The DEA:
Four Decades of Impeding And Rejecting Science

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Executive Summary

The Drug Enforcement Administration (DEA) is charged with enforcing federal drug laws. Under the Controlled Substances Act of 1970, its powers include the authority to schedule drugs (alongside other federal agencies) and to license facilities for the production and use of scheduled drugs in federally-approved research. Those powers are circumscribed by a statute that requires the agency to make its determinations based on scientific data.

The case studies compiled in this report illustrate a decades-long pattern of behavior that demonstrates the agency's inability to exercise its responsibilities in a fair and impartial manner or to act in accord with the scientific evidence – often as determined by its Administrative Law Judges.

The following case studies are included in this report:

- DEA Obstructs Marijuana Rescheduling: Part One, 1973-1994
- DEA Overrules Administrative Law Judge to Classify MDMA as Schedule I, 1985
- DEA Obstructs Marijuana Rescheduling: Part Two, 1995-2001
- DEA Overrules Administrative Law Judge to Protect Federal Monopoly on Marijuana for Research, 2001-2013
- DEA Obstructs Marijuana Rescheduling: Part Three, 2002-2013

These case studies reveal a number of DEA practices that work to maintain the existing, scientifically unsupported drug scheduling system and to obstruct research that might alter current drug schedules. The DEA's most common tactics include:

Failing to act in a timely fashion.
The DEA took 16 years to issue a final decision to the first marijuana rescheduling petition, five years for the second, and nine years for the third. In two of the three cases, it took multiple lawsuits to force the agency to act. Similarly, in the case of a researcher seeking an independent supply of marijuana for research purposes, it took the DEA 12 years – and another lawsuit – to deny the request.

Overruling DEA Administrative Law Judges.
A DEA Administrative Law Judge is a government official charged with evaluating the evidence on rescheduling and other matters before the DEA and making recommendations based on that evidence to the DEA Administrator. In three of the five cases – the first marijuana rescheduling petition, the decision to classify MDMA as Schedule I, and the case of the researcher seeking an independent marijuana supply – agency administrators overruled their Administrative Law Judges' recommendations. In the cases of the scheduling of marijuana and MDMA, the judges determined that that they should be placed in Schedule II instead of Schedule I, where they would be regulated by the Food and Drug Administration (FDA) as prescription medicines, but still retain criminal sanctions for non-medical uses.

Creating a regulatory Catch-22.
The DEA has argued for decades that there is insufficient evidence to support rescheduling marijuana or the medical use of marijuana. At the same time, it has – along with the National Institute on Drug Abuse – acted in a manner intended to systematically impede scientific research. Through the use of such tactics, the DEA has consistently demonstrated that it is more interested in maintaining existing drug laws than in making important drug control decisions based on scientific evidence.

The final section of this report will examine the DEA's speed in moving to ban MDMA, synthetic cannabinoids, and synthetic stimulants. In contrast to the DEA's failure to act in a timely fashion when confronted with evidence for scheduling certain drugs less severely, the agency has shown repeatedly that it can move quickly when it wants to prohibit a substance.

Recommendations:

1) Responsibility for determining drug classifications and other health determinations should be completely removed from the DEA and transferred to another agency, perhaps even a non-governmental entity such as the National Academy of Sciences.

2) The DEA should be ordered to end the federal government's unjustifiable monopoly on the supply of research-grade marijuana available for federally approved research. Such a step would follow the examples set by Canada, Israel, Czech Republic, England, and the Netherlands – all of which have successfully licensed private producers of medical marijuana for government-approved research. No other Schedule I drug is available from only a single governmental source for research purposes.

The Basis of the DEA's Authority to Schedule Drugs

Since its inception 40 years ago, the DEA has been charged with enforcing the nation's drug laws. Its authority is derived from the Controlled Substances Act (CSA), part of Richard Nixon's Comprehensive Drug Abuse and Prevention Act of 1970, and subsequent additions to it.

Before examining the CSA, it is useful to examine its history and intent. In the late 1960s, concern about rising levels of drug use was rife in Washington and throughout the U.S. Nixon's sweeping legislation was designed to confront the problem on multiple fronts, including drug treatment and rehabilitation, suppression of illegal drugs, and improved controls over licit drugs, the diversion of which was viewed as a serious issue.

A close reading of its legislative history shows that the CSA was intended to classify drugs based on medical and scientific evidence. As Bureau of Narcotics and Dangerous Drugs director John Ingersoll noted in his testimony at the time, an amendment being considered to expressly incorporate scientific evidence into drug scheduling decisions was deemed unnecessary because the bill already contained language that would do just that.

