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Critics say a handful of government agencies hobble gold-standard research with red tape and intimidation

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by [Ryan Schuette](#)

WASHINGTON — Speaking by phone, Anthony Fabrizio was on a roll about his career in cannabis research when he suddenly fell silent. You could hear the San Francisco-based research director stammering, then grunting. Silence again.

Fabrizio returned to the conversation more than 10 seconds later. He chose his next words gingerly, like someone trying to find a light switch in a dark room, placing one hand in front of the other.

“I ... just had a seizure,” he said. The research director for Terra Tech Corp., a public company based in Irvine, California, suffers absence seizures (sometimes called petit mal seizures) due to epilepsy. He credits smoking marijuana with reducing the number of seizures from about 20 a week to one every few months. Fabrizio, 27, a biochemist, has since become an [evangelist for medical marijuana](#), which is legally available in 23 states and the nation’s capital, with legislation underway [in other states](#).

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Despite the [growing momentum](#) for pot legalization, marijuana remains one of the most difficult substances to study in the United States.

Critics blame a labyrinthine federal approval process in which a handful of government agencies hobble gold-standard scientific research with red tape and intimidation and perpetuate a culture of fear and data illiteracy that delays reform.

“These are agencies in place to reflect a policy that marijuana is a prohibited Schedule I substance,” said Paul Armentano, the deputy director for the National Organization for the Reform of Marijuana Laws (NORML), a pro-legalization advocacy group based in Washington, D.C. “They are in the business of funding and approving research to reinforce that policy.”

A cornered market

The criminalization of cannabis dates back to 1971, when Richard Nixon’s administration called for a war on drugs. One year before, Congress had passed the Comprehensive Drug Abuse Prevention and Control Act, classifying marijuana as a Schedule I drug with no medical value and high abuse potential, right alongside Ecstasy and heroin.

Today a trio of federal agencies — the Drug Enforcement Administration (DEA), the National Institute on Drug Abuse (NIDA) and the Food and Drug Administration — regulate the federal marijuana research process, determining which research gets a government stamp of approval, along with research-grade cannabis.

At the federal level, researchers first need approval for their studies from the FDA and the Public Health Service, in an interdisciplinary review process. It isn’t unusual for agency review boards and applicants to engage in a back-and-forth revision process for their protocols. Critically, researchers also require a separate Schedule I license from the DEA. NIDA’s director has the final say on whether studies merit funding. Once studies are approved, the agency releases

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marijuana that it [grows under contract with the University of Mississippi](#), the site of the nation's only licensed pot farm and — [until recently](#) — the only institution with which it considered partnering.

Critics say the tightfisted multiagency approach bottlenecks marijuana research and invites poorer findings that opponents of reform then recycle into the public debate. The effect, they say, is quantity over quality.

For example, there are more than 21,000 studies available at PubMed.gov, a research database, with the words “marijuana” or “cannabis.” Only 1,674 are studies that scientists would consider more foolproof than others. According to an Al Jazeera America analysis, little more than half of these were randomized controlled trials, and more than a fourth administered placebos. Fewer than a quarter used double-blind procedures to shield the studies from bias.

The same search words turned up still fewer sources of research backed by the National Institutes of Health (NIH), with just more than 7,000 studies appearing in a [government database](#) from 1991 onward.

Armentano called the research standards a Catch-22.

“The federal government uses a very low scientific burden to assess harms associated with marijuana,” he said, adding that the agencies require that pot researchers use “the highest standards of scientific research — knowing that these regulatory and legal hurdles make doing this kind of research nearly impossible.”

Rick Doblin, the founder and executive director of the Multidisciplinary Association for Psychedelic Studies (MAPS) in Santa Cruz, California, called the regulatory reviews “repressive.” His organization was one of several that worked with lawmakers to make sure a [historic bill](#) to end medical marijuana prohibition unveiled in March included language that would roll back the oversight and make it easier for researchers to conduct cannabis studies.

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“Researching marijuana should not be more difficult than researching LSD,” he said.

For its part, NIDA is open about what its mission mandates. The agency said in an email that its purpose “has traditionally been to study the adverse effects of drugs” and explore treatment options for addiction. It also maintained that it’s “very interested” in any research innovations, including those that study the therapeutic possibilities for cannabinoids and that it provides marijuana as long as researchers have DEA and FDA approval.

NIDA defended that it’s only one of more than two dozen institutes and centers under the NIH that could back studies on marijuana and its components. According to the agency, it funded roughly \$62 million in marijuana research for the 2014 fiscal year, up from more than \$59 million the previous year. Through an agency drug program, NIDA said that it has provided marijuana to about 40 researchers since 2013.

According to the DEA, 372 researchers held Schedule I licenses as of February. About two-thirds were registered to conduct what a representative said was “bona fide research with marijuana, marijuana extracts and THC,” with some overlap. Seventeen researchers had DEA approval to test the effects of smoked marijuana on human subjects. It isn’t clear where the researchers worked or whether certain institutions employed more than others.

Armentano, Doblin and others hold that numbers like these are relatively few and that marijuana receives considerably more scrutiny than other Schedule I substances. Another criticism of theirs is that NIDA effectively cherry-picks cannabis research that favors its position at the expense of more solid studies.

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‘Un-American’ restrictions

Experts say that few researchers want to brave the approval process to conduct clinical trials on human subjects. Those who did so and succeeded in recent years typically needed the backing of prominent institutions and state legislatures.

