UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

LYLE CRAKER, M.D., Plaintiff, v. WILLIAM P. BARR, U.S. ATTORNEY GENERAL, TIMOTHY J. SHEA, ACTING ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION, AND THE U.S. DRUG ENFORCEMENT ADMINISTRATION	Civil Action No. 3:20-cv-30184

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

1. Plaintiff, Dr. Lyle Craker, is seeking federal registration to cultivate marijuana to support safe and effective medical cannabis[1] research. For the past four years, the Trump Administration has flouted the Administrative Procedure Act to block Plaintiff's application.

2. The medicinal use of marijuana is a public health issue that is vital to the well-being, health, and safety of millions of Americans. More than two-thirds of States have enacted comprehensive legislation allowing injured and sick Americans to use marijuana to help treat conditions ranging from chronic pain, treatment resistant PTSD, and chemotherapy induced nausea that may not be fully or adequately addressed by medicines approved by the Food and Drug Administration ("FDA").

3. The federal government refuses to recognize medical marijuana, purportedly due to a lack of evidence showing safety and efficacy in treatment. Meanwhile, the Defendants have systematically impeded the very research claimed to be lacking.

[1] The terms "marijuana" and "cannabis" are used interchangeably throughout this Complaint.

4. Under the Controlled Substances Act ("CSA"), all persons who seek to manufacture or distribute marijuana must register with DEA. Because marijuana is a Schedule I substance, DEA can grant an application for registration to grow marijuana only if the registration 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) ("Single Convention").

5. For decades, the government had asserted that an exclusive supply arrangement with a single marijuana supplier was the best way to fulfill our nation's obligations under the Single Convention.

6. The federally sanctioned product through this government monopoly is, however, of materially poor quality. It is dissimilar in potency and formulation from cannabis products widely used by patients and other consumers, undermining the credibility and reliability of scientific research.

7. Further, the federally sponsored cannabis cannot practically be used in FDA Phase 3 research because no sponsor of such research can be assured the consistent supply required for commercial drug development and, eventually, to supply patients themselves. An FDA-approved drug marketed and provided to patients must be the exact drug that was used in the underlying Phase 3 clinical studies. Commercial drug development and supplying patients has never been, and realistically will never be, the province of the federal government. Thus, for more than half a century, clinical research with marijuana has been effectively blocked by our own federal government.

8. Two decades ago, working closely with and supported by the Multidisciplinary Association for Psychedelic Studies ("MAPS"), Dr. Craker requested DEA registration authorizing him to cultivate marijuana for his own research. In collaboration with MAPS, Dr. Craker intends to do rigorous clinical research on the development of scientifically sound

cannabis-based medications.

9. After nearly a decade of delay – and only after Plaintiff filed a lawsuit in federal court alleging unreasonable delay – DEA denied Dr. Craker's application, ruling that, among other things, his registration was precluded as a matter of law because DEA had no authority to grant registrations outside of the government monopoly.

10. Shortly after that denial, in an about-face, DEA announced it was ending the monopoly, citing many of the same reasons that Craker had asserted in support of his registration. Due to the growing public interest in exploring the possibility that marijuana could be used to develop innovative new safe and effective therapies, on August 12, 2016, the Drug Enforcement Administration announced a new policy (hereinafter referred to in this Complaint as the "2016 Policy" or "Growers Program") reversing longstanding agency policies governing the cultivation and distribution of marijuana for medical research.

11. Dr. Craker then submitted his second application for DEA registration pursuant to the newly-announced Growers Program. But to date, DEA has unreasonably and unlawfully failed to act on Dr. Craker's second application.

12. A secret opinion from the DOJ's Office of Legal Counsel ("OLC") explains why. In the early years of the Trump administration, DOJ asked OLC to review the legality of DEA's August 2016 Obama Administration policy. In a memo dated June 6, 2018, OLC concluded that DEA's proposed new policies and procedures to implement the Growers Program violated the Single Convention.

13. Nevertheless, DEA did not formally deny Dr. Craker's pending application. DOJ issued the OLC opinion secretly and withheld it from public disclosure for nearly two years, until a federal court ordered DEA to release it.

14. Almost two years later, on March 20, 2020, DEA finally proposed new, draft

rules based on the OLC memo, claiming it must have new rules in order to act on Dr. Craker's application. But DEA has not approved new rules as of the date of this filing.