"The bill allows the Attorney General upon his own motion or on the petition of an interested person to bring a drug under control. However, he is authorized to do so only after requesting the advice in writing of the Secretary of Health, Education, and Welfare and the advice in writing of the Scientific Advisory Committee," Ingersoll said. "The intent of the amendment was to insure that the scientific and medical information necessary for a determination of whether a substance should be brought under control was available. But the legislation already insured that there would be sufficient medical and scientific input into any control decision."[1]

Similarly, the House floor debate showed that members intended the bill to create a mechanism for rigorously and scientifically determining how individual drugs should be treated. In fact, some members feared it would prove too cumbersome. Speaking in support of his proposed amendment to move methamphetamine into a more restrictive category by congressional vote instead of via the process foreseen in the bill, Rep. Claude Pepper bemoaned "the elaborate procedures,

administrative and judicial, that are provided for in this bill."

But in a sign that Congress intended for the Department of Justice and the Department of Health, Education & Welfare to make such determinations with "the scientific and medical information necessary," Pepper's amendment was defeated.

As Rep. John Jarman noted, "The Attorney General has the right…based on the evidence, to move these drugs from the present classification."

And speaking more generally in support of the bill, Rep. Lawrence Hogan emphasized that it would create procedures for the executive branch to make drug classification decisions.

"Title II provides another facet of needed action – that of control by the Justice Department of problems related to drug abuse," Hogan said. "The drugs to which these controls are initially enforced are listed in the bill…and a procedure is established for the classification of new drugs which create abuse problems, under which the Attorney General and the Secretary of Health Education and Welfare coordinate to determine if a drug should or should not be controlled. In the case of drugs provoking serious abuse or addiction problems, tighter controls are provided."[2]

While Hogan mentioned the possibility of classifying drugs more strictly in the face of newly identified information, there is no indication in the record that drug classification was seen as a one-way ratchet, with only tighter controls ever envisioned. To the contrary, widespread references to another provision of the bill providing for a commission to examine the status of marijuana (which would become the Shafer Commission), indicate that "down-classification" was certainly seen as within the realm of the possible.

It is worth noting that while lawmakers and administration officials alike took pains to describe the drug classification process as based on science and evidence, politics had influenced the process from the outset. In a recently published study of mid-century drug policy, historian Kathleen Frydl noted the inertial forces that helped create the CSA's drug schedules:

"While presented as a scientific evaluation, and offered as a lucid and legible categorization of drugs, in reality Schedule I was used to accommodate and continue the posture toward drugs regulated under the Harrison Narcotic Act (heroin); Schedule II drugs in turn inherited the practices and norms associated with the Drug Control Abuse Amendments of 1965 (amphetamines, barbiturates)," she wrote. "In this way, the CSA enshrined in law the arbitrary distinction drawn between two groups of drugs….The legislation was not a scientifically arbitrated scheme of drugs, but a political framework that consolidated a host of decisions, as well as some failures, to decide how to manage the drug portfolio of the United States."[3]

Still, it was the best that Congress managed to do, and it at least aspires to apply scientific and medical evidence in making drug classification decisions.

The CSA divides controlled substances into five schedules originally determined by Congress. The "most dangerous" drugs are listed in Schedule I, defined as including drugs with "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for the use of the drug…under medical supervision." Schedule I drugs include heroin, LSD, MDMA, marijuana, and, more recently, myriad new synthetic drugs.

Schedule II drugs also have "a high potential for abuse" and their abuse may lead to "severe psychological or physical dependence," but they have a "currently accepted medical use." Schedule II drug include the stronger opiate and opioid formulations, including codeine, Fentanyl, morphine, and methadone, as well as cocaine and injectable liquid methamphetamine.

Drugs in Schedules III through V have progressively lower potential for abuse, accepted medical uses, and their abuse could only lead to "limited physical dependence or psychological dependence." These drugs include lower-level prescription opiates and opioids and amphetamines (Schedule III), sleeping pills and sedatives (Schedule IV), and pain relievers that include other ingredients in addition to small amounts of opiates or opioids (Schedule V).

Under the Controlled Substances Act, the DEA may initiate proceedings to add, delete or change the schedule of a drug or substance, as may the Department of Health and Human Services (HHS). Additionally, interested parties, including drug manufacturers, medical or pharmacy associations, public interest groups, state or local governments, or individual citizens can petition to add, delete or change the schedule of a drug or

substance. When a petition is received by the DEA, they begin their own investigation of the drug. They may begin an investigation of a drug based on information received from state or local law enforcement and regulatory agencies, laboratories or other sources.

Once the DEA initiates an investigation of a drug, it collects relevant data. The DEA then requests that HHS conduct a scientific and medical evaluation and make a recommendation on whether the drug should be controlled or not and where it should be placed in the CSA schedule.

