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SCOTTSDALE RESEARCH INSTITUTE, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA
TUCSON DIVISION

SCOTTSDALE RESEARCH INSTITUTE LLC, Plaintiff, v. UNITED STATES DRUG ENFORCEMENT ADMINISTRATION and UNITED STATES DEPARTMENT OF JUSTICE. Defendants.	Case No. ___ **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

1. The Freedom of Information Act ("FOIA") prevents federal agencies from developing "secret law." The public has a right to know what government is doing and how it interprets and applies the law. These protections are especially critical when it comes to public health and safety.

2. On August 12, 2016, the Drug Enforcement Administration ("DEA") reversed a longstanding agency policy related to medical marijuana research. Prior to the August 2016 announcement, DEA had determined that an exclusive supply arrangement with a single marijuana supplier was the best way to fulfill our nation's obligations under an international treaty. The treaty, the Single Convention on Narcotic Drugs of 1961 ("Single Convention"), limits the manufacture and distribution of marijuana for medical or research purposes. In turn, the Controlled Substance Act ("CSA") permits the Attorney General to register applicants to manufacture marijuana only if registration would be "consistent with the public interest and with United States obligations under international treaties."

3. The August 2016 announcement reversing this longstanding policy followed an untenable situation in this country: While scores of Americans use medical marijuana and dozens of states have laws providing for medical marijuana, the federal government insists marijuana has "no currently accepted medical use in treatment in the United States" because the data supporting marijuana's clinical safety and efficacy remains thin. The main culprit is supply. The marijuana required to be used for federally sanctioned research is provided by a single supplier under an exclusive contract with the National Institute for Drug Abuse ("NIDA"). And it is junk, ill-suited for clinical trials, and genetically closer to hemp than the marijuana available from dispensaries and used by Americans nationwide. This marijuana sabotages clinical research and makes it impossible to do rigorous clinical trials with medical marijuana in the United States.

4. Better supply is needed for better research, and better research is needed not only because millions use medical marijuana every day, but also to facilitate informed policymaking at the federal and state levels, including legislation and drug scheduling decisions. At bottom, DEA's August 2016 announcement simply recognized what ought to be beyond dispute: good medical marijuana science isn't generated by sub-par weed.

5. Reflecting a commitment to science and improving the marijuana supply, DEA's 2016 announcement unveiled the "Growers Program." DEA indicated it would increase the number of registered marijuana growers who supply U.S. researchers. The announcement, posted in the Federal Register, explained how the new program would comply with the Single Convention: "DEA believes it would be consistent with the purposes of articles 23 and 28 of the Single Convention for DEA to register marijuana growers outside of the NIDA-contract system to supply researchers, provided the growers agree that they may only distribute marijuana with prior, written approval from DEA."[1]

6. But for three years, the Trump Administration deliberately blocked the Growers Program from moving forward. Relying on an undisclosed and spurious reinterpretation of federal law and United States international treaty obligations by the Department of Justice's Office of Legal Counsel, Defendants appear to contend that implementing the August 2016 Growers Program would violate the Single Convention and federal law, directly contradicting what DEA had announced in the Federal Register just three years earlier.[2] Defendants changed the law on a hotly contested issue of immense public importance—in secret.

7. After years of delay, last Friday morning on March 20, 2020, in the middle of a national health crisis, DEA filed a fifty-two-page document for public inspection noticing the public of DEA's proposed rules to govern the cultivation of marijuana in the United States.[3] The proposed rules were published in the Federal Register two days ago.[4] According to DEA, "[a]fter the publication of the 2016 policy statement, DOJ advised DEA that it must adjust its policies and practices to ensure compliance with the CSA, including the CSA's requirement that registrations be consistent with the Single

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[1] Ex. 1 (81 Fed. Reg. 53,846).

[2] *Contra Citizens for Responsibility & Ethics in Washington v. U.S. Dep't of Justice*, 922 F.3d 480, 483-84 (D.C. Cir. 2019) (OLC's "formal written opinions"—a "particularly important form of controlling legal advice"—are "presumpt[ively]" made public, thereby educating the nation "on some of the weightiest matters in our public life." (quotation marks omitted)).

[3] Ex. 30 (public inspection document for Notice of Proposed Rulemaking).

[4] Ex. 31 (85 Fed. Reg. 16,292).

Convention." The notice then explains how the proposed rules would be consistent with Articles 23 and 28 of the Single Convention.

8. If adopted, these proposed rules would radically overhaul how medical marijuana manufacture and research will proceed in this country.

