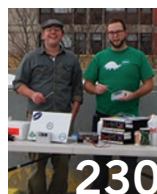




### Opening up:

Pfizer joins other companies in disclosing fees

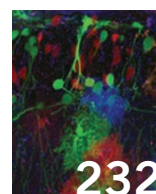
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## US drug agency blunts supply of marijuana for research

Proponents of medical marijuana are reeling after the US Drug Enforcement Agency (DEA) rejected a recommended ruling issued by the agency in 2007 and then refused to grant a license to grow marijuana for research to Lyle Craker, a plant and soil scientist at the University of Massachusetts.

The move—issued on 14 January, less than a week before the Bush administration left office—consolidates the status quo: marijuana for government-approved research is available only through the National Institute on Drug Abuse (NIDA). This creates a hurdle for studies; critics complain that research permitted by the Food and Drug Administration (FDA) can be subjected to unreasonable delays and then refused access to the NIDA marijuana. (In the UK, by comparison, companies can obtain a license from the nation's Home Office to grow marijuana for research and marketing.)

The 14 January ruling exposes a paradox: medical marijuana available in the 13 US states that allow its use comes from plant strains that have undergone clinical trials neither for efficacy nor for safety. Meanwhile, the strains of marijuana licensed by NIDA for research cannot be prescribed medicinally.

Craker says the most recent DEA ruling is an example of politics stifling science. “Rather than looking for answers that may relieve pain and suffering by researching the benefits of medical marijuana, the DEA has decided not to do the science,” he says.

Had the license been granted, Craker would have grown marijuana for groups such as the Multidisciplinary Association for Psychedelic Studies (MAPS), a small nonprofit pharmaceutical company that funds research aimed at developing controlled substances into prescription medicines.

MAPS allied with Craker to file the lawsuit against the DEA to challenge what they say is a federal monopoly that dictates the research agenda along political lines.

MAPS President Rick Doblin cites the case of Chemic Laboratories, a Massachusetts-based chemical analytics laboratory that since 2003 has been seeking to purchase ten grams of NIDA marijuana to investigate the effectiveness of the Volcano vaporizer, a device designed to



**Green with envy:** Scientists are upset that they lack alternatives to NIDA marijuana for research

extract the active ingredient from marijuana by heating rather than combusting the substance, thereby eliminating dangerous compounds associated with smoking.

“NIDA’s monopoly fundamentally obstructs FDA-approved research aimed at developing smoked or vaporized marijuana into prescription medicine,” Doblin says.

Scientists complain that the marijuana supply problems do not apply to all controlled substances. For example, in the late 1990s Ethan Russo, a neurologist and psychopharmacology researcher then at the University of Montana, tried and failed three years in a row to procure NIDA cannabis for a migraine study. He then obtained LSD for laboratory research in just two weeks through a state-approved supplier, Sigma-Aldrich.

Two years ago, DEA Administrative Law Judge Mary Ellen Bittner stated that it would be in the public interest for the DEA to issue Craker a license to grow marijuana for research studies. However, the decision was nonbinding.

Barbara Wetherell, a spokesperson for the DEA, says the denial of Craker’s application is open to appeal. She adds that the NIDA marijuana is “considered by the federal government to be good stuff and provides reliable outcomes.”

The NIDA marijuana is currently grown by Mahmoud ElSohly at the University of Mississippi, who declined to comment on the recent court ruling when contacted by *Nature*

*Medicine*. In a previous interview, ElSohly indicated that he did not think that his contract with NIDA constituted a monopoly or that another supply is required.

But others disagree. Doblin explains that research submitted to the FDA as part of a product approval should be conducted with the same drug that will be marketed. “No pharmaceutical company would spend \$10 million or more to obtain approval for a medicine and then have to purchase it from a monopolistic competitor,” he says.

With all sides firmly entrenched, medical marijuana advocates hope that the Obama administration will reverse the DEA’s decision. The DEA is poised to get a new head administrator and has accepted a 30 January motion to reconsider the decision on the Craker case.

In early February, 16 members of the US Congress sent a letter to Eric Holder, the country’s newly appointed attorney general, in support of Craker’s efforts to grow marijuana for research: “we urge you to see that the DEA acts swiftly to amend or withdraw the Final Order in this matter to permit President Obama’s new Deputy Attorney General and DEA appointees to review Prof. Craker’s application on its merits, once they are in office.”

If the 14 January decision remains unchanged, the effective date of this final ruling on the Craker case will be 1 April.

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