



1-1-2018

Big Pharma Takes On Marijuana Legalization: The Synthetic Marijuana vs. Botanical Marijuana Paradox

Katharine Pickle

Follow this and additional works at: <https://scholarlycommons.law.emory.edu/ecgar-perspectives>

Recommended Citation

Katharine Pickle, *Big Pharma Takes On Marijuana Legalization: The Synthetic Marijuana vs. Botanical Marijuana Paradox*, 5 Emory Corp. Governance & Accountability Rev. Perspectives 127 (2018).
Available at: <https://scholarlycommons.law.emory.edu/ecgar-perspectives/11>

This Perspective is brought to you for free and open access by the Journals at Emory Law Scholarly Commons. It has been accepted for inclusion in Emory Corporate Governance and Accountability Review Perspectives by an authorized administrator of Emory Law Scholarly Commons. For more information, please contact law-scholarly-commons@emory.edu.

BIG PHARMA TAKES ON MARIJUANA LEGALIZATION: THE SYNTHETIC MARIJUANA VS. BOTANICAL MARIJUANA PARADOX

INTRODUCTION

As legalization of marijuana spreads across the U.S., stigmas related to the drug seem to be declining. In 2016, California, Nevada, and Massachusetts passed measures legalizing marijuana for recreational use and sale; while Florida, North Dakota and Arkansas legalized the use of only medical marijuana.¹ The passage of these new laws brought the total number of states in which marijuana is legal in some form to 29; 7 states have legalized recreational use of marijuana, and 22 states have legalized only the medical use of marijuana.²

With marijuana remaining an illegal, Schedule I drug at the federal level, many legal questions and oddities surround the implications of federal law on state marijuana legalization. One point of apparent inconsistency is that while botanical marijuana continues to be highly disputed, synthetic versions of marijuana are legally produced and marketed nationwide by Big Pharma corporations.³ As the door continues to open for marijuana as a legal medical alternative, Big Pharma may be faced with a significant competitive adversary. There is some evidence to suggest that Big Pharma will respond by using its deep pockets not only to prevent legalization, but also to prevent research that would inform consumers of the beneficial effects of botanical marijuana vs. its synthetic counterpart.

I. BACKGROUND ON SYNTHETIC MARIJUANA

The term “synthetic marijuana” may call to mind illegal drugs like “K2” and “Spice,” substances that combine a variety of chemicals to try and mimic the effects of Tetrahydrocannabinol (THC), the main psychoactive ingredient

¹ David Crary, *Marijuana legalization pulls big victories on Election Night 2016*, THE CANNABIST (Nov. 9, 2016, 8:51 AM), <http://www.thecannabist.co/2016/11/09/marijuana-legalization-win-polls-election-2016/67176/>.

² *State Marijuana Laws in 2017 Map*, GOVERNING MAGAZINE, <http://www.governing.com/gov-data/state-marijuana-laws-map-medical-recreational.html> (last updated Sep 14, 2017).

³ See Nanette Porter, *Three Different Cannabinoid-Based Medicines Approved by the FDA*, MEDICAL JANE (May, 1, 2017), <https://www.medicaljane.com/2017/05/01/the-3-cannabis-based-medicines-approved-by-the-fda/>

in marijuana.⁴ These man-made drugs are illegal and commonly recognized as dangerous, and though they are referred to as “synthetic marijuana,” they are distinct substances from the synthetic marijuana products produced by Big Pharma corporations. The legal synthetic marijuana drugs produced by pharmaceutical companies actually contain THC, as opposed to a barrage of chemicals meant to copy THC; thus, these legal synthetic marijuana drugs are, in theory, more similar to the plant they seek to imitate.⁵

Synthetic marijuana began being produced by pharmaceutical companies in the U.S. in 1980, when the National Cancer Institute experimented with pills containing chemically created THC.⁶ The pills were given the generic name “dronabinol,” a term that would come to encompass other similar products engineered in the decades to come.⁷ The FDA began regulating the first legal synthetic marijuana drug in 1985, with the release of brand-name Marinol.⁸ Marinol was originally designated as a Schedule II drug available to cancer patients suffering the detrimental side effects of chemotherapy, but in 1999 was downgraded to a Schedule III drug, thus increasing its availability.⁹

