UMASS-AMHERST MEDICAL MARIJUANA RESEARCH FACILITY

BACKGROUND IN SUPPORT OF AN INDEPENDENT, PRIVATELY FUNDED SOURCE OF PRODUCTION

On February 12, 2007, DEA Administrative Law Judge (ALJ) Mary Ellen Bittner issued an Opinion and Recommended Ruling determining that DEA should grant the application of Professor Lyle Craker, University of Massachusetts-Amherst, for a Schedule I license to grow marijuana for distribution exclusively to federally approved researchers. Prof. Craker's proposed production facility would resolve the controversy over medical marijuana by determining whether it meets the FDA's standards for safety and efficacy.

Unfortunately, DEA is under no obligation to accept Judge Bittner's administrative ruling.

What is at issue?

Should DEA grant a Schedule I bulk manufacturer license to Prof. Lyle Craker, Director, Medicinal Plant Program, Dept. of Plant, Soil and Insect Sciences, UMass Amherst, to establish a privately funded facility to produce marijuana exclusively for federally approved and privately funded research?

What is the problem?

Despite the fact that federal law clearly requires adequate competition in the manufacture of Schedule I and II substances, since 1968 the National Institute on Drug Abuse (NIDA) has maintained an unjustified monopoly on the production of marijuana for legitimate medical and research purposes in the US. DEA helps to protect NIDA's monopoly by refusing to grant competitive licenses for marijuana production.

Currently, the only way for marijuana to be evaluated by the FDA to determine whether it meets the standards necessary to become a medicine under federal law is for privately-funded sponsors to conduct FDA-approved clinical trials. Unfortunately, NIDA's monopoly on the supply of legal marijuana is a fundamental obstruction to such privately funded research, which is currently not being conducted despite strong public interest.

The DEA wants to have it both ways, denying that marijuana is a medicine because the FDA has not approved it, while simultaneously blocking the appropriate administrative channels which would facilitate FDA clinical trials.

Arbitrary and Lengthy Delays: Despite the fact that it is not NIDA's mission to study the medicinal uses of marijuana or to advocate for such research, NIDA's monopoly on the supply of cannabis available for research results in arbitrary and lengthy delays. For example, Chemic Labs, a DEA-licensed analytical lab, was made to wait more than two years for a reply to its initial request to purchase 10 grams of marijuana for privately sponsored research into vaporizers, a non-smoking delivery system which the Institute of Medicine report recommended be developed. After two years of delay, the application was rejected. NIDA has also refused to provide marijuana to two other privately sponsored, FDA-approved protocols that sought to evaluate marijuana for AIDS wasting syndrome (IND #43-542) and for migraines (IND #58-177).

What is the resolution?

Congress should support and encourage DEA to accept the February 2007 Opinion and Recommended Ruling of Administrative Law Judge Mary Ellen Bittner. Furthermore, DEA should grant a Schedule I bulk manufacturer license to Prof. Lyle Craker, UMass Amherst, to establish a privately funded facility to produce marijuana exclusively for federally approved and privately funded research.

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Los Angeles Times

Ending the Marijuana Monopoly

Editorial | May 31, 2007

Federal officials should allow competition in growing the drug for needed studies on its medical use.

Discussion of medical marijuana has always been heavy on rhetoric, elisions and grandiose claims. What it has lacked is reliable research that might bring some of the discussion into line with reality. This is because access to the government's monopoly supply of research-grade marijuana is so restricted that the necessary research is effectively impossible. Now the Drug Enforcement Administration's chief administrative law judge is recommending that the federal drug police allow competition in growing marijuana for research purposes. The administration should follow her recommendation.

At issue is the supply of research-grade marijuana produced at the University of Mississippi and overseen by the National Institute on Drug Abuse. This supply is supposed to be made available to DEA-registered researchers who have undergone a rigorous review and approval process by the U.S. Public Health Service. However, both medical marijuana advocates and scientists say the institute routinely refuses to make its supply available even to licensed researchers for properly authorized studies. There are at least two FDA-approved studies that cannot go forward because no research samples are available.