Such was the case in California, which [passed a law](#) at the turn of the century that sanctioned clinical and preclinical trials involving cannabinoids, including smoked marijuana. The law provided roughly \$8 million to house the Center for Medicinal Cannabis Research at the University of California at San Diego.

Igor Grant, who directs the center and chairs the school’s psychiatry department, credited the state for several double-blind, placebo-controlled studies that he and other researchers eventually carried out.

Not every state is like California, however. Without funding or institutional support, “there’s a definite disincentive to do this kind of work,” he said.

Sometimes none of this is enough, as Lyle Craker learned — especially if you plan to vie with government agencies to create your own pot farm.

Craker, a professor and horticulturalist, gained notoriety when he sued for the right to grow his own research-grade weed at the University of Massachusetts at Amherst, alleging that the government’s single supplier didn’t provide enough marijuana or at the potencies needed for serious research.

He said he heard from other researchers who complained that the marijuana they were receiving “was really bad because [the federal government] wanted it to be bad.” He fought the DEA for more than a decade. Like Grant, he had friends: law firms that took on his case pro bono, support from Doblin and MAPS, backing from his administrators and even powerful political allies like Massachusetts’ then-Sens. Ted Kennedy and John Kerry, who [tried to secure its approval](#).

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Even so, the DEA overturned his application, which initially had internal administrative approval. A U.S. court of appeals later sided with government attorneys when it [rejected the bid in 2013](#).

Craker said that he was disappointed with the decision but that he felt it was clear early on that the DEA wanted to discourage his school's administrators. According to his account, visiting agents warned UMass administrators that the school's reputation could suffer if it allowed Craker to grow his own weed and provide it to other researchers.

"My suspicions were they were trying to make [marijuana research] too difficult," he said.

A DEA representative declined to respond to Craker's comments.

He isn't the only researcher to feel pressure in the limelight. As psychiatrist Sue Sisley can attest, it doesn't always come from the federal agencies either.

She grabbed headlines when she cleared most federal hurdles to conduct a placebo-controlled, triple-blind, randomized trial with smoked marijuana. The study, the first of its kind, reportedly won backing from veterans' groups with her plans to determine whether cannabis can alleviate post-traumatic stress disorder (PTSD) symptoms.

Then she got a pink slip. The University of Arizona, where she taught psychiatry and was working with authorities to secure a campus facility, fired Sisley in 2014. [According to The Daily Beast](#), she ran into opposition from state legislators and university administrators.

"We wanted PTSD veterans to smoke [marijuana] on campus," she said, referring to the opposition she received. She called her termination a gift, in retrospect, that provided her with the national platform to "talk about the barriers to marijuana research."

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As with Craker, MAPS took on her study. Colorado, which legalized recreational marijuana in 2012, [backed Sisley's study with a \\$2 million grant in December](#). She now plans to conduct her research in an independent capacity with veterans at multiple sites. Even so, she criticized NIDA for what she said was a months-long delay in responding with a price sheet that would provide her with marijuana and allow her to complete the trial.

“And yet every day that passes, we have more veterans taking their lives,” she added.

NIDA refuted her claims by email, saying that MAPS has yet to submit a complete application. The agency said that it had been “proactively working” with the organization and had recently harvested a marijuana crop specific to the PTSD study and that it planned to provide updated prices within a week.

Doblin described the research barriers as “un-American,” accusing reform opponents — a bevy of lawmakers, lobbyists and regulators — of what he said were “venal and vile motives” that politicized cannabis science.

Flawed studies

NIDA's website publishes cautionary letters to parents and teens from its director, Nora Volkow, whom it quotes [likening marijuana to tobacco](#) and [referring to “growing scientific evidence”](#) that pot use permanently decreases IQ in younger users.

That latter assertion likely builds on Duke University research that appeared in The Proceedings of the National Academy of Sciences in 2012. The position fails to account for [a critique published in the same journal six months later](#) that faulted flaws in the study's methodology and suggested the relationship between pot use and IQ “could be zero.”

Carl Hart, a professor of psychiatry at Columbia University and one of NIDA's advisers, said in an interview that Volkow “doesn't have evidence” to support

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her public statements, especially those dealing with marijuana's impact on brain health for younger users.

He isn't the only one to make that assertion. A congressman from Virginia [rebuked Volkow](#) for selectively withholding data that showed marijuana had medicinal value during testimony she gave last year.

Doblin said the misinformation shows that the agencies serve a much larger "message machine" with a clear interest in preserving the status quo. "I think there's this repressive situation, where the DEA and NIDA fear that the research into medical uses of marijuana will create a different kind of narrative," he said. "And [that this] will start causing people to change their minds about legalization."

Asked whether the current Senate medical marijuana bill would clear its hurdles and become law, Doblin said it probably would not right away, even with sister legislation expected in the House. He added that he felt change should come from the executive branch. "It's just [Barack Obama's] administration is not quite ready to end the NIDA monopoly," he said.

Other reforms may be coming quickly — from NIDA itself, with the agency set to decide whether to move its grow site beyond the University of Mississippi. With the contract with the school up this year, the agency [issued a solicitation](#) in 2014 that closed in November. NIDA said it plans to publish an award decision by the end of March.

Fabrizio said people used to approach him "vehemently" when he countered their arguments about weed. That made him frustrated too, until he learned to be more patient.

"I think people are somewhat frustrated that they were misled," he said. "Who would have thought that it would be easier to kill yourself drinking too much water and that [it's] virtually impossible to do so with cannabis?"

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