Marinol is used to treat the same symptoms as medical marijuana, and is prescribed to patients who would be otherwise eligible for a medical marijuana recommendation.¹⁰ Since the release of Marinol over 30 years ago, several other synthetic marijuana drugs have come on the market. Some incorporate cannabinoids other than THC that are also found in marijuana, like cannabidiol (CBD).¹¹ Examples include Sativex, a mouth spray containing THC and CBD, and Cesamet (generically “nabilone”), containing CBD.¹² It seems paradoxical that drugs like these, which contain elements of marijuana and serve the same purported purpose, are designated as Schedule II and III while botanical marijuana remains Schedule I.

⁴ Andrea Real, *What Is Synthetic Marijuana And How Does It Compare To Traditional Marijuana*, HUFFINGTON POST (Sept. 9, 2013, 5:40 PM), http://www.huffingtonpost.com/2013/09/11/synthetic-marijuana_n_3908171.html.

⁵ See Andrew Renehan, *Clearing the Haze Surrounding State Medical Marijuana Laws: A Preemption Analysis and Proposed Solutions*, 14 HOUS. J. HEALTH L. & POL’Y 299, 306.

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.* at 307.

¹⁰ *Id.*

¹¹ *10 Pharmaceutical Drugs Based on Cannabis* (Nov. 27, 2013, 10:44 AM), <https://medicalmarijuana.procon.org/view.resource.php?resourceID=000883>.

¹² *Id.*

Most recently, the drug Syndros became commercially available in the U.S., as a Schedule II substance.¹³ Syndros is a THC dronabinol substance like Marinol, except that it is marketed in liquid form rather than a pill.¹⁴ The drama surrounding the approval and release of Syndros raises questions about Big Pharma's role and motivations in a burgeoning legal marijuana industry.

II. BIG PHARMA THREATENED: INSYS, SYNDROS, AND THE 2016 ELECTION

Syndros' release is notable because of the drug's connection to lobbying efforts during the 2016 election. The synthetic marijuana compound is marketed by Insys Therapeutics, a pharmaceutical company that also recently made headlines when it faced multiple investigations into its sale of a dangerous opioid spray.¹⁵ Insys is based in Arizona, and was heavily involved in the state's last election—Insys donated \$500,000 to Arizonians for Responsible Drug Policy, an organization opposing a ballot measure that would have legalized recreational marijuana use in the state.¹⁶ Insys' donation accounted for 10% of all donations received by the organization.¹⁷ What's more, the donation was one of the largest individual contributions to an anti-legalization campaign in history.¹⁸ The effect of this considerable donation is clear: Arizona's marijuana legalization measure was the only one of its kind to fail at the polls in 2016.¹⁹

This sizable contribution aroused suspicions about Insys' possible ulterior motives, particularly when in March 2017, it was announced that the DEA had approved the production of Syndros, a synthetic formulation of THC that would be used to treat the same symptoms as traditional marijuana.²⁰ Those supporting legalization speculated that Insys was attempting "to kill a non-

¹³ Douglas W. House, *Insys launches Syndros in U.S.*, SEEKING ALPHA (Jul. 31, 2017, 11:30 AM), <https://seekingalpha.com/news/3283371-insys-launches-syndros-u-s>

¹⁴ *Id.*

¹⁵ Ken Alltucker, *Former executives of Chandler company face investigations over opioid spray, patient deaths*, AZ CENTRAL (Jun. 23, 2017, 9:29 PM), <http://www.azcentral.com/story/money/business/health/2017/06/24/legal-troubles-chandler-insys-opioid-fentanyl-deaths-doctor-bribes-accusations/416645001/>.