This leaves researchers -- and the 12 states that have so far approved marijuana for medical purposes -- in a Catch-22: Drug warriors object that there is no research demonstrating marijuana's efficacy while preventing such research from being done. Since 2001, a scientist with the University of Massachusetts Amherst has vainly petitioned the DEA for permission to produce, under conditions that even the DEA acknowledges present little risk of diversion for illicit use, another supply of research-grade marijuana.

In a recent ruling, Judge Mary Ellen Bittner agreed that that request would be in the public interest. Given its narrow confines, Bittner's recommendation makes sense. It has no bearing on the DEA's licensing of researchers, which would remain in place, nor would it remove the burden of proof on scientists who want access to research-grade marijuana. It would merely prevent situations in which, the judge noted, legitimate researchers who have completed all due diligence are still refused access to research samples.

The benefits of medical marijuana may turn out to be less impressive than advocates hope. All the more reason that research should be allowed to go forward, so that we can base the discussion on evidence rather than on the two sides' vehement -- but factually unsupported -- claims.

The Boston Globe

Botanist Asks OK to Grow Marijuana

By Andrew Miga, Associated Press | May 24, 2007

ARLINGTON, Va. -- A professor at the University of Massachusetts at Amherst who has waged a nearly six-year fight to persuade the government to let him grow marijuana for medical research pressed his case yesterday outside the offices of the US Drug Enforcement Administration.

Horticulturist Lyle Craker said he wants to boost research into potential medicinal benefits of marijuana.

"We've looked at this as just another medicinal plant that needs to be studied," Craker, who heads the school's medicinal plant program, said during a press conference outside DEA offices.

Craker is awaiting a DEA decision on his case. DEA spokesman Garrison Courtney said in an e-mail that it would be inappropriate to comment since the matter is pending.

Earlier this year, a federal administrative law judge recommended to the DEA that it grant Craker's application to grow marijuana in bulk for use by scientists in Food and Drug Administration-approved research. The nonbinding ruling said the government's supply was inadequate for medical research. It also concluded that Craker's request was in the public interest.

Craker is challenging the government's monopoly on research marijuana. A lab at the University of Mississippi is the government's only marijuana-growing facility. Craker's suit asserts government-grown marijuana lacks the potency medical researchers need.

DEA lawyers have defended the government's marijuana, saying its Mississippi growing center provides adequate quality and quantity for researchers.

Craker said his case has been hurt by DEA concerns about the drug falling into the hands of students. He said he was confident that security measures could be used at UMass to prevent that.

"They've gotten confused between recreational use and medical use," he said of the DEA. "That's what needs to be separated out. . . . When the DEA understands that, they'll be probably prepared to move forward."

The Washington Post

Researchers Press DEA to Let Them Grow Marijuana

Marc Kaufman | May 24, 2007

Armed with a legal decision in their favor, scientists and advocates of medical research on marijuana pressed the Drug Enforcement Administration yesterday to allow them to grow their own, saying that pot supplied by the government is too hard to get and that its poor quality limits their research.

The proponents said a DEA administrative law judge's recent ruling that it would be in "the public interest" to have additional marijuana grown -- and to break the government's monopoly on growing it -- had put them closer to their goal than ever before.

"The DEA has an opportunity here to live up to its rhetoric, which has been that marijuana advocates should work on conducting research rather than filing lawsuits," said Richard Doblin, president of the Multidisciplinary Association for Psychedelic Studies, which has fought for years for access to government-controlled supplies to test possible medical uses of marijuana.

"It's become more and more obvious that the DEA has been obstructing potentially beneficial medical research, and now is the time for them to change," he said.

The agency has opposed petitions that would end the government's marijuana monopoly, saying that the current system works well and that allowing other growers could lead to more diversion to illicit use. All the marijuana produced for research is grown at the University of Mississippi and distributed through the National Institute on Drug Abuse.

But a petition filed in 2001 by University of Massachusetts agronomy professor Lyle E. Craker seeking to grow marijuana in his greenhouses has worked its way through the DEA appeal process and resulted in a ruling against the agency earlier this year.