15. Meanwhile, Dr. Craker is neither able to proceed with his research nor pursue his administrative appeal rights until DEA issues a ruling on his application.

16. Dr. Craker seeks a court order directing the Attorney General, DEA, or its Acting Administrator to render a decision on Plaintiff's pending application to be registered as a manufacturer of marijuana under Section 823(a) of the Controlled Substances Act ("CSA").

17. Plaintiff further seeks a declaratory judgement that DEA is required to process applications submitted prior to promulgation of its Proposed Rules under the DEA rules in effect at the time the applications were submitted.

JURISDICTION AND VENUE

18. This Court has jurisdiction over this matter under 28 U.S.C. §§ 1331 and 1361.

19. The claims arise under the Administrative Procedures Act ("APA"), 5 U.S.C. § 706(1)) and Section 823(a) of the Controlled Substances Act ("CSA"), 21 U.S.C. § 823(a)).

20. Venue in the District of Massachusetts is proper under 28 U.S.C. § 1391.

PARTIES

21. Plaintiff Dr. Lyle Craker is Professor Emeritus of Botany and Plant Sciences at University of Massachusetts, Amherst's Stockbridge School of Agriculture. He resides in this District.

22. Since 2001, Dr. Craker has been working with MAPS to initiate and fund a drug development research program aimed at proving to the satisfaction of FDA that marijuana is safe and efficacious for specific medical uses and should become a legal, FDA-approved prescription medicine. If successful, MAPS would bring marijuana medications to market under a nonprofit pharmaceutical model.

23. Defendant William P. Barr is the Attorney General of the United States.

24. Defendant Timothy J. Shea serves as Acting Administrator of the DEA.

25. The U.S. Drug Enforcement Administration is the federal agency that exercises the Attorney General's authority under the CSA to license marijuana cultivation if the Attorney General determines that it would be "consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. § 823(a).

FACTUAL BACKGROUND

26. Under federal law, manufacturers of controlled substances in Schedule I must obtain a DEA license. Sections 822(a) and 823(a) of the CSA vest authority over registration for such licenses in the Attorney General. The Attorney General has delegated this function to DEA. 21 U.S.C. § 871(a), 28 C.F.R. § 0.100(b).

27. The CSA makes drug development and clinical trials with Schedule I substances difficult, but not impossible. In 2000, for example, MAPS began putting together an FDA-style clinical trial program for MDMA, a Schedule I controlled substance. By 2016 MDMA moved into Phase 3 studies, and in 2017 the FDA designated MDMA-assisted psychotherapy for PTSD as a Breakthrough Therapy. As of October 2020, MAPS completed the first of two Phase 3 studies and is currently starting its second Phase 3 study, with potential approval for prescription use projected for the end of 2022 or early 2023.

28. While marijuana is also a Schedule I substance, a unique barrier blocks clinical research and prohibits sponsors of such research, like MAPS, from moving forward with commercial drug development: a government-run monopoly. Since its founding in 1973, DEA has licensed only one grower to supply researchers with marijuana—the National Center for Natural Products Research ("National Center"), a division of the University of Mississippi.

The National Center grows and distributes the marijuana itself under contract with, and under the supervision of, the National Institute on Drug Abuse ("NIDA"), a component of the Department of Health and Human Services' National Institutes of Health.

A. The NIDA Monopoly Harms Clinical Research

29. The quality of the marijuana available for study under this monopoly is exceptionally poor, with a potency significantly different from the marijuana available for purchase at dispensaries nationwide. It is highly processed and ground up into particles. Recent studies suggest the marijuana produced by the National Center is, in fact, genetically closer to hemp than marijuana. Recent tests have also shown this marijuana to contain unacceptable levels of mold.

30. The marijuana produced under the monopoly is also ill-suited for innovation and serious clinical research. FDA-approved drugs must be the exact same drugs that were used in the underlying Phase 3 clinical studies, which is impossible to execute under the current regime.

31. Besides overseeing the cultivation of marijuana, NIDA has played a significant role in determining which researchers may obtain marijuana for medical or scientific use.