HHS in turn seeks information from the Commissioner of the Food and Drug Administration (FDA) – who delegates this task to the FDA's Controlled Substances Staff (CSS) – as well as evaluations and recommendations from the National Institute on Drug Abuse (NIDA). HHS may also seek input from the scientific and medical community at large. After consulting with FDA, NIDA, and any others, HHS submits to the DEA its medical and scientific evaluation of the drug and a recommendation on whether the drug should be controlled – and if so, in which schedule it should be placed.

While HHS's medical and scientific evaluations are binding on the DEA, its scheduling recommendations are not, with one exception: If HHS recommends that a substance not be controlled, then the DEA may not control or schedule it. After receiving the scientific and medical evaluation from HHS, the DEA Administrator will evaluate all the data and make a final decision.

DEA and other government scheduling proceedings are subject to judicial review, with the exception of the temporary placing of a substance in Schedule I "to avoid an imminent hazard to the public safety."[4] But the federal courts have tended to show great deference to the DEA's decisions, even when they have been hotly contested.

While the CSA sets out the means and procedures for scheduling drugs in accordance with science and medicine, the process has been hamstrung by its implementation. As the case studies below will illustrate, since its inception, the DEA has consistently demonstrated that it is incapable of accurately assessing the state of medical and scientific knowledge about those drugs and scheduling them appropriately.

Under Section 811 of the Controlled Substances Act, the Attorney General (or in this case, the designated agency, the DEA) "shall consider the following factors" in making its scheduling determinations: (1) The drug's actual or relative potential for abuse; (2) scientific evidence of its pharmacological effects, if known; (3) the state of current scientific knowledge regarding the drug or other substance; (4) its history and current pattern of abuse; (5) the scope, duration, and significance of abuse; (6) what, if any, risk there is to the public health; (7) its psychological or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled.

In addition to those factors, the DEA may consider "all other relevant data" in making its decisions.

DEA Obstructs Marijuana Rescheduling: Part One, 1973-1994

In 1972, a year before the DEA came into existence, the National Organization for the Reform of Marijuana Laws (NORML) filed the first petition to reschedule marijuana. After its establishment in 1973, the DEA assumed responsibility for dealing with rescheduling petitions. The DEA initially refused to process NORML's petition. NORML sought redress for the agency's inaction in the federal courts, where in 1974 the U.S. Court of Appeals for the District of Columbia ordered the DEA to fulfill the CSA's procedural requirements to review and act on such petitions.[5]

The DEA did not comply. After years of inaction by the DEA, NORML twice more sought redress in the federal courts, winning similar orders in 1977[6] and again in 1980.[7] In the 1980 decision, the appeals court ordered the DEA to begin the scientific and medical evaluations required by the NORML petition.

The DEA still took years to act on the petition. In 1986, they began what would become two years of public hearings on rescheduling, with dozens of witnesses and thousands of pages of documentation. At the end of that process, DEA Chief Administrative Law Judge Francis Young ruled that marijuana should be rescheduled because it did not meet the legal criteria for a Schedule I drug.

Marijuana in its natural form is "one of the safest therapeutically active substances known to man," he found. "The provisions of the (Controlled Substances) Act permit and require the transfer of marijuana from Schedule I to Schedule II."[8]

However, DEA Administrator John Lawn overruled the finding of the ALJ. Lawn's decision came in December 1989, just three months after President George Herbert Walker Bush declared a major escalation in the war on drugs in a televised address in which he famously waved a bag of crack cocaine that he said had been sold across the street from the White House in Lafayette Park.

As Robert Berkow, then editor-in-chief of the Merck Manual presciently noted, "There is still little evidence of biologic damage even among heavy users" of marijuana and "[t]he chief opposition to the drug rests on a moral and political, and not a toxicological, foundation."[9] And the federal courts would grant broad deference to the DEA, despite the conflicts of interest inherent in its decision-making. In 1994, the D.C. Court of Appeals affirmed the DEA Administrator's power to overrule Judge Young's decision.[10] Thus the first effort to reschedule marijuana by petitioning the DEA came to an end – 22 years after it was launched.

Meanwhile, in the midst of its decades-long denial of the NORML petition, the DEA announced in October 1985 that it had issued a notice of proposed rulemaking to reschedule synthetic dronabinol (Marinol), a pill form of tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana, from Schedule I to Schedule II, the same transfer it denied raw marijuana.[11] Marinol was officially rescheduled on July 13, 1986[12] for use in the control of nausea associated with cancer chemotherapy. Further research with the marijuana plant for this indication, which previous studies had shown worked better in some patients than Marinol, remained blocked.

DEA Overrules Administrative Law Judge to Classify MDMA as Schedule I

Although MDMA was synthesized in 1912 and patented by Merck in 1914, it slid into obscurity, surfacing briefly in the 1950s as a potential drug of interest in the CIA's and the Army's chemical warfare investigations. MDMA then returned to obscurity for another 20 years, until it was rediscovered by therapists and psychiatrists who used it as an adjunct to psychotherapy, with promising results.