The decision by DEA Administrative Law Judge Mary Ellen Bittner concluding that Craker should be allowed to grow marijuana for Doblin's group to use in its research became final last week.

Craker, who has studied medicinal plants for years, joined several other medical marijuana advocates at DEA headquarters yesterday to highlight the issue. "Working with medical marijuana seems so similar to the work we're doing with other medicinal plants that I've never understood the DEA's big problem with it," said Craker, whose facilities have been examined by DEA agents to determine if they are sufficiently secure.

Bittner's ruling was strongly supportive of Craker's petition but carries limited regulatory weight: The final decision on the government's marijuana monopoly will be made by the deputy administrator of the DEA, and the agency has already taken strong exception to Bittner's conclusions.

DEA spokesman Garrison K. Courtney said yesterday that "the matter is currently pending before the DEA, and it would be inappropriate for DEA to comment at this time."

Doblin, who contacted Craker about growing medical marijuana after he was turned down by government officials, said the public is losing confidence in the DEA's oversight of the issue. He said 12 states have legalized medical marijuana and others are likely to follow soon.

Doblin said that in addition to studying the potential benefits of smoked marijuana for pain relief and to control nausea in cancer patients and some symptoms of multiple sclerosis, his group wants to test vaporized marijuana. Inhaling marijuana vapors could reduce some of the potential risks associated with smoking it.

The New York Times ON THE WEB

Researchers Make Progress in the Lab, But Not in Washington

By John Tierney | May 24, 2007

There's more encouraging scientific news on the use of marijuana to alleviate pain: a study has shown that effective doses of cannabis can be delivered with vaporizers, which enable patients to get the therapeutic benefits without inhaling harmful smoke. Meanwhile, though, researchers are still struggling against their biggest bureaucratic obstacle, the Drug Enforcement Administration.

On Wednesday they made their case at a press conference on the sidewalk outside the headquarters of D.E.A., which still hasn't followed the recommendation of its own administrative law judge in a medical-marijuana case. In February, as I noted, the judge concluded "that there is currently an inadequate supply of marijuana available for research purposes" and ruled that Lyle Craker, a professor of plant and soil sciences at the University of Massachusetts, should be given permission by the D.E.A. to grow it for researchers.

The ruling became final last week, but the D.E.A. still hasn't acted and refuses to comment on the issue, as the A.P. and the Washington Post reported in articles about the press conference. Marc Kaufman of the Post quoted a researcher who joined Dr. Craker on the sidewalk:

"The D.E.A. has an opportunity here to live up to its rhetoric, which has been that marijuana advocates should work on conducting research rather than filing lawsuits," said Richard Doblin, president of the Multidisciplinary Association for Psychedelic Studies, which has fought for years for access to government-controlled supplies to test possible medical uses of marijuana.

"It's become more and more obvious that the D.E.A. has been obstructing potentially beneficial medical research, and now is the time for them to change," he said.

The Bush administration has been claiming that there's no evidence for the efficacy of medical marijuana, but a study in Neurology earlier this year found it was comparable to morphine at relieving pain. Now the lead author of that study, Donald I. Abrams, and colleagues have published a paper in Clinical Pharmacology & Therapeutics addressing another of the White House's criticisms of medical marijuana: the danger of inhaling toxic byproducts when it is smoked.

The researchers gave marijuana to patients through vaporizers that heated it just short of combustion. "This study," said Dr. Abrams, a professor of medicine at the University of California at San Francisco, "demonstrates an alternative method that gives patients the same effects and allows controlled dosing but without inhalation of the toxic products in smoke." Here are more details of the study from U.C.S.F.:

Under the study protocol, the participants received on different days three different strengths of cannabis by two delivery methods-smoking or vaporization-three times a day. Plasma concentrations of THC were measured along with the exhaled levels of carbon monoxide, or CO. A toxic gas, CO served as a marker for the many other combustion-generated toxins inhaled when smoking. The plasma concentrations of THC were comparable at all strengths of cannabis between smoking and vaporization. Smoking increased CO levels as expected, but there was little or no increase in CO levels after inhaling from the vaporizer, according to Abrams.