9. Plaintiff, as a non-commercial company dedicated to advancing the state of medical care through clinical research, is directly harmed by this unlawful secrecy. Because Defendants have failed to fully disclose their re-interpretation of federal law and treaty obligations as the law requires, Plaintiff lacks information necessary to protect its legal rights, including the right to have its application to manufacture marijuana for research processed in compliance with the Administrative Procedure Act and the CSA. Plaintiff suffers other informational injuries as well, such as the ability to fully and meaningfully participate in the notice-and-comment process, which ends on May 22, 2020.[5]

10. While DEA's unlawful and dilatory conduct harms the public generally, the secrecy and delay have been especially harmful to our nations' veterans. Nearly sixty percent of Americans support broad legalization of marijuana, more than ninety percent support medical use, and many rely on medical marijuana where pharmaceuticals have fallen short. Medical marijuana use is particularly prevalent among veterans who struggle with treatment-resistant post-traumatic-stress-disorder ("PTSD") at far higher rates than the rest of the public. We deserve not only to know the scientific truth about medical marijuana use, but candor from our government, which includes disclosure of the "secret law" the agency continues to rely on as a basis to delay and ultimately revamp the process for researching and manufacturing marijuana in this country.

11. Plaintiff brings this FOIA action so can understand the legal basis—if there is one—for the government's conduct surrounding the Growers Program.

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[5] The notice-and-comment process requires federal agencies to issue a notice of proposed rulemaking and allow interested parties an opportunity to comment. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96, (2015). The agency must then consider and respond to significant comments. *Id.* The primary purpose of the APA's notice-and-comment procedures is to give interested parties the opportunity to meaningfully participate in rulemaking and to ensure that the federal agency has before it all relevant information. *Nat. Res. Def. Council v. E.P.A.*, 643 F.3d 311, 321 (D.C. Cir. 2011).

PARTIES

A. Plaintiff Scottsdale Research Institute ("SRI")

12. Plaintiff Scottsdale Research Institute, a non-commercial Arizona limited liability company and clinical trials site located at 5436 E Tapekim Rd., Cave Creek, AZ 85331, is dedicated to advancing the state of medical care through clinical research. Its mission is to conduct high quality, controlled scientific studies to ascertain the general medical safety and efficacy of plant products, including marijuana, to treat pain and PTSD as well as for potential substitution of opioid dependence. Its clinical research is largely funded by grants. To date, it is the only entity federally approved to do clinical research into the effects of marijuana on veterans with treatment-resistant PTSD. SRI does not encourage or sanction recreational marijuana use, but it does support research to determine the applicability of marijuana as medicine.

13. SRI also has a nonprofit 501(c)(3) arm, the SRI Field to Healed Foundation, which shares in its mission and is also dedicated to raising awareness on the difficulties of medical marijuana research in this country.

14. SRI is run by Dr. Sue Sisley. A licensed physician in Arizona, Dr. Sisley has been treating veterans with PTSD in her private practice for over a decade. Dr. Sisley has received many honors and awards for her work, both in private practice and in research. In 2001, for example, she won the UA's Leo B. Hart Humanitarian Award from the University of Arizona College of Medicine. She also received the Arizona Medical Association's highest honor, the President's Distinguished Service Award. Dr. Sisley has received significant support from patient rights organizations and veteran groups around the country, including national veterans organizations. As part of SRI's mission, Dr. Sisley travels across the country and internationally, educating the public on the difficulties of doing medical marijuana research in the United States.

B. Defendant United States Department of Justice ("DOJ")

15. DOJ is an agency of the United States government with control of the records and information Plaintiff seeks.

C. Defendant United States Drug Enforcement Administration ("DEA")

16. DEA is an agency of the United States government with control of the records and information Plaintiff seeks.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

18. Venue is proper under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e). SRI's principal place of business is in the District of Arizona.

FACTUAL BACKGROUND

A. The Controlled Substances Act and the NIDA Monopoly.

19. Scores of Americans use medical marijuana, but our federal government says it has "no currently accepted medical use in treatment in the United States." The contradiction stems from an uncomfortable truth: despite a booming billion-dollar medical marijuana industry, the clinical data supporting the safety and efficacy of medical marijuana is quite thin.

20. The dearth of clinical evidence has a lot to do with legal restrictions and supply. All persons who seek to manufacture or distribute marijuana must register with DEA under the Controlled Substances Act. Because marijuana is a Schedule I substance with "no currently accepted medical use," DEA will grant a registration to grow marijuana only if it is consistent with (1) the public interest and (2) U.S. obligations under the Single Convention on Narcotic Drugs, 1961. 21 U.S.C. § 823(a).

21. For nearly fifty years, the federal government determined that an exclusive arrangement with a single supplier was the best way to fulfill its obligations under the Single Convention. According to DEA, because the demand for research-grade marijuana was relatively limited, one supplier could meet research demands, including demands for clinical research. That sole supplier is the University of Mississippi. So, for the past fifty years, all medical marijuana used in clinical or other types of federally sanctioned research has come from a single farm located at the University of Mississippi operating under an exclusive contract with NIDA. This is the "NIDA Monopoly."

22. The marijuana sent to researchers from the University of Mississippi is junk and sabotages legitimate clinical studies. It looks more like green talcum powder than marijuana:[6]

Samples SRI received had extraneous plant material like sticks and seeds, and many had mold:[7]

A recent manuscript reveals that the marijuana supplied by the University of Mississippi isn't even real medical marijuana: it is genetically closer to *hemp* than the medical marijuana sold at dispensaries nationwide.[8] Little wonder clinical evidence to support the safety and efficacy of medical marijuana use is thin.

