt to research the plant in a way that may lead to allowing its medical use, would be met with the same opposition from NIDA as it has in the past. However, with an effective Illinois law, the level of survey and anecdotal data, as well as scientific research, would increase dramatically, putting additional pressure on the federal government and Congress to act, and on NIDA to break down its barriers, allow other production facilities, and increase access to important research.

Research into the endocannabinoid system is exploding onto the medical field, and as it does, interest in the naturally occurring cannabinoids from the cannabis plant increases as well. Trends in public opinion are extremely high and increasing in states that have already passed laws. Ultimately, people understand that this isn't about "pot;" it's about compassion. They understand that there's no real dispute that cannabis helps, and if people are truly suffering, and their doctors agree, why not let them use it? Every year more legislation is introduced and passes at the state level, putting pressure on federal agencies to stop arresting patients who use cannabis, and to recognize that the plant helps many people. This activity sparks even more interest in research, creates additional pressure on federal agents to break down barriers to that research, and gives more patients the courage to try to obtain it illegally.

None of these factors show signs of letting up. The question is when Illinois will enter the picture. Illinois has an opportunity to position itself as a policy leader by implementing a program of strict oversight and regulation by the state, while acknowledging our responsibility to our citizens, in light of inaction and hostility by federal agents. Illinois' bill will correct the shortcomings of laws in other states, and will be a model for how an effective medical cannabis program can work. Most important, Illinois' bill will bring sense of justice to the thousands of Illinois citizens who are unjustly at risk for using a treatment option that works.

[22] Though, of course there would remain the problem of medical cannabis patients, who would continue to use and continue to be arrested as research was ongoing.

APPENDIX I: “THE ECONOMIST” RESPONSE TO APRIL 2006 FDA RELEASE ON MEDICAL CANNABIS

The Economist
April 27, 2006
http://www.economist.com/science/displaystory.cfm?story_id=6849915

Medical marijuana
Reefer madness

Marijuana is medically useful, whether politicians like it or not

If cannabis were unknown, and bioprospectors were suddenly to find it in some remote mountain crevice, its discovery would no doubt be hailed as a medical breakthrough. Scientists would praise its potential for treating everything from pain to cancer, and marvel at its rich pharmacopoeia - many of whose chemicals mimic vital molecules in the human body. In reality, cannabis has been with humanity for thousands of years and is considered by many governments (notably America's) to be a dangerous drug without utility. Any suggestion that the plant might be medically useful is politically controversial, whatever the science says. It is in this context that, on April 20th, America's Food and Drug Administration (FDA) issued a statement saying that smoked marijuana has no accepted medical use in treatment in the United States.

The statement is curious in a number of ways. For one thing, it overlooks a report made in 1999 by the Institute of Medicine (IOM), part of the National Academy of Sciences, which came to a different conclusion. John Benson, a professor of medicine at the University of Nebraska who co-chaired the committee that drew up the report, found some sound scientific information that supports the medical use of marijuana for certain patients for short periods even for smoked marijuana.

This is important, because one of the objections to marijuana is that, when burned, its smoke contains many of the harmful things found in tobacco smoke, such as carcinogenic tar, cyanide and carbon monoxide. Yet the IOM report supports what some patients suffering from multiple sclerosis, AIDS and cancer - and their doctors - have known for a long time. This is that the drug gives them medicinal benefits over and above the medications they are already receiving, and despite the fact that the smoke has risks. That is probably why several studies show that many doctors recommend smoking cannabis to their patients, even though they are unable to prescribe it. Patients then turn to the black market for their supply.

Another reason the FDA statement is odd is that it seems to lack common sense. Cannabis has been used as a medicinal plant for millennia. In fact, the American government actually supplied cannabis as a medicine for some time, before the scheme was shut down in the early 1990s. Today, cannabis is used all over the world, despite its illegality, to relieve pain and anxiety, to aid sleep, and to prevent seizures and muscle spasms. For example, two of its long-advocated benefits are that it suppresses vomiting and enhances appetite - qualities that AIDS patients and those on anti-cancer chemotherapy find useful. So useful, in fact, that the FDA has licensed a drug called Marinol, a synthetic version of one of the active ingredients of marijuana - delta-9-tetrahydrocannabinol (THC). Unfortunately, many users of Marinol complain that it gets them high (which isn't what they actually want) and is not nearly as effective, nor cheap, as the real weed itself.

This may be because Marinol is ingested into the stomach, meaning that it is metabolised before being absorbed. Or it may be because the medicinal benefits of cannabis come from the synergistic effect of the multiplicity of chemicals it contains.

Just what have you been smoking?

THC is the best known active ingredient of cannabis, but by no means the only one. At the last count, marijuana was known to contain nearly 70 different cannabinoids, as THC and its cousins are collectively known. These chemicals activate receptor molecules in the human body, particularly the cannabinoid receptors on the surfaces of some nerve cells in the brain, and stimulate changes in biochemical activity. But the details often remain vague - in particular, the details of which molecules are having which clinical effects.