32. Moreover, much of the information surrounding the National Center's cannabis is inaccessible to researchers. For example, neither NIDA nor FDA has made the Drug Master Files for the research marijuana publicly available. Further, the federal government requires the National Center to maintain the confidentiality of sensitive information and data provided by the government during performance of the contract and must obtain federal government approval before disclosing sensitive information. Serious commercial drug development cannot practically occur while this monopoly is in place.

B. DEA Obstructs, Delays, and Denies Dr. Craker's First Application.

33. In June 2001, Dr. Craker submitted an application to DEA to cultivate marijuana for research purposes. Several months later, DEA claimed the application could not be found. Plaintiff then submitted a photocopy of the application. DEA refused to accept those photocopies because they did not have original signatures.

34. Eventually, in an envelope without a cover letter or specific return address other than DEA headquarters, DEA returned to Plaintiff his original, date-stamped application showing it had been received shortly after Plaintiff had initially mailed it to DEA.

35. Dr. Craker mailed back to DEA this same original application, which DEA then accepted. But DEA did not respond to Plaintiff, at all, for the next three years.

36. In the interim, DEA took the position that applications like Dr. Craker's could not be granted under the CSA. For example, in a July 2002 letter, then-DEA Administrator Asa Hutchinson explained to former Representative Barney Frank that under the NIDA monopoly "the nation's sole source of research-grade marijuana has been the University of Mississippi" and that due to the CSA and Single Convention, "it is essential that this arrangement continue." Despite taking the position that research applications could not be granted by law, DEA refused to render a decision on Dr. Craker's application, thereby insulating from judicial review its stated rationale for refusing to grant the application.

37. More than three years after filing the original application, Dr. Craker filed a lawsuit in federal court alleging unreasonable delay. Shortly after Dr. Craker filed that lawsuit, DEA issued an order to show cause indicating its intention to deny the application, triggering Craker's right to administrative review under the APA, including an evidentiary hearing before a DEA-appointed administrative law judge (ALJ). After the conclusion of that February 2007 hearing, ALJ Mary Ellen Bittner issued an 80-page opinion recommending DEA grant

Plaintiff's application.

38. Almost two years later, DEA rejected ALJ Bittner's recommendation on the basis that the NIDA monopoly served satisfactorily to meet domestic research demand and was required by federal law and the Single Convention treaty. 74 Fed. Reg. 2101.

39. Plaintiff appealed the DEA's Final Order to the United States Court of Appeals for the First Circuit, which upheld the Final Order.

C. DEA Announces the 2016 Policy to Encourage and Register Additional Cultivators.

40. On May 6, 2016, the Bureau of International Narcotics and Law Enforcement at the State Department stated that the United States could issue multiple licenses for the cultivation of cannabis for medical and scientific purposes without violating the Single Convention.

41. Several months later, on August 12, 2016, DEA reversed its longstanding policy position that U.S. obligations under federal law and international treaties required DEA to ensure that only a single supplier be granted registration to manufacture marijuana

42. Recognizing the increasing research demands and public health needs – and with an ever-increasing number of states responding by legalizing medical marijuana under state laws – DEA finally committed to improving the supply of marijuana suitable for clinical research, explaining that, "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." 81 Fed. Reg. 53,767 at 53,768. DEA's then-Acting Administrator Chuck Rosenberg declared "[r]esearch is . . . the bedrock of science," and committed to "support and promote legitimate research regarding marijuana and its constituent parts." *Id.*

43. Consistent with this declaration, and after consulting NIDA and FDA, DEA

announced a plan to increase the number registrations to manufacture marijuana so that much-needed clinical research could be undertaken. 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.

44. DEA's August 2016 interpretation of the Single Convention aligned with that of the Bureau of International Narcotics and Law Enforcement at the State Department, which before DEA released the 2016 Policy had stated that "the Convention does not address the number of cultivation licenses that can be issued:

> 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.

45. The DEA announcement of the new policy, 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."

46. Shortly after DEA published its 2016 Policy, Dr. Craker submitted his second application for DEA registration to manufacture cannabis to support MAPS-sponsored clinical research and paid the application fee, relying on DEA's formal change in position.

47. In addition to Dr. Craker, more than thirty entities submitted applications to DEA to grow marijuana for research under the DEA's new policy. Until August 2019, DEA had not even begun processing them. To date, DEA has neither approved or denied any of these applications.