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[6] C. Hellerman, "Scientists say the government's only pot farm has moldy samples— and no federal testing standards," PBS (Mar. 8, 2017) (https://www.pbs.org/newshour/nation/scientists-saygovernments-pot-farm-moldy-samples-no-guidelines).

[7] Ex. 2 (Lab Report); See C. Ingraham and T. Chappell, "Government marijuana looks nothing like the real stuff. See for yourself," Washington Post (Mar. 13, 2017) (https://www.washingtonpost.com/news/wonk/wp/2017/03/13/government-marijuana-looks-nothinglike-the-real-stuff-see-for-yourself/?utm_term=.2dcae33401d3/).

[8] Ex. 3, A. Schwabe et al., "Research grade marijuana supplied by the National Institute on Drug Abuse is genetically divergent from commercially available *Cannabis*," bioRxiv preprint (Mar. 28, 2019).

B. SRI's Mission to Study the Safety and Efficacy of Medical Marijuana.

23. This country has an alarming veteran suicide problem. Research from the United States Department of Veterans Affairs shows that nationwide, about 20 veterans a day die by suicide. Between 2007 and 2017, the rate of suicide among veterans jumped ***almost 50 percent***.[9]

24. President Trump himself has acknowledged the emergency. On March 6, 2019, he signed an executive order titled "National Initiative to Empower Veterans and End Veterans Suicide." The order declared, "It is the policy of the United States to end veteran suicide through the development of a comprehensive plan to empower veterans and end suicide through coordinated suicide prevention efforts, prioritized research activities, and strengthened collaboration across the public and private sectors." At the signing ceremony, President Trump called the veteran suicide epidemic "one of the nation's heartbreaking tragedies," a "tragedy of staggering proportion," a "solemn crisis" that requires "urgent national action." He said: "To every veteran I want you to know that you have an entire nation of more than 300 million people behind you, you will never ever be forgotten."[10]

25. Dr. Sisley noticed the issue more than a decade ago. In her private practice, veteran clients returning from the wars in Iraq and Afghanistan reported symptoms of intractable PTSD. PTSD is a mental health condition experienced by some who go through traumatic events particularly prevalent among veterans. Symptoms vary from individual to individual. Common symptoms include anxiety, insomnia, depression, and nightmares. Some turn to suicide. Current pharmaceutical remedies for PTSD are limited. Only two anti-depressants, sertraline (Zoloft) and paroxetine (Paxil), are approved by the Food and Drug Administration ("FDA") to treat PTSD, and they do not always work. Dr. Sisley discovered that many of her veteran clients did not respond to conventional pharmaceuticals, and that

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[9] *See* L. Shane, "New veteran suicide numbers raise concerns among experts hoping for positive news," Military Times (Oct. 9, 2019) (https://www.militarytimes.com/news/pentagon-congress/2019/10/09/new-veteran-suicide-numbers-raise-concerns-among-experts-hoping-for-positive-news/).

[10] *See* A. Mallin, "President Donald Trump orders creation of new task force to prevent veteran suicide," ABC News (Mar. 5, 2019) (https://abcnews.go.com/Politics/president-trump-creating-task-force-prevent-veteran-suicides/story?id=61481048).

for some, marijuana worked better. In many cases, marijuana was the only drug that helped insomnia and eased depression/anxiety.

26. This observation made more than ten years ago is now a common consensus borne out by troves of anecdotal and survey evidence showing widespread reliance and interest in medical marijuana in this country. For example, a 2019 Member Survey from the Iraq and Afghanistan Veterans of America ("IAVA") shows that 20% of its members use medical marijuana or other cannabinoid products as medicine; 75% would be "very interested" in using medical marijuana; over 80% support legalizing medical cannabis; and nearly 90% support researching medical marijuana for medical purposes.[11] A 2017 survey from the American Legion reported similar findings.[12] Of course, non-veterans rely on medical marijuana as well. One in eight respondents identified at least one cancer-related symptom for which they were using cannabis to treat.[13] An article from the American Cancer Society journal puts the number at one in four.[14] It is beyond dispute that medical marijuana shows enormous promise, and yet, the *clinical* research is still remarkably thin.

27. It was this absence of robust scientific evidence coupled with Dr. Sisley's experiences in her private practice that inspired her ten years ago to attempt to collect robust clinical data on the safety and efficacy of medical marijuana use to treat PTSD.[15] It took Dr. Sisley seven years to even get close. In 2009, she began collaborating with the Multidisciplinary Association for Psychedelic Studies ("MAPS") on a proposal for the FDA. On November 11, 2010, MAPS' clinical research team submitted the protocol to the FDA. FDA approval came in April 2011. On July 30, 2012, the protocol was submitted to the University of Arizona Institutional Review Board ("IRB"), which approved the study

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[11] Ex. 4 (IAVA 2019 Member Survey) at 46.

[12] Ex. 5 (American Legion Survey Results).

[13] Ex. 6, K. Martell et al., "Rates of cannabis use in patients with cancer," Canadian Oncology (June 2018).

[14] Ex. 7, S. Perham et al., "Cannabis Use Among Patients at a Comprehensive Cancer Center in a State With Legalized Medicinal and Recreational Use," Cancer (Nov. 15, 2007).