¹⁶ Christopher Ingraham, *A pharma company that spent \$500,000 trying to keep pot illegal just got DEA approval for synthetic marijuana*, WASHINGTON POST (Mar. 24, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/03/24/a-pharma-company-that-spent-500000-trying-to-keep-pot-illegal-just-got-dea-approval-for-synthetic-marijuana/?utm_term=.f174164d0f02.

¹⁷ *Id.*

¹⁸ Ricardo Baca, *Marijuana's Biggest Enemy Is Not Jeff Sessions- It's Big Pharma*, ESQUIRE (Mar. 29, 2017), <http://www.esquire.com/lifestyle/health/a54160/big-pharma-against-legal-weed/>.

¹⁹ *Id.*

²⁰ Ingraham, *supra* note 16.

pharmaceutical market for marijuana in order to line their own pockets.”²¹ It is undoubtedly ironic that a company which said it “firmly believes in the clinical benefits of cannabinoids” would so vigorously campaign against the cannabinoid rich plant on which its synthetic version is directly based.²²

III. SYNTHETIC MARIJUANA VS. BOTANICAL MARIJUANA—WHICH IS BETTER FOR PATIENTS?

Comments by Insys spokesmen imply that Syndros, and other synthetic marijuana products, are in some way superior to traditional marijuana, in the categories of both effectiveness and safety.²³ Though research on the effects of botanical marijuana is somewhat sparse, evidence does seem to indicate that the plant is as good as, if not better than, its synthetic counterparts.²⁴

The main distinction is that while synthetic marijuana drugs marketed by pharmaceutical companies isolate one cannabinoid, like THC or CBD, botanical marijuana contains over 525 known components that the plant’s proponents argue have a cumulative effect that cannot be achieved by THC or CBD alone.²⁵ The effectiveness of traditional marijuana depends on its specific strain, maturity, and several other variables, and many believe that synthetic marijuana cannot accurately copy it.²⁶ Additionally, many patients are unsatisfied with the effects of synthetic products, like Marinol.²⁷ 45% of patients who were prescribed Marinol reported negative side effects, and stopped using the drug after completing only one round of the prescription.²⁸

Also potentially significant is the difference in ingestion. Synthetic marijuana is in pill or liquid form while botanical marijuana is traditionally smoked for maximum effectiveness. Though smoking has its naysayers, there is some evidence that smoking marijuana might be superior to consuming it.²⁹ Smoking’s main advantage is that patients are in complete control of the amount of THC they are inhaling, and can take in as little or as much as they

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ See Moira Gibbons, *The Cannabis Conundrum: Medication v. Regulation*, 24 HEALTH LAW 1 (2011).

²⁵ Elena Quattrone, *The “Catch-22” of Marijuana Legalization*, 22 B.U. J. SCI. & TECH. L. 299, 303-04

²⁶ William Vertes & Sarah Barbantini, *Caught in the Crossfire: The Dilemma of Marijuana “Medicalization” for Health Care Providers*, 58 WAYNE L. REV. 103, 114 (2012).

²⁷ Debra Borchardt, *Cannabis Drug Marinol To Get Reboot In Chewing Gum*, FORBES (Mar. 28, 2017, 9:00 AM), <https://www.forbes.com/sites/debraborchardt/2017/03/28/cannabis-drug-marinol-to-get-reboot-in-chewing-gum/#57f551326029>.

²⁸ *Id.*

²⁹ Nathan Seppa, *Not Just a High*, SCIENCE NEWS, Vol. 177 No. 13, Jun. 19, 2010, at 17.

want.³⁰ In contrast, with pills, patients must take a set amount of THC that may not be fully necessary to relieve their symptoms.³¹ Some researchers also believe that smoking marijuana is more therapeutic overall, and better relieves the symptoms for which medical marijuana is prescribed.³² Conflicting studies exist on this subject, but not very many modern studies have been conducted.³³

Botanical marijuana is also, generally, cheaper than synthetic marijuana. Drugs like Marinol are sold for \$18 per 5 mg capsule, the equivalent of \$3,600 per gram.³⁴ In contrast, botanical marijuana can be obtained for \$15 a gram, though potency and price of the plant can vary.³⁵ For patients without insurance, legal botanical marijuana provides an affordable option to relieve their symptoms.³⁶