48. DEA is required, generally, to promptly publish in the Federal Register notice of applications filed for DEA Registration, which is a two-page filing that acknowledges receipt of the application. While DEA published many of these notices between 2016 and 2018 in regard to applications to manufacture other substances, it did not publish any notices in the Federal Register for the marijuana cultivation applications that were submitted in response to the 2016 Policy Statement. Nor did it take any other action, until more than two and a half years after accepting applications for filing.

49. The delay was—and still is—unprecedented. DEA claims it takes "4 to 6 months" to process applications to manufacture controlled substances, and it routinely processes applications within this timeframe. Dr. Craker and other applicants repeatedly contacted DEA between 2016 and 2019 to check the status of their applications. DEA's "response" was the same: no progress and no explanation.

D. The Trump Administration Secretly Shuts Down the Growers Program.

50. Unbeknownst to Dr. Craker, the other applicants, Congress, or the public, the Trump Administration secretly sabotaged the Growers Program through a secret OLC Memorandum, effectively ordering DEA not to implement the 2016 Policy. Rather than disclosing the shutdown or delays to the public or the applicants or their supporters in Congress – and rather than denying the applications for registration on the basis of the OLC Memorandum to permit judicial review – DOJ and DEA disclosed nothing and simply sat on the pending applications with no agency action or explanation.

51. What is now known from Congressional testimony and news reports, is that the DOJ, fueled by anti-marijuana bias, ordered OLC to review the legality of the DEA's 2016 policy, to deliberately block the Growers Program and impede scientific research critical to the public health of millions of Americans.

52. For example, an August 2017 Washington Post article explains that DOJ "effectively block[ed]" DEA from acting on pending applications to cultivate marijuana for research. DEA was "at odds" with the Trump administration, but DEA needed DOJ approval to move forward and DOJ was not willing to provide it. Acting DEA Administrator Chuck Rosenberg indicated in a call with reporters from the Post that he stood by DEA's August 2016 Policy Statement in favor of multiple licenses.

53. A later September 2018 Wall Street Journal article reported that DOJ, under Attorney General Sessions, was not "eager to advance the applications" and threw the Growers Program into doubt by asking DOJ's Office of Legal Counsel to review the legality of the Growers Program. In Spring 2018, DOJ lawyers had floated a new policy that included significant additional restrictions, but DEA officials found it "convoluted," that it "would strain agency resources," and would be "impossible to implement." As a result, as of September 2018, the effort was "still on hold."

54. DOJ's private opinions did not align with DEA's view. On May 8, 2018, DEA Acting Administrator Robert Patterson, a thirty year veteran of the agency, explained that DEA has been "pretty vocal about [DEA's] belief in the research towards the medicine that could come from marijuana," that the "application process that [DEA] put in August of 2016 showed [DEA was] trying to help the industry in terms of understanding where that research may go with giving additional growers," and that DEA would "absolutely" favor a comprehensive scientific health study on marijuana.

55. Less than one month after Patterson's testimony, however, DOJ's OLC transmitted the secret memo to DEA, blocking implementation of the Growers Program. The memorandum, dated June 6, 2018, is titled "Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs," signed by Henry C. Whitaker, Deputy Assistant AG, Office of Legal Counsel, and addressed to Robert C. Gleason, Acting Chief Counsel, Drug Enforcement Administration.

56. Less than two weeks after DOJ sent DEA the OLC Opinion, Patterson retired, describing running the agency as a temporary fill-in to be "increasingly challenging."

57. Rather than approve or deny any of the applications, however, DOJ and DEA continued to sit on the applications, keeping the OLC Opinion secret. DEA did not disclose the OLC Opinion until April 29, 2020, after another applicant for registration under the Growers Program, Scottsdale Research Institute, brought a lawsuit under the Freedom of Information Act (FOIA) in March 2020.

58. The OLC opinion states that under 21 U.S.C. § 823(a), the United States must enact provisions to comply with the Single Convention, which requires countries to either prohibit marijuana cultivation altogether, or if they permit cultivation, "to establish 'a single government agency' to oversee marijuana growers and generally monopolize the wholesale trade in the marijuana crop." It concludes that the arrangement with the National Center violated the Single Convention; that DEA must change its current policies and practices to comply with the Single Convention; and that "the federal government may not license the cultivation of marijuana without complying with the minimum requirements of the [Single Convention]."