[15] This is discussed in more detail on CNN's "Weed 3: The Marijuana Revolution," an April 19, 2015 special report by CNN's chief medical correspondent Dr. Sanjay Gupta available at https://www.youtube.com/watch?v=d1a7k2RRJJw.

months later. After IRB approval, the proposal was sent to NIDA and the Public Health Service. After a series of rejections, these agencies approved the protocol around March 2014, which allowed the study to purchase federally legal cannabis from NIDA, the sole source of marijuana legal for use in federally regulated research. On November 2, 2015, the protocol was submitted to the DEA. As part of the approval process, the DEA inspected SRI. In April 2016, the DEA approved Dr. Sisley's Schedule I license to do research with cannabis, which is still active. That license removed the last barrier to the study.

28. In early 2019, SRI completed its Phase II clinical trials titled "Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Four Different Potencies of Smoked Marijuana in 76 Veterans with Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)."

29. The quality of the NIDA marijuana SRI had to use for its clinical trial had an adverse impact on the study results and sometimes on the study subjects. For example, Dr. Sisley noticed that bronchial irritation was a common complaint among the study subjects, a side effect that could have been mitigated if not eliminated had SRI been able to grow and use its own marijuana or simply if SRI could have used marijuana other than that provided by NIDA. The government's marijuana was not only inadequate for the Phase II trial SRI completed, but it will be inadequate for further studies, such as Phase III clinical trials or other Phase II clinical trials. The presence of sticks, stems, and seeds and significant mold problems make this drug unsuitable for clinical research in certain patient populations such as those who are immunocompromised.

C. DEA Announces the Growers Program to Approve Additional Cultivators.

30. Recognizing the serious issues caused by the single supply system—such as those experienced by SRI—on August 12, 2016, DEA enacted a new policy to support the marijuana researchers in this country. This new approach reversed longstanding agency policy that an exclusive supply arrangement with a single supplier of marijuana was the best way to fulfill our nation's obligations under federal law and international treaties.

31. The same day, DEA denied a petition to reschedule cannabis as a Schedule I substance, concluding science had yet to show safety and efficacy. But recognizing growing research demands to

prove it, DEA also committed to improving the supply of marijuana suitable for clinical research. It explained, "the available evidence is not sufficient to determine that marijuana has an accepted medical use" and that "more research is needed into marijuana's effects, including potential medical uses for marijuana and its derivatives." [16] DEA's then Administrator Chuck Rosenberg declared "[r]esearch . . . the bedrock of science," and committed to "support and promote legitimate research regarding marijuana and its constituent parts."[17] Consistent with this declaration, DEA announced a plan to increase the number of entities registered to manufacture marijuana, so that the clinical research could be done in the coming years. It explained it no longer considered the longstanding exclusive arrangement with the University of Mississippi to be the best way to satisfy our nation's obligations under the applicable international drug control treaty, and it concluded that the best way to satisfy the researcher demand was to increase the number of federally authorized marijuana growers. [18]

32. DEA reached this determination after consulting NIDA and the FDA. The new approach would both allow additional marijuana growers to apply to become registered and would comply with U.S. treaty obligations and the CSA, so long as growers agree (1) that they may only distribute marijuana with prior, written approval from DEA and (2) that a registered grower could operate independently if the grower agreed in a written memorandum of agreement with DEA that it would only distribute marijuana with prior, written approval from DEA. Persons who would be registered to grow marijuana to supply researchers were only be authorized to supply DEA-registered researchers whose protocols have been determined by the Department of Health and Human Services ("HHS") to be scientifically meritorious. DEA's August 2016 interpretation of the Single Convention also aligned with that of the Bureau of International Narcotics and Law Enforcement at the State Department, which before the announcement stated that "the Convention does not address the number of cultivation licenses that can be issued":

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[16] Ex. 8 (81 Fed. Reg. 53,767) at 53,768.

[17] *Id.*

[18] Ex. 1 (81 Fed. Reg. 53,846).

> Nothing in the text of the Single Convention, nor in the Commentary, suggests that there is a limitation on the number of licenses that can be issued, nor, on the other hand, is there a prohibition against member states imposing such a limitation. While the language is clear that a government agency (or agencies) is to exercise control over the cultivation of marijuana, this is done through the granting of licenses to cultivators.[19]

33. Shortly after DEA's August 2016 policy statement, SRI applied to manufacture cannabis to support its clinical research.

D. The Trump Administration Sidelines the Growers Program with Silence.

34. Three-and-a-half years later, the Growers Program has barely gotten off the ground. More than thirty entities submitted applications to DEA to grow marijuana for research, but to date, none has been approved or denied. And until August 2019, DEA had not even begun processing them.

35. The delay was unprecedented. DEA claims it takes "4 to 6 months" to process applications to manufacture controlled substances, and it routinely processes applications within this timeframe.[20] The CSA provides numerous concrete statutory deadlines for noticing and processing applications in terms of months, not years, especially when an application relates to clinical trials.[21] Dr. Sisley repeatedly reached out to DEA between 2016 and 2019 to check the status of SRI's application, and every time, the message was the same: no progress and no explanation.

