Should Marijuana Be Rescheduled?

By Kevin Sabet

Thanks to legalization advocates, an issue mostly confined to scholarly and legal debates -- that of the scheduling of drugs as laid out in the Controlled Substances Act (CSA) -- has recently gained prominence.

I address this at length in a recent Law Review article I wrote called "Much Ado About Nothing."

In short, the reason marijuana hasn't been rescheduled is because no product of whole, raw marijuana has a "currently accepted medical use" in the U.S., which is part of the legal definition of Schedule I defined by the Controlled Substances Act.

By contrast, Schedule II substances have a currently accepted medical use in the U.S. or a currently accepted medical use with severe restrictions (and, like Schedule I drugs, a high potential for abuse).

More importantly, regardless of the schedule, any substance may be prescribed by physicians and dispensed by pharmacists only when incorporated into specific FDA-approved products. That is why Schedule II opioid products can be obtained in pharmacies by prescription, but raw opium, despite being in Schedule II, cannot be prescribed.

This fact is sometimes articulated as follows: "Schedule II substances may be prescribed." This abbreviated description, however, is incomplete and has caused significant confusion. "An approved product comprised of a Schedule II substance may be prescribed" or even "An approved product based on ingredients found in Schedule I substances can be prescribed" would be accurate statements.

So why doesn't whole marijuana have a "currently accepted medical use"? Well, there have not been scientific studies, of adequate size and duration, showing that a product comprised of raw, whole marijuana (smoked or vaporized or otherwise ingested) has medicinal value. FDA has never approved crude plant materials as a prescription medicine, partly because there is no way to administer it in defined doses and without any toxic by-products. However, there have been studies showing that components or constituents within marijuana have medical value. This is where many people get

confused. ***That is why both statements "marijuana has no medical value" and "marijuana is a medicine" are both untrue.***

Which components within marijuana have accepted medicinal value? At least one, and maybe even more than that. Right now, a capsule, Marinol, entirely containing lab-made THC, the active ingredient in marijuana (e.g. what gets you high) is in Schedule III and widely available (though not often prescribed) at pharmacies. Marinol was approved first for nausea/vomiting from cancer chemotherapy and again during the height of the AIDS epidemic, specifically for people who could not eat (scientists have long known that THC boosts appetite). THC has also been tested (but not yet approved) as an analgesic - meaning it helps lessen severe pain (like the pain associated with cancer).

But we know that THC isn't the only interesting component in marijuana. Recently scientists have discovered that CBD (Cannabidiol) has powerful anti-seizure and other therapeutic properties. CBD does not get you high and barely exists in the modern marijuana found on the street today. Some US state-sanctioned medical dispensaries do contain expensive, specially grown strains of smoked/ingested/extracted (in an oil, for example) marijuana with very high levels of CBD (and low levels of THC - not enough to get you high). These products have not been properly tested and standardized, however.

So what about CBD as a product? Almost two-dozen countries have approved a product comprised of an extract of marijuana that mainly contains CBD and THC called Sativex. Sativex is an oral spray that does not get you high, and has been shown to have positive effects on spasticity associated with MS and severe cancer pain. Sativex is currently in late-stage Phase III trials with the FDA.
So where does that leave us? While raw marijuana does not meet criteria for a Schedule II drug, that doesn't mean we can't harness the medicinal value contained within it. We do this with several drugs today, including a drug like GHB (a powerful Schedule I drug associated with date-rape). A product called Xyrem is not Schedule I and is based on the active ingredient in GHB, prescribed for narcolepsy and loss of muscle control.

The issue of "scheduling" is distracting and essentially meaningless, since the differences between Schedules I and II are mainly technical. That is why rescheduling marijuana would mainly serve as a symbolic victory for marijuana advocates - since it would do nothing to change marijuana's non-placement in the pharmacopeia or even decrease marijuana-specific penalties for use or trafficking.

Marijuana's components have medicinal value, though, like the Institute of Medicine (IOM) concluded in the most sweeping independent review of this issue, its future as a medicine does not lie in its smoked or ingested raw form. Rather than promote a non-accountable system of "dispensaries" run by non-medical staff with ties to the underground economy and who sell marijuana to anyone with a pulse, groups like Project SAM (Smart Approaches to Marijuana) are trying to work with federal and state agencies to ensure we can study marijuana's medicinal value and develop pharmacy-obtainable medications that are safe and effective, with reliable dosage and known composition. In the meantime we could even enroll the seriously ill into research programs, as long as they understand potential risks, so they can get these promising products today (including children with uncontrollable seizures).

Don't the seriously ill deserve at least that much?