Chief among them was psychologist and psychotherapist Leo Zeff, who had worked with LSD since 1961 and MDMA since 1977. He not only used MDMA as an adjunct to psychotherapy himself, but also was so impressed with his results that he introduced the drug to hundreds of psychiatrists and therapists prior to its criminalization.[13]

Zeff's experiences were recounted in Myron Stolaroff's *The Secret Chief: Conversations with a Pioneer of the Psychedelic Therapy Movement* (1997). Although Zeff had already been dead for nine years then, his real name was not revealed for fear that his past patients and associates risked legal problems because of MDMA's banned status. In 2004, his identity was revealed in a new edition, *The Secret Chief Revealed*.

However, by the early 1980s, MDMA had leaked into the non-medical drug market, where it became a huge hit in Texas nightclubs under the name Ecstasy – and came to the attention of the DEA. By 1982, the drug was on the DEA's radar, and by 1984, the open sales of Ecstasy resulted in a request from Sen. Lloyd Bentsen for the DEA to schedule it. In July 1984, the DEA filed a formal notice in the Federal Register announcing it intended to place MDMA in Schedule I.

Unaware of the drug's history, the DEA was taken by surprise when psychiatrists and therapists formally requested a DEA hearing on its scheduling. Numerous respected scientists and researchers submitted letters requesting a hearing and either opposing scheduling it under the CSA at all or calling for it not to be placed in Schedule I.

"I would regard the scheduling of this drug as a scientific calamity," wrote psychotherapist Nathaniel Branden. "On the basis of a review of the literature concerning the uses of this drug in psychotherapy, and on the basis of reports from highly-respected colleagues who have experimented with MDMA as an adjunct to psychotherapy, I implore you to leave the door open to further research, exploration, and study in this area – by opposing any rulings that would restrict the use of MDMA such that scientific investigators and psychotherapists would no longer have free and uncomplicated access."[14]

Dr. Alexander Shulgin, one of the pioneers of MDMA research, echoed Branden's concerns, but was willing to accept scheduling at a lesser level.

"I believe that it should be scheduled, as it has been shown to have some real abuse potential," he wrote. "But it may best be scheduled in some intermediate category, perhaps Schedule III, as it has unquestioned medical utility. An intermediate position such as Schedule III would in no way impede the DEA in controlling and eliminating illicit laboratories and illegal trade in improper MDMA, but it would enormously simplify the tasks of the several medical researchers who are presently seeking out IND [Investigational New Drug] approvals and research protocols with the FDA."[15]

The DEA administrative hearing process got underway that fall. Defenders of the drug's medical use argued that it should properly be placed in Schedule III, allowing physicians to prescribe it and scientific research to continue. Witnesses testified that MDMA did not have high potential for abuse, did have accepted medical use, and did have accepted safety for use under medical supervision.

In response, the DEA argued that MDMA need not have caused any actual harm to be placed in Schedule I and that the *potential* for abuse was sufficient. The DEA also maintained that only the FDA could approve a drug for medical use, and without that approval, no drug could be considered safe under medical supervision.

Yet DEA Administrative Law Judge Frances Young disagreed with agency attorneys, issuing a final ruling in May 1986 recommending that MDMA be placed in Schedule III. Judge Young found that MDMA had a low potential for abuse, had accepted medical uses, and that it was acceptably safe to be used under medical supervision. He also noted a logical inconsistency in the CSA, which blocked drugs with only medium or low abuse potential but without accepted medical use from being scheduled at all.[16]

Judge Young's recommendation was overruled by DEA Administrator John Lawn, and MDMA was placed in Schedule I.[17] MDMA advocates immediately appealed to the U.S. First Circuit Court of Appeals, which ruled in September 1987 that the DEA's contention that Congress intended for the FDA to have the exclusive right to determine accepted medical use was incorrect. The appeals court voided the placement of MDMA into Schedule I and ordered the agency to reconsider.[18]

The DEA reconsidered and came to the same conclusion as before: MDMA belonged in Schedule I. It did so by creating a series of eight criteria that were virtually identical to those needed for FDA approval, only without involving the FDA in order to get around the court's objections. Out of money and patience, and hopeful that pending medical marijuana rescheduling petitions would address the issue of FDA approval, the lawsuit plaintiffs set aside any further appeals. MDMA has remained in Schedule I ever since.

