CROP BLOCKERS

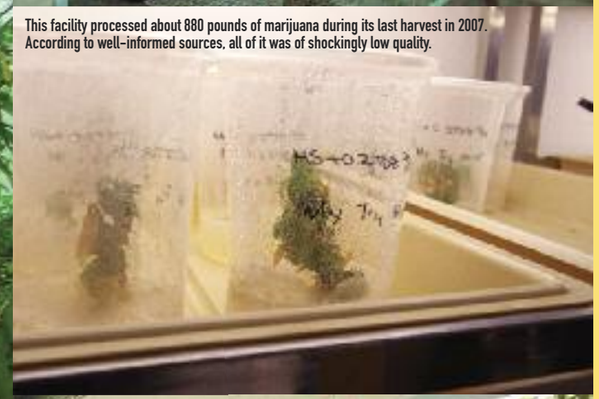
Scientific researchers can access all the medical marijuana they need, directly from the federal government's massive cannabis-production facility in Mississippi– so long as they don't try to prove that it works. BY DAVID JAY BROWN

Dr. Mahmoud ElSohly oversees the nation's only federally legal marijuana farm, housed at the University of Mississippi. Previously, he studied poison ivy.

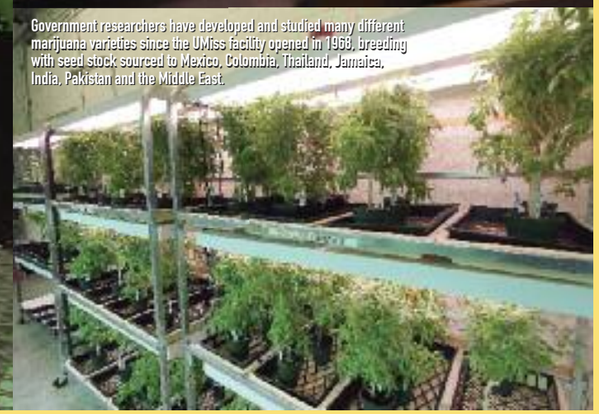
PHOTOS BY MATTHEW SHARPE

Indoor cultivation takes place under tight security year-round, while the outdoor gardens are only planted in years when the federal government places an order.

This facility processed about 880 pounds of marijuana during its last harvest in 2007. According to well-informed sources, all of it was of shockingly low quality.



Government researchers have developed and studied many different marijuana varieties since the UMiss facility opened in 1968, breeding with seed stock sourced to Mexico, Colombia, Thailand, Jamaica, India, Pakistan and the Middle East.



Rick Doblin is a patient man. Since founding the Multidisciplinary Association for Psychedelic Studies (MAPS) in 1986 to help develop marijuana and psychedelic drugs into legal prescription medications, he's spent decades tirelessly wading through bureaucratic red tape. Along the way, he helped set in motion the first government-approved medical study of MDMA (a.k.a. Ecstasy) in the United States, as well as kick-started a global renaissance in psychedelic research. So when he says that a situation has been "incredibly frustrating," he really means it—and that's exactly how Doblin describes his attempts to obtain just a few grams of marijuana for two MAPS-sponsored studies that have already been approved by the US Food and Drug Administration (FDA).

Currently, far more controversial psychedelic drugs—including MDMA, LSD and psilocybin—are being studied in clinics all over the world to determine their safety and efficacy in treating conditions such as post-traumatic stress disorder (PTSD) and end-of-life anxiety. But despite this welcome resurgence in psychedelic-drug research—as well as the numerous promising pilot studies and mountains of anecdotal evidence—scientific investigation into the medical benefits of cannabis here in the US has been routinely blocked by the National Institute on Drug Abuse (NIDA), which holds a government-enforced monopoly on the legal supply of research cannabis.

In fact, marijuana is the only Schedule 1 drug for which the federal government not only controls the entire legal research supply, but also requires a special review of all scientific protocols. And while 14 states and the District of Columbia have already passed laws allowing access to medical marijuana for qualified patients, the federal government's all-out prohibition effectively prevents scientists from obtaining their research supplies simply by ordering them from a medical-marijuana dispensary or collective. So, in addition to obtaining approvals from the FDA and the Drug Enforcement Administration (DEA), would-be marijuana researchers must also apply to NIDA for their cannabis and have their study vetted by a special NIDA/Public Health Service (PHS) review panel.