36. This enigmatic delay with respect to an important national program drew bi-monthly requests for information from Congress starting in Spring 2018. On April 12, 2018, former Senator Hatch and Senator Harris asked for an update on applications to manufacture cannabis for research and a commitment to resolve outstanding applications by August 11, 2018.[22] On July 25, 2018, a bipartisan group of eight senators inquired about the status of the applications and requested answers by August 10.[23] On August 30, 2018, a bipartisan group of congressmen wrote to the Secretary of Veterans

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[19] Ex. 9 (Responses to Questions from Senator Gillibrand's Office).

[20] *See* Ex. 10 (April 2016 DEA Presentation) at 32.

[21] *E.g.*, 21 U.S.C. § 823(i) (prescribing periods in terms of days, not years, for decisions to be made).

[22] Ex. 11 (Apr. 12, 2018 Press Release).

[23] Ex. 12 (July 25, 2018 Ltr.).

Administration about the need to conduct "a rigorous clinical trial into the safety and efficacy of medicinal cannabis for veterans with post-traumatic stress disorder (PTSD) and chronic pain so that we can better understand the potential benefits or dangers of medicinal cannabis."[24] On August 31, 2018, another bipartisan group of congressmen urged DEA to end the delay.[25] On September 28, 2018, another bipartisan group of fifteen congressmen expressed concern over DEA's delay.[26] On March 28, 2019, Senators Schatz and Booker urged the Attorney General to move forward.[27] On April 2, 2019, another bipartisan group of six senators questioned DEA's efforts to process applications.[28] And on May 7, 2019, another bipartisan group of thirty congressmen urged the agency to do more "because the matter is of such importance."[29] All were met with silence.

37. While DEA and DOJ responded to none of these letters, across several news stories and between the lines of agency testimony in congressional hearings, the issue revealed itself: to stymie the Growers Program, the administration, using the DOJ's Office of Legal Counsel, secretly adopted an interpretation of the Single Convention and federal law contrary to the view DEA put forward in its August 2016 Policy Statement.

38. An August 2017 Washington Post article entitled "Justice Department at odds with DEA on marijuana research, MS-13" explains, DEA "needed the approval of the DOJ to continue with the program it had announced in August 2016, but that DOJ was not willing to provide it." Thus, DOJ "blocked the DEA from acting on the pending applications to grow marijuana to use in research." Shortly after the Administrator of the DEA Chuck Rosenberg resigned, when asked by the Washington Post if

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[24] Ex. 13 (Aug. 30, 2018 Ltr.).

[25] Ex. 14 (Aug. 31, 2018 Ltr.).

[26] Ex. 15 (Sept. 28, 2018 Ltr.).

[27] Ex. 16 (Mar. 28, 2019 Ltr.).

[28] Ex. 17 (Apr. 2, 2019 Ltr.).

[29] Ex. 18 (May 7, 2019 Ltr.).

he had changed his mind about his prior statements from August 2016, Rosenberg stated he stood by what he had written.[30]

39. In April 2018, Sessions explained the lack of progress in approving or denying applications, pointing the finger at the Single Convention:

> We are moving forward, and we will add—fairly soon, I believe, the paperwork and reviews will be completed, and then we will add additional suppliers of marijuana under the controlled circumstances. But, there is—a lot of people didn't know, I didn't know—a treaty—international treaty of which we are a member, that requires certain controls in that process. ***And the previous proposal violated that treaty.*** We've now gotten language I believe complies with the treaty and will allow this process to go forward.[31]

40. A September 8, 2018 Wall Street Journal article entitled "Marijuana-Research Applications Go Nowhere at Justice Department" explained that the Growers Program was blocked by an opinion from the DOJ's Office of Legal Counsel. While DEA officials believed their push to expand research complied with federal law, "the Trump administration threw the effort into doubt by asking the Justice Department's Office of Legal Counsel to review the policy's legality," and DOJ "concluded it violated a 1961 United Nations treaty that aims to curb drug trafficking." Thus, an opinion from the Office of Legal Counsel ("OLC Opinion") blocked the program.

41. On February 8, 2019, then-Acting Attorney General Whitaker offered a similar vague explanation. Responding to a question, Whitaker again alluded to DOJ's adopted interpretation of the Single Convention:

> For the 3 months that I have been the Acting Attorney General, this is an issue that I have been aware of, and I have actually tried to get the expansion and the applications out. ***We have run into a very complicated matter regarding a treaty that we are trying to work around. We have some international treaty obligations that may not allow the way the marijuana has to be handled from the research facilities to the researchers—or the grow facility to the researchers.*** So it is something that I am very aware of. It is something I am trying to push. Unfortunately, I have 6 days left in this chair at the most. I don't know if I am going to successfully get to it, but I understand the concern and know that we are trying to make it work.

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[30] *See* M. Riggs, "Jeff Sessions Just Made the Chief of the DEA Look Like a Pot Head's Hero," Reason (Sept. 27, 2017) (https://reason.com/2017/09/27/jeff-sessions-just-made-the-head-of-the/).