Several years after MDMA was placed in Schedule I, Dr. Marsha Rosenbaum and Rick Doblin assessed the results of its criminalization in an article in *Studies in Crime, Law and Justice.*[19]

"The most recent 'recreational' drug to be made illegal is MDMA, or 'ecstasy.' Its criminalization never should have happened. MDMA had a beneficial therapeutic use prior to scheduling. Hundreds of therapists and psychiatrists used MDMA-assisted psychotherapy with thousands of patients suffering from terminal illness, trauma, marital difficulties, drug addiction, phobias, and other disorders. MDMA was also used outside of therapeutic circles. With many anecdotal claims of benefits, users showed little evidence of problematic physiological or psychological reactions or addiction," they wrote.[20]

"Scheduling and the attendant media attention on the controversial public hearings *created* an expanded market," they continued. "But the scheduling process was fraught with problems, with the Drug Enforcement Administration's emergency scheduling itself declared illegal by the courts and its scheduling criteria overturned. Ultimately, criminalization had little deterrent effect on the recreational user population while substantially reducing its therapeutic use. Perhaps the most profound effect of MDMA's illegality has been the curtailment of scientific research and experimentation with a drug that held therapeutic potential."[21]

DEA Obstructs Marijuana Rescheduling: Part Two, 1995-2001

In 1995, a second effort to petition to reschedule marijuana got underway. Filed by researcher Dr. Jon Gettman and *High Times* magazine, this time petitioners downplayed marijuana's medical uses, emphasizing instead that it did not have the "high potential for abuse" required for Schedule I or Schedule II status.

The argument was based on studies of the brain's cannabinoid receptor system conducted by the National Institute of Mental Health between 1988 and 1994. Those studies, as well as other research cited by petitioners, indicated that marijuana has only an indirect effect on dopamine transmission and suggested that its psychoactive effects are produced by a different mechanism than those of other drugs.

"One of the key scientific developments since marijuana's original placement in Schedule I by Congress was the discovery of the cannabinoid receptor system in 1988. In effect, scientists discovered how marijuana produces its effects on the human body, and this discovery revolutionized research on marijuana," Gettman later explained. "Prior to this discovery research sought to explain how marijuana affected the body and to confirm concerns that it was a harmful and dangerous drug. Subsequent research, however, has established the opposite – that marijuana is a relatively safe drug with tremendous medical potential. This discovery has produced considerable scientific research in the last two decades – research that fulfills the requirements for marijuana's rescheduling."[22]

As the DEA stalled, the White House Office of National Drug Control Policy (ONDCP) asked the Institute of Medicine (IOM) to review the scientific evidence around the health risks and therapeutic benefits of marijuana and its cannabinoids. In its 1999 report, *Marijuana and Medicine: Assessing the Science Base*, the Institute recommended that marijuana be allowed for some patients in the short term and that preparations of isolated cannabinoids be developed as a safer alternative to smoked marijuana.[23] (At the time of the IOM report, NIDA-funded researcher Dr. Donald Tashkin, UCLA, had not yet conclusively demonstrated that smoked marijuana did not cause lung cancer, a finding that is now the scientific consensus.)[24]

While petitioners and other advocates of medical marijuana and/or rescheduling found support for their

position in the report, the DEA found the opposite. The DEA publication *Exposing the Myth of Smoked Medical Marijuana* interpreted the report's concerns about smoked marijuana to mean that it had no medical uses.

The DEA denied the second rescheduling petition on April 18, 2001.[25] Petitioners appealed to the DC Circuit Court of Appeals, but in a May 24, 2002 ruling (*290 F.3d 430*), the court held that petitioners did not have standing to challenge the DEA's decision in federal court. The court made no ruling on the merits of the case.

Meanwhile, the DEA again rescheduled Marinol on July 2, 1999, moving it from Schedule II to the even less restrictive Schedule III (*64 FR 35928*). Raw marijuana remained in Schedule I.

DEA Overrules ALJ to Protect Federal Monopoly on Marijuana for Research: 2001-2013

Beginning in 1968, the National Institute of Mental Health (NIMH) has held a monopoly on the production of marijuana legally available for FDA-approved research and medical purposes in the U.S. In 1974, the monopoly was transferred to the National Institute on Drug Abuse (NIDA), which had just been created. No other Schedule I drug is available from only a single governmental source for research purposes.

In 1999, HHS issued guidelines for the provision of NIDA's marijuana to privately-funded studies. The guidelines explicitly state that if the goal of the research is to develop the marijuana plant into an FDA-approved prescription medicine, then NIDA's marijuana is not to be provided:

"The goal of this program must be to determine whether cannabinoid components of marijuana administered through an alternative delivery system can meet the standards enumerated under the Federal Food, Drug, and Cosmetic Act for commercial marketing of a medical product.[26] As the IOM report stated, 'Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, non-smoked cannabinoid delivery systems.'"[27]

The NIDA monopoly has stymied research on various aspects of the plant and its cannabinoids. This makes very little sense given that the DEA has licensed privately funded manufacturers of methamphetamine, LSD, MDMA, heroin, cocaine, and virtually all other controlled substances.