To make matters worse, since 1968 the DEA has licensed only one cannabis-production facility in the entire United States, housed at the University of Mississippi and currently under the direction of pharmacologist Mahmoud ElSohly, who has an exclusive contract with NIDA to cultivate marijuana for research purposes. This tightly controlled supply line means that if NIDA decides not to sell marijuana to a group of researchers, their study becomes impossible to conduct. And NIDA rather blatantly refuses to approve *any* scientific study seeking to prove or even explore the medical benefits of cannabis—a policy consistent with its stated aim of wiping out all marijuana use. To that end, NIDA has denied the sale of marijuana to a number of researchers, including MAPS' two FDA-approved studies, thereby setting a precedent that has had a chilling effect on medical-marijuana research nationwide.

"NIDA and the Public Health Service have done their very best to create a burdensome and exceptional review process that exists for no drug other than marijuana," Doblin observes. Unlike the 30-day timetable that the FDA must follow when it evaluates research protocols, the NIDA/PHS review process has no fixed deadline. As a result, says Doblin, "NIDA can screw things up just by doing nothing for a very long time." He should know: MAPS had to sue NIDA for unreasonable delay after receiving absolutely no response for two whole years following its initial request for 10 grams of cannabis to be used in a vaporizer study.

At the same time, however, NIDA is quick to support research into the allegedly harmful effects of marijuana. For example, Donald

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ElSohley once attempted to capitalize on medical marijuana by patenting a THC suppository. "People really don't like suppositories," he later admitted, "so it really didn't make it on the market."

Abrams, a clinical researcher at the University of California at San Francisco, tried for many years to obtain a batch from NIDA in order to research how cannabis might help AIDS patients. But NIDA steadfastly refused to provide any—until Abrams changed the focus of his study to investigating whether marijuana was *dangerous* for people with AIDS. At that point, NIDA not only supplied the research cannabis, but also gave him $1 million in funding.

Seeing the writing on the wall, Doblin and MAPS decided to try an end run around NIDA in 2001 by supporting the creation of an independent marijuana-production facility overseen by Lyle Craker, the director of the Medicinal Plant Program at the University of Massachusetts at Amherst. "This MAPS-funded facility would break NIDA's monopoly, eliminate its lengthy and biased review process, and end the stranglehold on medical-marijuana research for the first time in more than four decades," Doblin says. With MAPS' support, Craker applied to the DEA for a license to open the new facility. The DEA ultimately denied the request in 2007, after which MAPS appealed that decision—sparking a legal conflict that continues to this day.

Meanwhile, there are four American citizens who have no trouble whatsoever getting marijuana from NIDA—in fact, a metal container of pre-rolled, taxpayer-funded joints arrives at their doctors' offices once a month, courtesy of the government's now-defunct Compassionate Investigational New Drug (IND) Program. NIDA began the program in 1978 as part of a lawsuit settlement with Robert Randall, a glaucoma sufferer who was arrested for cultivating marijuana but won his case using a "medical necessity" defense. The Compassionate IND Program was officially terminated in 1992, but a handful of patients continue to receive their regular shipments direct from the government facility at the University of Mississippi (see "Medicine Man," page 56), along with a federal license to smoke it—even in states with no laws protecting medical use.

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Unfortunately, even for those lucky few, there's one major problem. "If you speak to any of the patients who have been part of this program, you'll find that they have consistently complained about the quality of the material they're getting from the government," says Dr. Craker, whose proposed UMass facility would focus on providing medical-grade marijuana to all government-approved studies in a timely manner—a significant break from NIDA's current practices—and also produce marijuana containing significant amounts of cannabidiol (CBD). A naturally occurring molecule in the cannabis plant that modulates how THC is metabolized in the body, CBD has been shown to be of major importance in reducing anxiety and treating chronic ailments. However, NIDA's marijuana fails to provide the necessary levels of CBD.

As Doblin notes: "ElSohly claims that this is because nobody has ever asked him for it—despite the fact that researchers have been talking about CBD as an important medicinal cannabinoid for many years. We would be producing marijuana with the goal of maximizing its therapeutic potential and minimizing its risk profile, while it seems that ElSohly and NIDA grow marijuana to maximize the risk profile and minimize the therapeutic potential. The marijuana that they send out is an old, dried, low-potency product with sticks and stems; it does not in any way meet the standards that we would set."

