

Scientists stir the pot for right to grow marijuana

US scientists are waging a campaign urging the government to allow them to grow marijuana for research purposes. The US Drug Enforcement Administration (DEA), which oversees licenses to grow the plants, is mulling a landmark legal decision that could transform marijuana research in the country.

Scientists can access most illegal drugs, such as MDMA (methylenedioxymethamphetamine, or 'ecstasy') and lysergic acid diethylamide (LSD), from various accredited laboratories. But the only legal source for marijuana for medical research in the US is the National Institute on Drug Abuse (NIDA). Even after researchers have Food and Drug Administration approval for their studies and clear their work with the DEA, NIDA can refuse to supply them with the product.

This effectively allows NIDA to dictate the research agenda along political instead of scientific lines, critics charge. "The role that

NIDA plays in marijuana research is unique," says Rick Doblin, founder and president of the Multidisciplinary Association for Psychedelic Studies (MAPS), a nonprofit group that funds research on controlled substances.

Even when NIDA has come through, the quality of the product has been poor, containing stems and seeds from the plant, critics say.

In a 2007 study that used NIDA marijuana, Donald Abrams of the University of California, San Francisco, found that 14 of 18 participants preferred vaporized to smoked marijuana (*Clin. Pharmacol. Ther.* doi:10.1038/sj.cpt.6100200). "In general the NIDA marijuana, which is dehydrated and requires hydration, can be quite harsh," Abrams says. "The vaporizer smoothes that out."

Hoping to end NIDA's monopoly, Lyle Craker, professor of plant, soil and insect sciences at the University of Massachusetts Amherst, in 2004 filed a lawsuit against the DEA. His lawsuit is supported financially by MAPS, which hopes to allocate his crop to other scientists.

On 12 February, a DEA court ruled in support of Craker, who has extensive experience growing other plants for medicinal use. The agency has since filed a series of objections against the ruling, citing security concerns, likening MAPS founder Rick Doblin to the Colombian drug lord Pablo Escobar and claiming Craker's supply would contravene the UN Single Convention on Narcotic Drugs treaty, which requires governments to own stocks of cannabis. The agency declined to comment on the case.

The treaty is not viewed as problematic in the UK, where GW Pharmaceuticals cultivates

cannabis for Sativex, an under-the-tongue spray for multiple sclerosis. Mark Rogerson, press officer for the company, says countries can grant licenses for medical research within the terms of the convention.

"There are no treaty problems," adds Doblin. "The DEA is concerned about the research working out and contradicting their propaganda about marijuana."

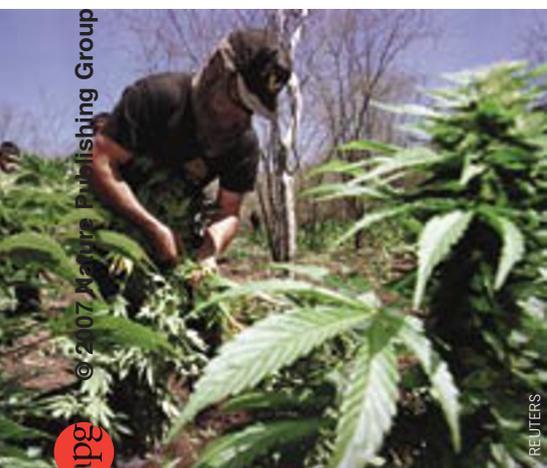
Mahmoud ElSohly, project director of the National Center for Natural Products Research, has overseen the US marijuana cultivation program for more than 25 years, and questions whether another source of marijuana is necessary. "We are fulfilling the [research community's] needs so they have no need for another contract," he says.

ElSohly says that quality issues have been addressed since the installation of a deseeding machine in 2001. "People that say the supply is not there and that the quality is not there. I can tell you categorically that is not true," he says.

ElSohly, who testified against Craker's application to grow marijuana in the lawsuit, himself holds a license to grow cannabis and extract the active ingredients—cannabinoids—for use by pharmaceutical companies. MAPS's lawyers claim this is evidence that the DEA can allow other scientists to grow marijuana without violating the treaty.

In the meantime, the DEA's deputy administrator has an undefined period to respond to the court's ruling. More than 35 members of Congress have signed a letter urging the agency to grant Craker a license.

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REUTERS

New schemes aim to boost minority participation in research

If you were to try to guess the characteristics of a clinical trial participant in the US, two safe bets would be 'white' and 'male'.

The government—and pharmaceutical giant AstraZeneca—are trying to change that sorry *status quo* by giving scientists the training and tools to boost minority participation in clinical trials.

Chronic under-representation of ethnic and racial minorities, women, the poor and the elderly in trials "is a persistent and evolving problem," says Garth Graham, deputy assistant secretary at the US Office of Minority Health.

For example, 88.8% of people enrolled in cancer clinical trials between 2003 and 2005 were white, even though African-Americans are more likely both to get cancer and to die from it than are whites. Nearly two-thirds of cancer patients are also 65 and older, but they make up less than one-third of the trial participants.

Experts point to various reasons for the low participation of minorities in clinical trials. These groups may not know about the trials or may not be invited to enroll, for example. In the case of the elderly, they may be ill with

other conditions or may be taking other drugs that make them ineligible for the trials. Some groups may also mistrust the medical system, and cultural, language and financial barriers may prevent them from signing up.

In May the Office of Minority Health, along with the Office on Women's Health and Baylor College of Medicine, launched two projects to accelerate recruitment of minorities.

The Culturally and Linguistically Appropriate Standards and Clinical Trials (CLAS-ACT) project will develop guidelines to help researchers design trials and recruit minorities. The second project, BackPack, aims to identify successful strategies in existing programs. Both expect to deliver new recommendations by April 2008.

"We're working to create a central resource," says Graham. "This is a new and important push that we hope will have a domino effect."

Once before, in 1993, the US Congress passed the National Institutes of Health Revitalization Act, which mandated that women and minorities be included in all clinical trials funded by the agency. The guidelines developed to comply with the law went into effect in September 1994 and require