Human studies on any Schedule I drug must gain approval from the FDA, yet for studies with marijuana, researchers must submit their protocols for an additional review process by NIDA and the Department of Health and Human Services (HHS) that exists for no other drug. This extra review process has been imposed on medical marijuana research as a result of NIDA's monopoly power, which persists despite federal law that requires adequate competition – and an uninterrupted supply – in the production of Schedule I drugs.[28] The HHS/NIDA review has no deadlines and no formal appeals process, in contrast to the FDA's 30-day deadline. Thus, NIDA's monopoly results in lengthy delays or refusals in providing research material.

NIDA has refused to supply marijuana to two FDA-approved protocols sponsored by Multidisciplinary Associations for Psychedelic Studies (MAPS), preventing these studies from taking place.[29] In addition, for the last decade, NIDA has refused to sell 10 grams of marijuana to a laboratory study evaluating the effectiveness of a marijuana vaporizer, a nonsmoking drug delivery device that eliminates the products of combustion that patients would inhale after burning marijuana.[30] NIDA has prevented this study from taking place, despite the fact that the development of nonsmoking drug delivery devices was recommended by the Institute of Medicine in its 1999 report on medical marijuana.

NIDA did, however, approve a clinical study in March 2013, led by Dr. Sue Sisley of the University of Arizona evaluating marijuana in 50 U.S. veterans with chronic, treatment-resistant posttraumatic stress disorder (PTSD). However, NIDA will not be able to provide the marijuana until January 2015.

Even for those researchers whose protocols it approves, NIDA provides inferior, low-potency marijuana. NIDA's marijuana has limited cannabinoid profiles, so researchers are unable to optimize the strain of marijuana they prefer to use for costly FDA drug development efforts. The highest potency marijuana available from NIDA for research is 7 percent THC; the marijuana used by patients in states where it is legal is frequently documented to be between 15 percent and 24 percent THC, along with varying levels of other therapeutically significant cannabinoids.

NIDA cannot even provide any marijuana for prescription use if FDA clinical trials ultimately determine that it meets federal guidelines for safety and efficacy. This limitation makes any drug development effort using NIDA marijuana a futile exercise. Sponsors will not invest millions of dollars into research studies until there is reliable access to a consistent supply of high-quality research material that can be used both in research and – if the research should prove successful – as an FDA-approved prescription medicine.

The DEA has compounded the problem by protecting NIDA's monopoly. The DEA has blocked appropriate administrative channels, such as licensing a source of marijuana for research purposes outside the NIDA monopoly that would facilitate privately-funded FDA-regulated clinical trials. At the same time, it denies that marijuana is a medicine because the FDA has not approved it.

The experience of Professor Lyle Craker, director of the University of Massachusetts-Amherst's Medicinal Plant Program, is a case in point.

Dr. Craker, aided by MAPS, applied for a license from the DEA to establish a marijuana production facility for FDA-approved research in June 2001. Late that year, the DEA claimed the application was lost. A resubmitted photocopy of the application was rejected in February 2002 as invalid because it didn't have an original signature. In July 2002, the original application was returned, unprocessed, with a DEA date stamp showing it had been received in June 2001. Craker resubmitted a signed application to the DEA on August 20, 2002, which they finally acknowledged receiving.

On July 24, 2003, DEA finally filed a notice in the Federal Register about Craker's application, with a public comment period ending on September 23, 2003. On October 23, 2003, Massachusetts Senators Ted Kennedy and John Kerry wrote a letter to the Administrator of the DEA expressing their strong support for DEA licensing of the facility. On December 10, 2004 – after Craker, MAPS, and medical marijuana patient Valerie Corral sued the DEA for unreasonable delay – the DEA finally took action and rejected the application.

Prof. Craker then filed a lawsuit against the DEA for rejecting the application. He also requested a DEA Administrative Law Judge hearing, which was granted. After nearly two years of extensive testimony and evidence-gathering, on February 12, 2007, DEA Administrative Law Judge Ellen Bittner issued an 87-page Opinion and Recommended Ruling in favor of granting Craker's application. Judge Bittner ruled it was in the public interest to end the decades-long NIDA monopoly on marijuana production for research purposes.

"NIDA's system for evaluating requests for marijuana has resulted in some researchers who hold DEA registrations and requisite approval from [HHS and FDA] being unable to conduct their research because NIDA has refused to provide them with marijuana," Judge Bittner concluded. "I therefore find that the existing supply is not adequate."[31]

On September 17, 2007, 45 members of the U.S. House of Representatives sent a letter to DEA Administrator Karen Tandy urging her to accept Bittner's February ruling.