"Using CO as an indicator, there was virtually no exposure to harmful combustion products using the vaporizing device. Since it replicates smoking's efficiency at producing the desired THC effect using smaller amounts of the active ingredient as opposed to pill forms, this device has great potential for improving the therapeutic utility of THC," said study co-author Dr. Neal L. Benowitz, U.C.S.F. professor of medicine, psychiatry and biopharmaceutical sciences. He added that pills tend to provide patients with more THC than they need for optimal therapeutic effect and increase side effects.

Researchers hope to do more experiments with vaporizers, but they're stymied by the limited supply of marijuana available from the only legal source, a federal farm in Mississippi. They're also frustrated by what they say is the poor quality of that product. They say that a new supply of better marijuana from Dr. Craker would be a boon to research.
Does anyone have any guess why the D.E.A. keeps refusing to give him permission to grow it?

sacbee The Sacramento Bee
Life. Captured daily.

Rejected in Court, Medical Pot Advocates Turn to DEA

By Claire Cooper | April 15, 2007

A federal appeals court's rejection of Angel Raich's plea for permission to ease her suffering without fear of prosecution has medical marijuana advocates looking for reform in a surprising venue - -- the Drug Enforcement Administration.

Raich's loss severely diminishes prospects of reform through litigation. But a February "opinion and recommended ruling" by a DEA administrative law judge holds out the possibility that prescription marijuana will be developed and approved by the Federal Drug Administration, ending the long federal-state standoff over medical pot.

Mary Ellen Bittner, a Department of Justice appointee who hears regulatory cases for the DEA, tentatively ruled it "would be in the public interest" to let Lyle E. Craker, a medicinal plant specialist at the University of Massachusetts, Amherst, grow pot for use by DEA-registered scientists in prescription drug research and clinical trials authorized by the FDA. If Bittner's ruling becomes final, it could punch a hole in the wall that federal agencies -- the DEA and the National Institute on Drug Abuse -- have erected around legal marijuana, stymieing research into an effective, legal pharmaceutical. Doctors could be prescribing pot as easily as methadone, codeine or morphine, perhaps in seven or eight years.

That would be a long time for Raich, whose serious ailments include an inoperable brain tumor, and for other people who depend on marijuana to stay alive or ease the pain of dying. But it would be a short time in the myth-driven history of marijuana regulation that began in the United States with the Marihuana Tax Act of 1937. Passage of the Controlled Substances Act in 1970 imposed a ban on pot production, distribution and use that remains almost absolute because of the federal government's stubbornly held position that pot poses extreme risks and has no proven medical value.

Evidence to the contrary has been building. In 1999, the Institute of Medicine of the National Academy of Sciences reported that most regulatory concerns could be overcome by developing marijuana delivery systems, such as vaporization, that should avoid the lung damage caused by smoking. As recently as two months ago researchers reported that HIV-positive patients at San Francisco General Hospital who smoked marijuana found relief from searing pain in their hands and feet. Other studies have shown that pot can stimulate appetite and reduce nausea and muscle spasticity.

Yet as Bittner noted, scientists have been winning federal approval to conduct promising medical marijuana research projects only to be denied access to the sole legal pot supply in the country, grown for NIDA at the University of Mississippi. NIDA specifies how much shall be grown each year. The professor in charge in Mississippi testified in 2005 that he had grown no marijuana for three years because he had enough inventory to cover research needs.

California researchers have received pot produced in Mississippi for use in state-authorized safety and efficacy studies, but they are not developing a prescription drug. John Vasconcellos, the former state senator whose legislation established the University of California Center for Medical Cannabis Research, testified before Bittner that the purpose was not to get FDA drug approval but "to demystify the roaring contentions of contrary viewpoints and to find out by science, whether in fact (marijuana is) of any use."

Bittner concluded that more research-grade pot is needed and that competition to supply it is inadequate. She will make her final recommendation to the DEA -- which will have the last word -- on the basis of comments submitted by lawyers for the DEA and for Craker.