[31] Ex. 19 (April 25, 2018 Subcomm. Hrg.) at 28.

42. A March 2019 Vox article entitled "People are lining up to grow marijuana for research. Trump's Justice Department won't let them" noted that the problem wasn't DEA—it was DOJ. A former DEA official who worked on the research program indicated DEA was ready to move forward, but that DOJ intervened. DOJ concluded that approving more cannabis researchers could violate international anti-drug treaties, a conclusion the DEA employee called "bullshit." The article explained that this argument "seemed to give Sessions and the Justice Department *the cover they needed internally* to oppose allowing more growers for research."[32]

E. Facing Interminable Delay, SRI Files a Legal Action.

43. After thirty months of utter silence, SRI petitioned the United States Court of Appeals for the District of Columbia Circuit in June 2019 for a writ of mandamus to compel DEA to notice its application to grow cannabis for its clinical trials, which the agency had unlawfully withheld and unreasonably delayed.[33] The court ordered DEA to respond to SRI's petition by August 28, 2019.

44. On August 26, 2019, two days before the deadline to respond in the *In re: Scottsdale Research Institute LLC* action,[34] DEA, its Acting Administrator, DOJ, and the Attorney General went on record in press releases declaring progress with the program, but announcing more delay because DEA needed to promulgate new rules to "conform the program to relevant laws," i.e., the OLC Opinion interpreting Section 823(a) and the Single Convention:

> Before making decisions on these pending applications, DEA intends to propose new regulations that will govern the marijuana growers program for scientific and medical research. The new rules will help ensure DEA can evaluate the applications under the applicable legal standard and ***conform the program to relevant laws***. To ensure transparency and public participation, this process will provide applicants and the general public with an opportunity to comment on the regulations that should govern the program of growing marijuana for scientific and medical research.[35]

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[32] Ex. 20, G. Lopez, "People are lining up to grow marijuana for research. Trump's Justice Department won't let them," Vox Media (Mar. 26, 2019) (emphasis added).

[33] Ex. 21 (*In re: Scottsdale Research Institute LLC*, SRI Amended Petition). SRI incorporates allegations and statements in the petition by reference.

[34] *In re Scottsdale Research Institute LLC*, Case No. 19-1120 (D.C. Cir.).

[35] Ex. 22 (Aug. 26, 2019 Press Release) (emphasis added).

45. The next day, DEA noticed SRI's application and all the other pending applications.[36] In the notice, DEA explained that it had not even begun to review them: "in accordance with the criteria of section 823(a), DEA *anticipates evaluating the applications* and, of those applications that it finds are compliant with relevant laws, regulations, and treaties."[37] Then, it stated that "because the size of the applicant pool is unprecedented in DEA's experience, the Agency has determined that adjustments to its policies and practices with respect to the marihuana growers program are necessary to fairly evaluate the applicants under the 823(a) factors, including 823(a)(1)."[38] DEA also said it needed to promulgate new rules and supersede the 2016 policy statement—a process that will undoubtedly take significant time—because of DOJ's interpretation of the Single Convention and 823(a):

> Over the course of this policy review process, the Department of Justice has also determined that adjustments to DEA's policies and practices related to the marihuana growers program may be necessary. Accordingly, before DEA completes this evaluation and registration process, DEA intends to propose regulations in the near future that would supersede the 2016 policy statement and govern persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, consistent with applicable law.

46. DEA then responded to SRI's petition on August 28, 2019. Its Response did not dispute a single factual or legal point in SRI's Petition, for example, that DEA's delay in processing these application (SRI's in particular) puts public health at risk. Nor did it put forward any legal or factual reason for its delay. SRI's allegation that DEA and DOJ acted illegally went unrebutted. Rather than attempt to justify the delay, DEA argued that because it had published the Notice of Application the day before—the relief SRI had requested—the case was moot.[39]

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[36] Ex. 23 (84 Fed. Reg. 44,920).

[37] *Id.* (emphasis added).

[38] *See id*. As SRI pointed out in a filing in the *In re: Scottsdale Research Institute LLC* action, the reason for the unprecedented number of pending applications was the unprecedented delay. The backlog of 33 noticed-but-not-decided applications was because Defendants did not process a single application for three years.

[39] *See* Ex. 24 at 1-2 (*In re: Scottsdale Research LLC*, DEA Reply). SRI disagrees that DEA provided the relief SRI had requested.

47. The court dismissed the case six weeks later, but invited SRI to return if the agency continued to significantly delay.[40]

F. DEA Publishes the Proposed Rule and Relies on the Secret OLC Opinion.

48. In August 2019, NIDA revised its web page, directing "[q]uestions on the authority to issue additional registrations" to DEA.[41] But inquiries to DEA after its August 2019 announcement continued to be met with silence.

49. For example, on December 6, 2019, a bipartisan group of lawmakers sent a letter to DOJ requesting a policy change to allow researchers to access marijuana from state-legal dispensaries to improve studies on the plant's benefits and risk.[42] The letter requested a response in writing by December 20, 2019. To SRI's knowledge, no response was provided. On December 11, 2019, eight senators sent a letter to HHS, DEA, and Office of National Drug Control Policy, to inquire: "In light of the Drug Enforcement Administration's (DEA) most recent [August] announcement that it will issue additional marijuana manufacturing licenses for research purposes."[43] The letter requested a response by January 10, 2020. To SRI's knowledge, no response was provided.