59. Yet, despite the OLC Opinion's conclusion, the DEA continued to license the National Center, directly contravening the OLC Opinion, the government's basis for years of

delay. On February 7, 2019, six months after the OLC Opinion, the National Center was granted a new registration to cultivate marijuana. 84 Fed. Reg. 2578.

60. The unreasonable and unlawful delay in implementing the Growers Program and silence from the Trump Administration did not go unnoticed by Congress. Starting in Spring 2018, Congress began sending almost bi-monthly requests for information to federal agencies and government officials:

a. On April 12, 2018, former Senators Hatch and Harris asked for an update on applications to manufacture cannabis for research and a commitment to resolve outstanding applications by August 11, 2018.

b. On July 25, 2018, a bipartisan group of eight senators inquired about the status of the applications and requested answers by August 10.

c. On August 30, 2018, a bipartisan group of congressmen wrote to the Secretary of Veterans 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."

d. On August 31, 2018, another bipartisan group of congressmen urged DEA to end the delay.

e. On September 28, 2018, another bipartisan group of fifteen congressmen expressed concern over DEA's delay.

f. On March 28, 2019, Senators Schatz and Booker urged the Attorney General to move forward.

g. On April 2, 2019, another bipartisan group of six senators questioned DEA's efforts to process applications.

h. On May 7, 2019, another bipartisan group of thirty congressmen urged the agency to do more "because the matter is of such importance."

61. DEA and DOJ responded to none of these letters, and they never explained that the program had been shut down.

62. Worse, the Trump Administration made public statements as if the program was moving forward all along. For example, on April 25, 2018, weeks before the OLC Opinion, then-Attorney General Sessions testified that DOJ and DEA were "moving forward," that the paperwork and reviews will be completed "fairly soon," and that additional suppliers of marijuana will be added "under the controlled circumstances." Sessions discussed an "international treaty of which we are a member, that requires certain controls in that process. And the previous proposal violated that treaty." A year later, in February 2019, his successor testified that he thought DOJ/DEA was "mov[ing] forward on it" and "it's very important to get those additional suppliers."

E. DEA Announces New Rules to Govern Applications for Registration under the Growers Program

63. On June 11, 2019, another applicant, Scottsdale Research Institute filed a mandamus petition with the U.S. Court of Appeals for the D.C. Circuit seeking an order compelling Defendants DOJ, DEA, and Barr to act on the pending cultivation applications. The U.S. Court of Appeals for the D.C. Circuit ordered the DEA to respond by August 28, 2019.

64. On August 26, 2019, in a press release, DEA again announced it was moving forward. In reality, it was taking one step forward and two steps back. The agency did the minimum: it noticed all of the pending applications. Then – relying on the still-undisclosed OLC Opinion – stated that before making decisions on pending applications, it had to promulgate new rules before it could further process the applications.

65. DEA explained that for the three years since the 2016 Policy announcement, and to ensure that the Growers Program was consistent with applicable laws and treaties, DOJ had engaged in a "policy review process." Over the course of the "policy review process," DOJ had "determined" that adjustments to DEA's policies and practices related to the marijuana Growers Program were necessary, and that DEA intended to propose regulations that would supersede the 2016 policy statement and govern persons seeking to become registered with DEA to grow marijuana.

66. On August 27, 2019, FDA and NIH responded to a March 20, 2019 letter from Senator Schatz "strongly support[ing] the need for additional research on cannabis and its constituent compounds." The agencies identified the NIDA monopoly on cannabis cultivation as a barrier to research and note that NIDA cannabis is unsatisfactory for clinical drug development.

67. By December 2019, no new rules had been announced. And on December 6, 2019, twenty-one members of congress wrote to Attorney General Barr asking for clarification of DOJ's current and proposed policies regarding the access of research-grade cannabis, including new regulations governing Schedule I licenses to manufacture cannabis for research. Days later, 8 senators wrote to HHS Secretary Azar, DEA Acting Administrator Dhillon, and ONDCP Director Carroll requesting written guidance on how DEA will make these licenses available to qualified researchers in a timely manner.

68. In a January 2020 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. DEA again confirmed that the reason for the delay and abandonment of the Growers Program was a secret DOJ interpretation

of international treaty obligations adopted by DEA.

69. On March 20, 2020, with public and government attention increasingly consumed by the global pandemic, DEA finally unveiled its proposed new rules explicitly intended to replace and supersede DEA's 2016 Policy. The Notice of Public Rule Making ("NPRM") was 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.