A final recommendation in favor of Craker almost certainly would have been doomed in years past and may still be. The Multidisciplinary Association for Psychedelic Studies, which would fund research, estimates chances of success at one in three. But medical pot advocates vow to make a strong push for support from the new Congress, where the atmosphere for marijuana reform should be more hospitable than it's been in a long time. Although the lobbyists don't expect a major drug law overhaul before the 2008 elections, they see friends in key leadership positions.

Among those listed in a recent article by Bill Piper, director of national affairs for the Drug Policy

Alliance, are Ohio Democrat Dennis Kucinich, chairman of the House Government Reform and Oversight Committee, which oversees the White House drug czar's office, the coordinator of national drug control policy. Kucinich has gone on record in support of removing medical pot users from the criminal justice system. Piper also pointed to Michigan Democrat John Conyers, the new chairman of the House Judiciary Committee; Virginia Democrat Robert C. Scott, chairman of the House Subcommittee on Crime; and Wisconsin Democrat David Obey, chairman of the House Appropriations Committee. Even in 2006, when putting pressure on the DEA had to be taken as a futile gesture, 163 members of the House voted to end federal raids on patients complying with their states' medical marijuana laws.

By contrast, prospects for reform through the courts look dimmer than at any other time since California passed the nation's first Compassionate Use Act in 1996.

The ruling last month against Raich by the 9th U.S. Circuit Court of Appeals, the nation's most progressive federal appellate court, seems to close the door to the strongest common-law and constitutional arguments for peaceful coexistence of the state and federal marijuana regulatory schemes.

The 9th Circuit ruled on several grounds. Though the judges didn't doubt Raich's suffering -- the Oakland woman has regularly appeared in their courtroom looking X-ray thin -- they rejected an argument that federal authorities should be enjoined from busting her because her marijuana use is a medical necessity. If the DEA does prosecute her, that would be the time to assert her medical necessity defense, the judges said.

They also ruled that Raich has no fundamental due-process right to use marijuana "to avoid intolerable pain and preserve life and bodily integrity," though they predicted legal recognition of such a right once more states pass medical marijuana laws. New Mexico's legislature approved a medical marijuana law the day before the 9th Circuit issued its decision, making that state the 11th to follow California's lead. The 9th Circuit also found that California has no 10th Amendment right as a sovereign state to have its own marijuana laws prevail over conflicting federal law.

The 10th Amendment argument isn't quite dead yet. It's now being asserted by the city of Santa Cruz as a plaintiff in federal court in San Jose. The city may have a stronger case because its own ordinance authorizes it to provide marijuana to its residents who qualify to use the drug under the state law.

However, the U.S. district judge in the Santa Cruz case is Jeremy Fogel, a by-the-book jurist who's not likely to adopt a novel legal theory. The Santa Cruz case had been on hold pending the Raich decision and soon will move toward resolution.

Finally, the 9th Circuit's opinion held out a possibility that medical pot users could claim an exemption from federal penalties under the "plain language" of the Controlled Substances Act. For the time being that's probably a meaningless concession.

The federal statute permits possession of a controlled substance if it's obtained "pursuant to a valid prescription or order" by a physician. But "order" has been interpreted to mean "prescription," and the federal government doesn't let doctors prescribe pot. Under California's Compassionate Use Act, the state's doctors can only "recommend" it to qualifying patients.

This is where Craker comes in. Pot grown by him would be subsidized by the Multidisciplinary Association for Psychedelic Studies, a nonprofit pharmaceutical company that would sponsor the development of marijuana as a prescription medicine within the framework of the FDA drug approval process. The research likely would include pot vaporization studies that MAPS has been trying to get under way for at least four years.

FDA approval of a marijuana drug that doctors can prescribe seems to be no pipe dream. While the agency has opposed state medical marijuana laws as premature, its official position for several years has been to encourage research needed to take a marijuana drug through the approval process.

Robert Meyer, head of the FDA's Office of Drug Evaluation II, testified in 2004 congressional hearings that his agency and its parent Department of Health and Human Services "recognize the need for objective evaluations of the potential merits of cannabinoids (the 66 compounds unique to pot) for medical uses."

"If the scientific community discovers a positive benefit," said Meyer, "HHS also recognizes the need to stimulate development of alternative, safer dosage forms."