Approving Craker's application "would be in the public interest," the House members wrote. "The University of Massachusetts-Amherst is one of the nation's distinguished research universities, and it is highly qualified to manufacture marijuana for legitimate medical and research purposes with effective controls against diversion. Granting a license to Prof. Craker would allow the initiation of privately-funded FDA-approved research designed to evaluate the medical utility of marijuana for patients undergoing chemotherapy or suffering from AIDS, glaucoma, multiple sclerosis, or other diseases."[32]

In 2009, after failing to respond for almost two years – and just days before the inauguration of President Obama – DEA Administrator Michele Leonhart rejected that recommendation. Craker sought a formal reconsideration, which Leonhart denied in 2011.[33] "I am saddened that the DEA is ignoring the best interests of so many seriously ill people who wish for scientific investigations that could lead to development of the marijuana plant as a prescription medicine," said Professor Craker in a statement after the decision. "Patients with serious illnesses deserve legitimate research that might establish medical marijuana as a fully legal, FDA-approved treatment. Today, that effort has been dealt a serious blow."[34]

In an editorial decrying the decision, the *Los Angeles Times* lambasted not only the decision but the institutional culture of the DEA:

"Members of Congress have urged Atty. Gen. Eric H. Holder Jr. to amend or overrule the order, and he should do so. Then he should go further and change the culture of the agency. Instead of thwarting the advancement of science, the DEA should encourage cannabis research … On Monday, President Obama signed a 'scientific integrity presidential memorandum' and promised that his administration would base its public policies on science, not politics; the DEA is one of many federal agencies ready for enlightenment."[35]

Craker then appealed to the First Circuit Court of Appeals, with oral arguments taking place in May 2012. In its decision in April, 2013, the First Circuit upheld Leonhart's denial. In so doing, it dismissed Craker's claims that the DEA had changed the rules in the middle of the game and that the supply of marijuana from the NIDA facility was inadequate and uncompetitive.

Leonhart's interpretation of the Controlled Substances Act was permissible and her findings were "reasonable and supported by the evidence," the court held.[36] Prof. Craker and MAPS decided that it was pointless to appeal to the U.S. Supreme Court, pausing their 12-year effort to obtain a DEA license to produce marijuana exclusively for use in federally-regulated research.

DEA Obstructs Marijuana Rescheduling: Part Three, 2002-2013

In 2002, armed with an increasing amount of research on marijuana's therapeutic benefits and the fact that medical marijuana had already been legalized in a handful of states, Dr. Jon Gettman, a group of medical marijuana patients, and other petitioners filed a third marijuana rescheduling petition.

The petition argued that marijuana should be rescheduled because it does have accepted medical use in the United States, that it is safe to use, and that it has relatively low dependence and abuse liabilities, especially when compared to other drugs in the pharmacopeia. The petition provided copious evidence to support its claims.[37]

The DEA formally accepted the petition the following year, but then stalled for the next eight years. As the DEA pondered, the nation's two largest physician groups came out in support of a serious review of marijuana's placement in Schedule I. The American College of Physicians, the country's second-largest physician group and largest organization of internal medicine physicians, passed a February 2008 resolution calling for an "evidence-based" review of marijuana's status. That was followed by a November 2009 vote by the country's largest physician organization, the American Medical Association (AMA), to reverse its long-standing position that marijuana should remain in Schedule I.

The AMA did so by adopting a report by its Council on Science and Public Health, which concluded that "short term controlled trials indicate that smoked cannabis reduces neuropathic pain, improves appetite and caloric intake, especially in patients with reduced muscle mass, and may relieve spasticity and pain in patients with multiple sclerosis" and urged that "the Schedule I status of marijuana be reviewed with the goal of facilitating clinical research and development of cannabinoid-based medicines and alternate delivery systems."[38]

After repeated requests for action on their petition, the Coalition for Rescheduling Cannabis filed suit in the D.C. Circuit Court of Appeals to compel the DEA to formally respond. The DEA's failure to act on the petition "presents a paradigmatic example of unreasonable delay under *Telecommunications Research & Action Ctr. v. FCC*," they argued in their writ of mandamus.[39]

Just six weeks after the lawsuit was filed, the DEA acted, notifying the Coalition in a June 21, 2011 letter that it would deny the petition and formalizing that decision with a July 8, 2011 Final Determination on the Petition for Rescheduling. The DEA concluded that there were not enough "adequate and well-controlled studies proving efficacy," and thus no "currently accepted medical use."[40]

"Marijuana continues to meet the criteria for Schedule I control under the CSA because marijuana has a high potential for abuse, marijuana has no currently accepted medical use in treatment in the United States, and marijuana lacks accepted safety for use under medical supervision," the DEA maintained. "According to established case law, marijuana has no 'currently accepted medical use' because the drug's chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts, and the scientific evidence is not widely available."[41]

As the *Los Angeles Times* noted at the time, the DEA decision did not gibe with the reality of ongoing research and had the effect of leaving researchers (and the patients who would benefit from that research) ensnared in a bureaucratic Catch-22.