More clinical research would help. In particular, the breeding of different varieties of cannabis, with different mixtures of cannabinoids, would enable researchers to find out whether one variety works better for, say, multiple sclerosis-related spasticity while another works for AIDS-related nerve pain. However, in the United States, this kind of work has been inhibited by marijuana's illegality and the unwillingness of the Drug Enforcement Administration (DEA) to license researchers to grow it for research.

Since 2001, for example, Lyle Craker, a researcher at the University of Massachusetts, has been trying to obtain a license from the DEA to grow cannabis for use in clinical research. After years of prevarication, and pressure on the DEA to make a decision, Dr Craker's application was turned down in 2004. Today, the saga continues and a DEA judge (who presides over a quasi-judicial process within the agency) is hearing an appeal, which could come to a close this summer. Dr Craker says that his situation is like that described in Joseph Heller's novel, Catch 22. We can say that this has no medical benefit because no tests have been done, and then we refuse to let you do any tests. The US has gotten into a bind, it has made cannabis out to be such a villain that people blindly say no.

Anjuli Verma, the advocacy director of the American Civil Liberties Union (ACLU), a group helping Dr Craker fight his appeal, says that even if the DEA judge rules in their favour, the agency's chief administrator can still decide whether to allow the application. And, as she points out, the DEA is a political organisation charged with enforcing the drug laws. So, she says, the ACLU is in this for the long haul, and is already prepared for another appeal - one that would be heard in a federal court in the normal judicial system.

Ms Verma's view of the FDA's statement is that other arms of government are putting pressure on the agency to make a public pronouncement that conforms with drug ideology as promulgated by the White House, the DEA and a number of vocal anti-cannabis congressmen. In particular, the federal government has been rattled in recent years by the fact that eleven states have passed laws allowing the medical use of marijuana. In this context it is notable that the FDA's statement emphasises that it is smoked marijuana which has not gone through the process necessary to make it a prescription drug. (Nor would it be likely to, with all of the harmful things in the smoke.) The statement's emphasis on smoked marijuana is important because it leaves the door open for the agency to approve other methods of delivery.

High hopes

Donald Abrams, a professor of clinical medicine at the University of California, San Francisco, has been working on one such option. He is allowed by the National Institute on Drug Abuse (the only legal supplier of cannabis in the United States) to do research on a German nebuliser that heats cannabis to the point of vaporisation, where it releases its cannabinoids without any of the smoke of a spliff, and with fewer carcinogens.

That is encouraging. But it does not address the wider question of which cannabinoids are doing what. For that, researchers need to be able to do their own plant-breeding programmes.

In America, this is impossible. But it is happening in other countries. In 1997, for example, the British government asked Geoffrey Guy, the executive chairman and founder of GW Pharmaceuticals, to come up with a programme to develop cannabis into a pharmaceutical product.

In the intervening years, GW has assembled a library of more than 300 varieties of cannabis, and obtained plant-breeder's rights on between 30 and 40 of these. It has found the genes that control cannabinoid production and can specify within strict limits the seven or eight cannabinoids it is most interested in. And it knows how to crossbreed its strains to get the mixtures it wants.

Nor is this knowledge merely academic. Last year, GW gained approval in Canada for the use of its first drug, Sativex, which is an extract of cannabis sprayed under the tongue that is designed for the relief of neuropathic pain in multiple sclerosis. Sativex is also available to a more limited degree in Spain and Britain, and is in clinical trials for other uses, such as relieving the pain of rheumatoid arthritis.

At the start of this year, the company made the first step towards gaining regulatory approval for Sativex in America when the FDA accepted it as a legitimate candidate for clinical trials. But there is still a long way to go.

And that delay raises an important point. Once available, a well-formulated and scientifically tested drug should knock a herbal medicine into a cocked hat. No one would argue for chewing willow bark when aspirin is available. But, in the meantime, there is unmet medical need that, as the IOM report pointed out, could easily and cheaply be met - if the American government cared more about suffering and less about posturing.

APPENDIX II: REGISTRATION REQUIREMENTS FOR SCHEDULE I OR II SUBSTANCE MANUFACTURERS – Controlled Substances Act 1970

§ 823. Registration requirements.

- **(a) Manufacturers of controlled substances in schedule I or II**

  The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such 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;
- (2) compliance with applicable State and local law;
- (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
- (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
- (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
- (6) such other factors as may be relevant to and consistent with the public health and safety.

APPENDIX III:

DEA Administrative Law Judge Francis L. Young

Excerpts from:
United States Department of Justice
Drug Enforcement Administration
OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW AND DECISION OF ADMINISTRATIVE LAW JUDGE

Sept. 6, 1988