For his part, ElSohly defends the government's current approach. "The advocates of medical marijuana, their ultimate goal is not to have this material available for investigators, but rather for patients," he argues. "They're not thinking about it in terms of who is going to be out there ready to manufacture this material as a pharmaceutical product." At the same time, few stand to lose more if a new production facility moves forward than ElSohly, who not only earns a paycheck overseeing the government's marijuana farm, but also makes a substantial personal profit selling THC for a generic version of the FDA-approved drug Marinol. ElSohly, who is convinced that pharmaceutical production and non-smoking-based delivery

GOVERNMENT-GROWN GRASS

A timeline of the National Institute on Drug Abuse's Compassionate Investigational New Drug Program.

1941

After more than 100 years of use as an herbal remedy, the American Medical Association officially removes *Cannabis sativa* from the US Pharmacopeia following passage of the Marihuana Tax Act of 1937 and the Food, Drug and Cosmetic Act of 1938.

1976

Glaucoma sufferer Robert Randall employs the obscure, common-law "doctrine of necessity" to defend himself against criminal charges of marijuana cultivation (*US v. Randall*). Federal Judge James Washington rules in favor of Randall, on the grounds that his use of marijuana constitutes a "medical necessity."

1978

As part of the settlement agreement of *Randall v. US*, the federal government creates a legal means to supply medical marijuana to individual patients, who are admitted one at a time into the Compassionate IND Program and provided a prescription for marijuana, along with a steady supply from NIDA's production facility at the University of Mississippi—previously used solely to provide marijuana for research purposes.

1992

When the FDA seeks to expand the Compassionate IND Program to include HIV/AIDS patients, along with those afflicted by neurological disorders like paralysis, multiple sclerosis and muscular dystrophy, the DEA responds by denying that marijuana has any medical utility at all. In March 1992, President George H.W. Bush responds to this standoff by killing the program. According to Robert Randall, the first Compassionate IND patient, "The FDA dumped hundreds of Compassionate IND applications into the trash, and scores of patients were arbitrarily denied promised access to medical care. Only a handful of patients—those already receiving medical marijuana—were spared."

2010

Only four of the original IND patients remain, each still receiving monthly shipments of medical cannabis from the federal government (see "Medicine Man," page 56).

Huge barrels store the end product, a ground-up mix of buds, leaves and stems that will eventually be machine rolled into joints, packaged in metal containers, and sent to the four remaining medical-marijuana patients still supplied by the federal government.

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systems are the future of medical marijuana, has also used his unique position to secure patents on marijuana suppositories and methods for creating oral THC capsules that may benefit him financially in the future.

So a great deal was at stake when the question of licensing Craker's facility came before the DEA. In February 2007—after two weeks of testimony, hearings, and hundreds of thousands of dollars in legal expenses—the DEA's administrative-law judge, Mary Ellen Bittner, issued a recommendation affirming that it would be in the public interest to grant Craker a license. According to Bittner's ruling, federal officials had repeatedly failed to act on reasonable cannabis-research requests in a timely manner or had denied them outright, creating a clear need for an additional facility.

To no one's surprise, the DEA simply ignored this non-binding recommendation from its own administrative-law judge for almost two years. Then, six days before the end of the Bush administration, Acting DEA Administrator Michele Leonhart officially rejected the recommendation and denied Craker's license. According to Doblin, the DEA justified its rejection with evidence that was not part of the lawsuit's official record, and did so in a biased and selective way. So, with the help of lawyers from the American Civil Liberties Union (ACLU), MAPS submitted a motion to reconsider, which is still pending. In the meantime—and to the dismay of many in the medical-marijuana community—the Obama administration has decided to nominate Leonhart as its DEA administrator, though she still awaits confirmation by the Senate.

But even as the government continues to dig in its heels, the will of the people has clearly moved past the debate over whether or not medical marijuana works and should be made available, with nearly 70 percent of Americans supporting medical marijuana and an increasing number of states passing laws to protect those who use cannabis with a doctor's recommendation. Still, as Doblin points out, validating medical marijuana through the FDA remains at least a 10-year process, even though chronically ill people are suffering now. "There should therefore be a combined strategy—making marijuana a medicine through the FDA, while simultaneously trying to make it available to more patients sooner through state laws."

Doblin also stresses that the most important way for people to help break NIDA's monopoly is by contacting their senators and urging them to reject Leonhart's nomination as DEA administrator unless she agrees to accept Judge Bittner's ruling and grant Craker a license. Only then can the proper research really begin, allowing us to resolve—fully, scientifically, and once and for all—whether marijuana is a safe, effective medicine.