

# Lacking quality weed extract, US researchers turn to Canada

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Dr. Fatta Nahab, a neurologist who directs the Functional Imaging of Neurodegenerative Disorders Lab at the University of California San Diego Health's Movement Disorder Center, sits at his desk Monday, Sept 17, 2018, in San Diego. Nahab spent years going through regulatory hoops to get approval to import marijuana from Canada, to study whether cannabis can help treat essential tremor, a shaking condition affecting millions of people. (AP Photo/Julie Watson)

In a rare move, the U.S. government has approved the importation of marijuana extracts from Canada for a clinical trial, highlighting a new

avenue for American researchers who have long had trouble obtaining the drug for medical studies.

The University of California San Diego's Center for Medicinal Cannabis Research announced Tuesday the Drug Enforcement Administration has OK'd its plans to import capsules containing two key cannabis compounds—CBD and THC—from British Columbia-based Tilray Inc. to study their effectiveness in treating tremors that afflict millions of people, especially those over 65.

Marijuana remains illegal under federal law, making it impossible for researchers to simply obtain forms of the [drug](#) from one of the many medical [marijuana](#) programs approved by individual states—even a state with a pot culture as prevalent as California's.

Instead, federal law dictates that researchers typically must obtain any weed for [clinical trials](#) through the National Institute on Drug Abuse, which uses cannabis grown at the University of Mississippi. Scientists have long complained about the difficulty of obtaining that marijuana, as well as its limited quality, variety and usefulness for clinical research.

The University of California San Diego researchers said they needed marijuana extracts in capsule form because it's easier to monitor the doses that patients receive, compared to having patients smoke or vaporize it. They also believed many older patients would be reluctant to participate in the study if they had to inhale the drug, according to Dr. Fatta Nahab, a UCSD neurologist and the tremor study's principal investigator.

NIDA doesn't offer capsules, so the researchers spent about two years going through regulatory hoops to obtain permission to import the drug from Canada, where medical marijuana is federally legal and where recreational sales begin nationwide next month.

Paul Armentano, deputy director of the marijuana law reform organization NORML, said that illustrates how badly American researchers need alternative sources for cannabis. The House Judiciary Committee last week passed a bill to require the Justice Department to issue at least two more licenses to U.S. facilities to grow pot for research.

"It's very telling that you have researchers in the U.S. willing to exert the patience and go through the regulatory hurdles to make this happen at the same time the United States has its own domestic supply source," Armentano said.

Marijuana compounds have been imported for clinical trials before, including by Britain-based GW Pharmaceuticals, which won approval this year to sell its purified CBD capsule, Epidiolex, to treat severe forms of epilepsy—the first cannabis drug approved by the U.S. Food and Drug Administration. While GW Pharmaceuticals developed that drug in-house before bringing it to the U.S. for testing, Tilray, which recently became the first marijuana company to complete an initial public stock offering in the U.S., said it can work with researchers to develop the cannabis formulations they hope to study.

"It's a really big milestone for Tilray and also just for the whole industry," said Catherine Jacobson, Tilray's director of clinical research. "Researchers in the U.S. have really been limited to doing research using dried flower. We have been able to prove to the FDA that we can manufacture investigational study drugs containing cannabinoids that meet their standards."

Neither the Food and Drug Administration, which regulates clinical trials, nor the DEA had immediate details on how often the agencies have approved the import or use of foreign-made cannabis drugs in research, but DEA spokeswoman Katherine Pfaff said: "It is done. There

are definitely situations where, when there's no source in the U.S., a registrant can import a cannabis-derived drug from another country."

The National Institute on Drug Abuse usually provides marijuana as bulk flower or joints to be vaporized or smoked, though it also can supply cannabis oil.

NIDA intends to expand how much marijuana the University of Mississippi grows for research. The agency's contract with the university provides for the possibility of offering cannabis capsules, but it has not yet done so, said Don Stanford, assistant director of the Research Institute of Pharmaceutical Sciences at the university.

There is no drug designed to treat essential tremor, a shaking condition. Unlike Parkinson's disease, which causes shaking when someone is not moving, people with essential tremors shake when they are, making everyday activities like writing, drinking and speaking difficult. The condition afflicts 10 million people nationally and millions more across the globe, according to the International Essential Tremor Foundation.

Many patients try to control the shaking by repurposing other drugs, such as blood pressure medicine, with limited success.

Nahab said he started looking into whether marijuana could be used to treat essential tremor after two patients showed sudden improvement after smoking pot or consuming CBD purchased online.

The FDA application outlined the drug formula—a 20:1 ratio of CBD to THC, to minimize any high study participants might feel—as well as its purity, toxicity, shelf life and other details. Researchers also had to get safety approvals from the university and present their plans to a California research advisory panel.

The university hopes to have 16 to 20 patients in the study, which will begin early next year. Researchers will monitor the tremors with a device placed on the wrist and record changes in the severity of the shaking.

Tilray is providing the drug and limited financial support but said it will have no role in reviewing the study's results.

"Essential tremor is 10 times more common than Parkinson's and yet nobody really knows about [essential tremor](#)," Nahab said. "That we're finally getting to a potential therapeutic option in an area that is untapped is a big deal."

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