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Opinions

The FDA just opened the door to transforming marijuana policy

by John Hudak June 27 at 8:08 AM

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The Food and Drug Administration did something entirely routine and completely unprecedented Monday: It approved a drug called Epidiolex.

What makes this move historic? For the first time, the agency approved a cannabis-based medicine. The FDA has previously approved a synthetic cannabis medicine, but Epidiolex is different; it is manufactured from plant matter, a chemical compound in the cannabis plant called cannabidiol, or CBD.

The approval of Epidiolex, manufactured by GW Pharmaceuticals, flies in the face of decades of political rhetoric, public policy and the legal standards underpinning cannabis prohibition. With this decision, public officials can dramatically change the manner in which the U.S. government engages with cannabis. The question remains: Will the government take this potentially transformational opportunity?

This marks the first time the FDA has admitted that cannabis has medical value, specifically to treat serious epilepsy disorders. Under 1970's Controlled Substances Act, the cannabis plant and its products have been labeled Schedule I substances, making them illegal in all circumstances. As part of that designation, Congress (not scientific or medical experts) determined that cannabis has no accepted medical use; cannot be used safely, even under medical supervision; and has high abuse potential. Approving Epidiolex directly refutes the legal basis for the absolute prohibition of cannabis in the United States.

That said, the approval of Epidiolex does not legalize medical cannabis, nor does it authorize the 30 states that have approved medical cannabis programs. In fact, it doesn't even legalize CBD. The law continues to hold the vast majority of those substances illegal (the only exception being products developed from industrial hemp, as per the 2014 farm bill).

Despite this approval — the FDA's finding that the drug is safe and effective — Epidiolex remains a Schedule I substance. Another action is still required. To bring this product to market, the FDA, in conjunction with the Justice Department, must take another historic step: rescheduling a cannabis-based compound.

Since the 1970s, federal regulators have denied rescheduling petitions for cannabis. The decision to approve this drug effectively forces their hand on rescheduling. And given GW Pharmaceuticals' assessment of the drug's abuse

potential — demonstrating it to be low — Epidiolex may be rescheduled from Schedule I to Schedule III or IV.

This historic drug approval, however, came after a long and sometimes bureaucratic road for the drugmaker. GW Pharmaceuticals is a British firm, which is fitting, given that the barriers to conducting research into the medical efficacy of cannabis are so numerous in the United States. A combination of bureaucracy and politics has meant that researchers abroad are beating U.S. researchers in studying this plant. In fact, most of the cannabis that GW uses for research is grown by a private British firm. That's not surprising, as research-grade cannabis in the United States typically leaves scientists unsatisfied.

Under our current system, cannabis used in research is typically supplied by a single domestic source: a farm at the University of Mississippi. That monopolistic control over the supply was ostensibly broken in 2016 when the Drug Enforcement Administration signaled that it was open to expanding the number of domestic producers. However, since that time and despite dozens of applications from legitimate institutions, the Justice Department under Attorney General Jeff Sessions has refused to approve a single one.

This political and bureaucratic hurdle signals something broader in American policy when it comes to cannabis: Despite the FDA's statement Monday that it will "continue to support rigorous scientific research on the potential medical uses of marijuana-derived products," other entities within the government constantly and purposefully stand in the way.

Given the expansion of state-level medical cannabis programs, the federal government should strongly encourage such research. In approving Epidiolex, the FDA has signaled to the rest of the government — specifically the DEA — that cannabis-based medicines can have medical value and can be regulated for safe medical use in this country. This moment of liberation is long overdue, and the Justice Department should see this historic step as an invitation to stop letting politics guide the department's choices on federal cannabis policy. Now is the time for the government to join the legions of medical and scientific realists who believe that cannabis has medical potential. When federal regulators stand in the way of high-quality, serious research, they are standing between patients and treatments that could improve or save lives. Epidiolex must mark the beginning of a new policy conversation that breaks down the numerous barriers facing medical cannabis research.

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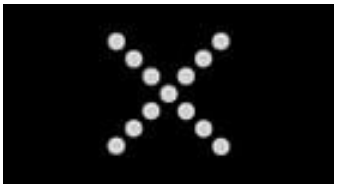

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