"The DEA's decision comes as researchers continue to identify beneficial effects," the newspaper reported. "Dr. Igor Grant, a neuropsychiatrist who is the director of the Center for Medicinal Cannabis Research at UC San Diego, said state-supported clinical trials show that marijuana helps with neuropathic pain and muscle spasticity. He said the federal government's position discourages scientists from pursuing research needed to test the drug's medical effectiveness. 'We're trapped in kind of a vicious cycle here,' he said. 'It's always a danger if the government acts on certain kinds of persuasions or beliefs rather than evidence.'"[42]

In response to the DEA's decision, one of the petitioners, Americans for Safe Access, appealed to the D.C. Circuit in January 2012. A year later, a three-judge panel ruled in favor of the DEA, deferring to the agency's prerogatives and finding that the DEA's stance was not "arbitrary and capricious."[43] The plaintiffs unsuccessfully filed an appeal seeking a hearing before the U.S. Supreme Court, but the high court did not accept their appeal.[44]

Meanwhile, even though the Supreme Court ruled that the federal government's blanket ban on marijuana superseded state medical marijuana laws in 2005's Gonzales v. Raich, Justice John Paul Stevens wrote in a footnote to the majority opinion that if the scientific evidence presented by medical marijuana supporters there was true, it would "cast serious doubt" on marijuana's Schedule I classification.[45]

Now, the DEA is considering a fourth petition to reschedule marijuana to Schedule II, filed by Washington State Gov. Christine Gregoire and Rhode Island Gov. Lincoln Chafee in 2011. The state of Colorado has signed on as well.[46]

"Sadly, patients must find their way along unfamiliar, uncertain paths to get what their doctors tell them would help – medical cannabis to relieve their suffering," Gregoire said in a press release. "People weak and sick with cancer, multiple sclerosis, and other diseases and conditions suddenly feel like – or in fact become – law breakers. In the year 2011, why can't medical cannabis be prescribed by a physician and filled at the drug store just like any other medication? The answer is surprisingly simple. It can. But only if the federal government stops classifying marijuana as unsuitable for medical treatment."[47]

The DEA has yet to officially respond.

The DEA Can Act Quickly – When It Wants to Ban Drugs

In contrast to the languor with which the DEA has responded to efforts to change marijuana's classification or expand access to it for research purposes, it has repeatedly demonstrated that it is capable of quick decision-making when it comes to imposing tighter controls on substances it deems a threat.

MDMA

As mentioned above, the recreational use of MDMA first came to the DEA's attention in 1982, and by 1984, Texas Senator Lloyd Bentsen had requested that the DEA schedule it. In March 1984, the DEA began moving to schedule MDMA, and in July of that year the DEA filed a formal notice in the Federal Register announcing its intent to place MDMA in Schedule I.

Despite strong opposition to placing MDMA in Schedule I, the DEA moved swiftly, and the drug was banned in 1986.

Synthetic Cannabinoids

Products containing synthetic cannabinoids (sold under names such as Spice and K-2) first gained attention in the U.S. in 2009. A handful of states moving to ban them the following year. The DEA named the synthetic cannabinoid JWH-018 a "drug of concern" in 2010, based largely on reports from law enforcement and poison control centers of an increasing number of people suffering ill effects from its use, even though there was little evidence it was addictive or especially toxic.

In November 2010, Republican Senator Orrin Hatch of Utah sent a letter to the DEA complaining that the use of synthetic cannabinoids was "at epidemic proportions" among his state's youth and urging the DEA to "exercise its emergency scheduling authority to classify Spice as a Schedule I substance."[48]

One week later, the DEA announced it was using its emergency scheduling powers to temporarily ban five synthetic cannabinoids to "avoid an imminent public health crisis" while it undertook the normal rule-making process to make the ban permanent. The emergency ban designated synthetic cannabinoids as Schedule I substances.

Further DEA action was obviated by Congress, which passed a bill permanently placing synthetic cannabinoids and other synthetic drugs (see below) in Schedule I in 2012. President Obama signed the Synthetic Drug Control Act of 2011 into law in July 2012.

Synthetic Stimulants

Like synthetic cannabinoids, unregulated synthetic stimulant drugs began showing up in the U.S. and on the DEA's radar in late 2009, prompting a number of states to enact bans against them that year, and more the following year. The DEA named the new substances "drugs of concern" the same year.

In January 2011, New York Senator Charles Schumer called for a federal ban on two synthetic stimulants – mephedrone and MPDV – and by that summer, Congress was considering three separate bills banning synthetic stimulants, one of which would also ban synthetic cannabinoids.

In September 2011, the DEA announced it was using its emergency scheduling powers to temporarily ban three synthetic stimulants – mephedrone, MPDV, and methylone – "to protect the public from the imminent hazard posed by these dangerous chemicals."[49]

As with synthetic cannabinoids, further DEA action was obviated by the Synthetic Drug Control Act, signed into law in 2012.

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