50. On January 16, 2020, at a hearing entitled "Cannabis Policy For the New Decade," held by the Energy and Commerce Subcommittee on Health, DEA, FDA and NIDA witnesses all agreed that the current supply of cannabis for study purposes is inadequate and that researchers should have access to a wider range of marijuana products. And DEA again confirmed the reason for the delay and abandonment of the Growers Program as outlined in the 2016 policy statement was a secret DOJ interpretation of international treaty obligations adopted by DEA.[44] DEA Senior Policy Advisor Matthew Strait explained:

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[40] Ex. 25 (*In re: Scottsdale Research LLC*, Order Dismissing Case).

[41] *See* Ex. 26, "NIDA's Role in Providing Marijuana for Research," NIDA (Revised Aug. 2019) (https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research).

[42] Ex. 27 (Dec. 6, 2019 Ltr.).

[43] Ex. 28 (Dec. 11, 2019 Ltr).

[44] *See* https://youtu.be/1-DaR4QEDN8.

> Since publication of the 2016 Policy Statement, the Department of Justice has subsequently engaged in a review of the Policy Statement and the proposed changes, ***and determined*** that adjustments to DEA's policies and procedures may be necessary under applicable U.S. law to be consistent with certain treaty functions. As DEA explained in its August 2019 letter to each of the then-33 pending applicants who sought authority to grow marihuana, given that the size of the applicant pool is unprecedented in DEA's experience, the agency has determined that adjustments to its policies and practices with respect to the marihuana growers program are necessary to fairly evaluate the applicants under the factors outlined in 21 U.S.C. 823(a), including 823(a)(1), which requires that DEA "limit the … bulk manufacture of [Schedule I and II] controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research and industrial purposes."[45]

51. Finally, two days ago, on March 23, 2020, DEA published in the Federal Register a notice of proposed rulemaking entitled "Controls to Enhance the Cultivation of Marihuana for Research in the United States."[46] The notice summarizes much of the above:

- how, in 2016, DEA issued a policy statement aimed at expanding the number of manufacturers who could produce marijuana for research purposes, but that subsequent to that policy statement, DOJ "undertook a review of the CSA, including the provisions requiring consistency with obligations under international treaties such as the Single Convention, and determined that certain changes to its 2016 policy were needed";
- how, according to the Defendants, Articles 23 and 28 of the Single Convention contain certain requirements for the supervision, licensing, and distribution of marijuana; and
- that DEA proposes new rules so it can directly take physical possession of cannabis crops, and have the exclusive right to import, export, wholesale trade, and maintain stocks of non-medicinal cannabis, consistent with its legal interpretation of the Single Convention.

52. The public, including Plaintiff, have until May 22, 2020 to submit formal comments on the proposed rules to DEA.

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[45] Ex. 29 (Statement of Matthew Strait (Jan. 15, 2020)) (emphasis added).

[46] Ex. 31 (85 Fed. Reg. 16,292).

53. While the notice explains that "DOJ advised DEA that it must adjust its policies and practices to ensure compliance with the CSA, including the CSA's requirement that registrations be consistent with the Single Convention," it leaves Plaintiff and the public in the dark with respect to several critical considerations, including but not limited to: (1) what DOJ advised DEA to do; (2) which parts of DEA's proposal are supposedly necessary to bring DEA's regulations in line with the CSA's requirement that DEA regulations be consistent with the Single Convention; and (3) which parts of its proposal are supposedly necessary to bring DEA regulations in line with other CSA requirements. The answer to these questions and others presumably lies in the undisclosed OLC Opinion and related records that animated DOJ's decision to sideline the Growers Program and prompted DEA to embark on this notice-and-comment rulemaking in the first place.

54. In sum, using a secret OLC Opinion interpreting the CSA and a 1961 international treaty, DEA delayed processing applications to cultivate marijuana for research and now proposes to radically revamp federal law through rulemaking—rules which will loom large over the future of medical marijuana research, manufacture, and distribution going forward.

CLAIMS FOR RELIEF

55. Congress designed FOIA "to pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny."[47]

56. Corruption, government inefficiency, and mistrust of public institutions all flourish "unless the people are permitted to know what their government is up to."[48] Signing FOIA into law on July 1966, President Johnson declared:

> This legislation springs from one of our most essential principles: A democracy works best when the people have all the information that the security of the Nation permits. No one should be able to pull curtains of secrecy around decisions which can be revealed without injury to the public interest.[49]

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[47] *Dep't of Air Force v. Rose*, 425 U.S. 352, 361 (1976) (quot. omitted)).

[48] *Dep't of Justice v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 772-73 (1989) (quot. omitted).

[49] H.R. Rep. 104-795, 8, 1996 U.S.C.C.A.N. 3448, 3451.

