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The DEA Is Getting Past Just Saying No: Scientific Research Into Medical Uses of Marijuana Is a Bridge Toward a Policy Shift

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The U.S. Drug Enforcement Agency (DEA)'s recent decision declining to reschedule cannabis is a step bridging the national discussion — a step toward a possible agreement on medical cannabis through scientific research.[1] The federal agencies are calling for more research and "work to … ensure support by the federal government for the efficient clinical research using marijuana."[2] These calls create an opportunity for research scientists in Oregon, Washington and elsewhere, as well as opportunities for universities and initiatives like the University of Washington Cannabis Law and Policy Project.[3] They are also a reminder not to squander first-mover benefits.

The Next Administration Will Likely Support Medical Marijuana Rescheduling and the Federalist Approach. Presidential candidate Clinton favors the current federalist approach allowing states to operate as the laboratories of democracy (testing new legalization policies).[4] Clinton also favors the progressive approach of easing the restrictions on researching cannabis by reclassifying cannabis from Schedule I to Schedule II. Presidential candidate Trump is reported to have similar leanings on the medical side of the equation and has sounded open to the laboratories-of-democracy approach.[5] In view of the shifting political winds, the federal agencies may generally await guidance from the next administration, with exceptions like the Food and Drug Administration's recent approval of synthetic cannabis products for AIDS and chemotherapy patients.[6] More generally,

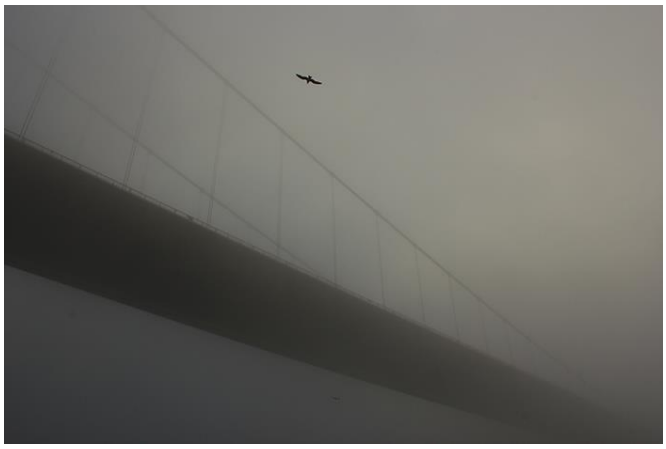
> "The FDA believes that scientifically valid research conducted under an IND [Investigational New Drug] application is the best way to determine what patients could benefit from the use of drugs derived from marijuana. The FDA supports the conduct of that research …"

[1] The Drug Enforcement Administration, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, Aug. 12, 2016, at https://www.federalregister.gov/articles/2016/08/12/2016-17954/denial-of-petition-to-initiate-proceedings-to-reschedule-marijuana.
[2] *Id.*
[3] https://www.law.washington.edu/Programs/Cannabis/default.aspx.
[4] http://www.nasdaq.com/article/clinton-or-trump-find-out-which-candidate-the-marijuana-industry-favors-cm661468.
[5] *Id.*
[6] Insys Therapeutics Announces FDA Approval of Syndros™, https://globenewswire.com/news-release/2016/07/05/853588/0/en/Insys-Therapeutics-Announces-FDA-Approval-of-Syndros.html.

the agencies apparently feel that medical research on botanical marijuana is no longer a hot-button social issue.

The DEA Is Getting Past Just Saying No. Reading the DEA's recent "Denial of Petition to Initiate Proceedings to Reschedule Marijuana" calls to mind Ury's book, "Getting Past No: Negotiating with Difficult People."[7] The book offers strategies for those who are disappointed with the DEA's decision — don't react, disarm them, change the game and make it easier to say yes and more difficult to say no. Those strategies might have softened some of the visceral reactions in the last few days. Yet, the FDA and Department of Health and Human Services (HHS) are already changing the game by opening the dialogue about medical research, getting past no on a national level.

Rescheduling cannabis from Schedule I to Schedule II requires acknowledgement from the DEA that cannabis has a currently accepted medical use in the U.S. View this piece on why rescheduling matters.



Building a National Bridge Through Medical Research. What is interesting about the announcement from the DEA is that it opens the door to future study, which may give rise to an accepted medical use of marijuana. The announcement notes that there is "no complete scientific analysis" and "scientific and medical research has not progressed" to the point of currently accepted medical use. The FDA has affirmatively stated that it supports medical research.[8] The future research may produce an accepted medical use that warrants rescheduling from Schedule I to Schedule II.

Future rescheduling could be aided by a new policy adopted by the DEA. The policy is to increase the number of entities registered to manufacture cannabis for research purposes. Since 1968 the DEA has only issued one license — to the University of Mississippi — to manufacture cannabis as part of the National Institute on Drug Abuse's (NIDA) mandate to research and study cannabis. In 2015, NIDA awarded the University roughly $69 million to grow and study cannabis. The DEA states that increasing the number of registered manufacturers should provide researchers with a "more varied and robust supply" of cannabis. The DEA's shift should be viewed as a bridge to rescheduling. The new supplies of cannabis should encourage new research and may produce the scientific and medical evidence HHS needs to support a paradigm shift on the national level. The goal should be to win over the DEA through patient, thoughtful persistence. Meanwhile, the state laboratories of democracy continue to test regulatory models.

Building Regional Benefits Through Research and Investment. The University of Washington is performing some of the research in the area. Its researchers may benefit from more federal

[7] William Ury, *Getting Past No: Negotiating With Difficult People*, Bantam Books, 1991.
[8] FDA and Marijuana: Questions and Answers, http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm

research dollars, but the state and its industry also need to step up with research dollars.[9] The same applies in Oregon. In 2015, the Oregon legislature created a task force to "research cannabis." The task force's Chair (Mowgli Holmes, PhD) recommended an "Oregon Institute for Cannabis Research." But the legislature has not created this entity and funded the recommended research, and the tax revenues has been earmarked for items other than research. That should be changed.

There are first-mover and follower advantages. The FDA's call for more research reminds the nascent industries in Alaska, Colorado, Oregon and Washington that state legalization without adequate research funding and investment undercuts first-mover advantages.

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[9] Bob Young, Local researchers may see benefits from easing of pot rules, Seattle Times, Aug. 11, 2016, http://www.seattletimes.com/seattle-news/marijuana/local-researchers-may-see-benefits-from-easing-of-pot-rules/.