The problem is that the true effects of botanical marijuana are not well-researched, since it remains a Schedule I drug at the federal level.³⁷ Researchers must get the approval of 4 federal agencies before conducting research, and can only experiment with “research-grade” marijuana, which does not necessarily have the same beneficial effects as other available strains.³⁸ The lack of concrete medical evidence on botanical marijuana’s benefits makes it easier for Big Pharma companies to argue that their synthetic marijuana products are better and safer for patients, despite plausible theories to the contrary.

Lobbying efforts like those of Insys in Arizona work to prevent the possibility of botanical marijuana being downgraded from a Schedule I substance, and thus prevent the possibility of further research into the plant’s effectiveness. By the same token, Insys and similar companies do not have to show that synthetic marijuana is actually more effective than botanical marijuana at treating the same symptoms because there is a lack of evidence that says otherwise. With their significant resources and virtual monopoly on accepted research, pharmaceutical companies could make it nearly impossible for consumers to realize the potential benefits of botanical marijuana, let alone have the choice to legally obtain it.

³⁰ *Id.*

³¹ *Id.*

³² *Marijuana Research*, SCIENTIFIC AMERICAN, Vol. 291 No. 6, Dec. 2004, at 8.

³³ Gibbons, *supra* note 23, at 4.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Marijuana Research*, *supra* note 31, at 8.

³⁸ Quattrone, *supra* note 24, at 315.

IV. BIG PHARMA'S EFFECT ON MARIJUANA'S FUTURE

The actions of Insys in the 2016 election suggest that Big Pharma companies have an incentive to fight hard for their piece of an industry which is gaining public acceptance. Insys is a relatively small company compared to other Big Pharma giants, but it nonetheless showed significant political influence, which raises questions about the potential influence of larger companies that also produce synthetic marijuana products, like GW Pharmaceuticals.³⁹ Though companies claim good intentions in campaigning against a potentially dangerous substance, what corporations like Insys are really doing is restricting what could be a cheaper and more effective treatment for their consumers' medical conditions. Big Pharma companies want botanical marijuana to remain illegal because it is financially beneficial to them, not because synthetic marijuana is decidedly better for patients.⁴⁰

Big Pharma will have to be careful in drawing a line between its synthetic marijuana products and the botanical alternative—otherwise, Big Pharma companies could end up contributing to the declassification of the plant by proving the medical benefits of its elements.⁴¹ The paradox may only extend so far until it becomes clear that synthetic marijuana is substantially similar to botanical marijuana, but perhaps not as useful or cost-effective. Though Big Pharma corporations could launch into botanical production were marijuana legal nationwide, this is not the best outcome for pharmaceutical companies because anyone with a dirt patch in their backyard could theoretically compete. If Big Pharma companies like Insys are going to continue to lobby against marijuana legalization, they should have to prove that their products are actually better and safer, not just legal because of a loophole.

KATHARINE PICKLE*

³⁹ See *Insys Therapeutics' Undervalued Cannabis Pipeline*, SEEKING ALPHA (Jun. 14, 2017), <https://seekingalpha.com/article/4081423-insys-therapeutics-undervalued-cannabis-pipeline> (discussing Insys' current valuation as compared to GW Pharmaceuticals [with their synthetic marijuana drug Sativex], and how Syndros might increase the company's market cap)

⁴⁰ Andre Bourque, *Is Big Pharma for or Against Legalizing Medical Marijuana? Maybe Both.*, ENTREPRENEUR (Aug. 8, 2017), <https://www.entrepreneur.com/article/297984>.

⁴¹ *Id.*

* Katharine Pickle is a second-year student at Emory University School of Law. Katie is originally from San Diego, CA, and received her Bachelor's Degree from the University of Virginia. She is in the transactional law certificate program at Emory, and currently interns remotely for a general practice firm in Birmingham.