57. Thus, FOIA creates "a broad right of access to 'official information'" and is particularly concerned with records that "shed[] light on an agency's performance of its statutory duties."[50] In particular, Congress crafted the affirmative disclosure portions of FOIA, 5 U.S.C. § 552(a)(1) and (2), to prevent the proliferation of "secret law" and to allow individuals "to know what their government is up to."[51]

COUNT ONE
Violation of FOIA – 5 U.S.C. § 552(a)(2)

58. Plaintiff repeats and incorporates by reference each allegation of the prior paragraphs as if fully set forth herein.

59. Defendants have violated and continue to violate 5 U.S.C. § 552(a)(2), which was established to prevent the creation of "secret law." The statute requires federal agencies to make certain agency records "available for public inspection in an electronic format" including "final opinions . . . made in the adjudication of cases," "statements of policy and interpretations which have been adopted" by DOJ and DEA that are not published in the Federal Register, as well as "instructions to staff that affect a member of the public." 5 U.S.C. § 552(a)(2)(A)-(C).

60. To block the Growers Program, DOJ formulated—through the OLC Opinion and related records—and DEA adopted an undisclosed interpretation of the Single Convention and federal law contrary to the view espoused and published by DEA in the August 2016 Policy Statement, and contrary to the view of the State Department.

61. For more than three years, Defendants relied on this undisclosed interpretation, contained in the OLC Opinion and related records, to make an end-run around the Administrative Procedure Act by unlawfully withholding and unreasonably delaying agency action on marijuana cultivation applications. The OLC Opinion has guided DEA's actions—and its inaction. Now, it relies on the same OLC Opinion and related records to propose new rules to revamp how the agency handles marijuana cultivation applications and medical marijuana more generally going forward, and apply those rules

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[50] *Reporters Comm.*, 489 U.S. at 772, 773.

[51] *See id.* at 772 n.20, 773 (emph. and quot. omitted).

retroactively to evaluate applications submitted and paid for long ago. The government's unlawful conduct under FOIA prevents Plaintiff and those similarly situated from timely and effectively vindicating legal rights under the Administrative Procedure Act, effectively rendering its protections and judicial review provisions meaningless.

62. The OLC Opinion and records interpreting 21 U.S.C. § 823(a) and the Single Convention inform DOJ's view of the law, which DEA has adopted, and therefore constitute information that must be made available pursuant to 5 U.S.C. § 552(a)(2)(A)-(C). The OLC Opinion is an opinion that was formulated during the adjudication of Plaintiff's application before the agency, it embodies the DEA's effective law and policy, and has been adopted and followed by DEA and its staff. Therefore, it must be affirmatively disclosed under FOIA regardless of whether a member of the public to file a FOIA request.

63. Despite FOIA's nondiscretionary mandate to affirmatively disclose these records to the public,[52] no records, including the OLC Opinion, are available to the public on DOJ or DEA's website or in any other electronic format.

64. Plaintiff's inability to inspect or understand Defendants' unpublished interpretation of an international treaty and federal law harms Plaintiff in several ways. Because Defendants have failed to disclose their interpretation, Plaintiff lacks information necessary to effectively protect its legal rights, including a right to have its application processed based on proper and reasonable interpretations of the law and without unreasonable delay, as well as a right not to have its application (submitted under the 2016 Growers Program) subjected to retroactive administrative rules that Plaintiff had no knowledge of at the time it crafted its application, submitted it to the agency, and paid the related fees. Defendants' undisclosed interpretation of the Single Convention and 21 U.S.C. § 823(a) is quintessential "secret law," effectively unreviewable, and because of its secrecy, deprives Plaintiff the opportunity to challenge agency action and of its right to due process of law. Plaintiff also lacks the information necessary to fully participate in the notice-and-comment process. Finally, DOJ's undisclosed interpretation of the Single

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[52] *See Animal Legal Def. Fund v. United States Dep't of Agric.*, 935 F.3d 858, 869-71 (9th Cir. 2019).

Convention and 21 U.S.C. § 823(a) directly impacts Plaintiff's chances of being approved as a manufacturer of marijuana under 21 U.S.C. § 823(a).

65. Plaintiff is entitled to a preliminary and permanent injunction directing the agency to make available records containing Defendants' interpretation of the Single Convention and 21 U.S.C. § 823(a), including the OLC Opinion, which DEA has adopted and seeks to apply retroactively to Plaintiff and others through its proposed rule.

PRAYER FOR RELIEF

For these reasons, Plaintiffs respectfully prays that the Court grant the following preliminary and permanent relief:

a. Declare that it is unlawful for Defendants to fail to make available records containing Defendants' interpretation of the Single Convention and 21 U.S.C. § 823(a), including the OLC Opinion, which have been adopted by DEA;

b. Order Defendants to make available records containing Defendants' interpretation of the Single Convention and 21 U.S.C. § 823(a), including the OLC Opinion, which have been adopted by DEA;

c. Award Plaintiffs their costs and reasonable attorneys' fees pursuant to FOIA, 5 U.S.C. § 552(a)(4)(E); and

d. Grant such other and further relief as this Court may deem just and proper.

Dated: March 25, 2020

Respectfully submitted,

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