70. Consistent with the OLC Opinion, the NPRM explains the five controls required by Article 23 of the Single Convention, and how DEA's proposed rules, if adopted, would ensure compliance with the Single Convention and "would supersede the 2016 policy statement." 85 Fed. Reg. 16294.

71. The NPRM provides no timelines, deadlines, or procedures for DEA to take action on currently pending applications or applications submitted after the rules are final and promulgated. There is no indication or requirement that the DEA approve or deny currently pending applications under the DEA's rules in place at the time those applications were submitted. The Proposed Rule presents no opportunity for applicants who submitted applications prior to promulgation of these new rules to amend their applications in light of the new rules. There are no procedures (other than federal court intervention to compel agency action unreasonably withheld) for applicants to compel timely agency action.

72. DEA projected that it would release Final Rules in October 2020. As of the time of this filing, those Final Rules have not been released by DEA.

COUNT I
(APA Unlawful and Unreasonable Delay – 5 U.S.C. § 706)

73. Plaintiff incorporates each of the preceding allegations by reference.

74. Plaintiff applied to cultivate marijuana for research on February 22, 2017.

75. DEA has not made a final decision on Plaintiff's application.

76. Defendants have unlawfully and unreasonably delayed making a final decision on Plaintiff's application.

77. Plaintiff is aggrieved by DEA's unlawful and unreasonable delay.

78. DEA and DOJ secretly enacted a moratorium to discontinue the processing of cultivation applications.

79. DEA and DOJ's reliance on the OLC Opinion was and is pretextual.

80. DOJ, the parent agency of DEA, acted intentionally, unlawfully, and in bad faith. Beyond the allegations disclosed above, discovery is expected to reveal more evidence of bad faith or improper behavior. Discovery is warranted in view of the demonstrable bad faith and manifestly improper behavior by Defendants and their predecessors.[2]

81. The OLC Opinion constitutes final agency action that effectively required DEA to deny Plaintiff's application under the standards in effect as of June 2018, so that Plaintiff can seek judicial review of the basis of the denial under the CSA and APA.

82. Plaintiff seeks an order compelling DEA to approve or deny Plaintiff's cultivation application.

COUNT II
(Declaratory Judgment – No Retroactive Application of New Rules)

83. Plaintiff incorporates each of the proceedings allegations by reference.

84. Plaintiff submitted his application before DEA created new rules for processing applications to cultivate marijuana for research.

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[2] *See Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2574 (2019); *e.g.*, *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212, 231 (E.D.N.Y. 2006). For example, in *Tummino*, the plaintiffs challenged the the FDA's failure to approve over-the-counter access to the emergency contraceptive drug known as "Plan B." The FDA delayed responding to the application for OTC access for five years. Soon after the initial application for over-the-counter access was filed in 2003, the FDA's Non–Prescription Drug Advisory Committee voted unanimously that Plan B was safe for use in a non-prescription setting. Senior management, however, opposed. The agency then engaged in a calculated "filibuster" designed to avoid making a decision subject to judicial review.

85. The only reason new rules are supposedly necessary is due to the agency's own bad faith and unlawful conduct.

86. Rules under the APA may not be applied retroactively.

87. Plaintiff seeks a declaratory judgment that his application is entitled to be processed without regard to rules promulgated after the date of Plaintiff's application.

COUNT III
(Mandamus – 28 U.S.C. § 1361)

88. Plaintiff incorporates each of the proceeding allegations by reference.

89. Defendants Barr and Shea are federal officers that owe Plaintiff a clear, non-discretionary duty to process his application.

90. Plaintiff has no adequate means for review.

91. Plaintiff seeks mandamus to compel Defendants Barr and Shea to approve or deny his application.

Prayer for Relief

WHEREFORE, Plaintiff Dr. Lyle Craker requests that this Court enter judgment providing the following relief:

A. compelling Defendants to register Plaintiff, or serve an order to show cause upon the applicant in accordance with section 824(c) of the CSA;

B. declaring that DEA must apply rules in effect at the time Plaintiff's applications was submitted; and

C. awarding Plaintiff all other relief in law and equity to which Plaintiff may be entitled in this matter, including attorney fees.

Dated: December 2, 2020

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