

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND**

MMJ BIOPHARMA CULTIVATION INC.,

Plaintiff,

v.

MERRICK B. GARLAND, in his official capacity as U.S. Attorney General, UNITED STATES DEPARTMENT OF JUSTICE, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, ANNE MILGRAM, in her official capacity as Administrator of DEA, TERESA A. WALLBAUM, in her official capacity as an Administrative Law Judge of DEA, and THE UNITED STATES OF AMERICA

Defendants.

Civil Action No. 1:24-cv-00127

MOTION TO AMEND COMPLAINT

NOW COMES the Plaintiff, MMJ BioPharma Cultivation, Inc., who, by and through its undersigned counsel, moves pursuant to Fed. R. Civ. P. 15(a)(2) to amend its Complaint which was originally filed on April 4, 2024. A copy of the proposed amended complaint (hereinafter “Proposed Pleading”) is attached hereto as Exhibit A, and a redline of the changes made is attached as Exhibit B. Plaintiff now moves for this Court to grant this Motion to Amend the Complaint. Plaintiff respectfully submits that their motion should be granted because they have acted diligently and in good faith and the filing of the Proposed Pleading would not cause unfair

prejudice to the Defendants. Indeed, this amendment was indeed one that was brought to the Plaintiff's attention by the Defendants who elucidated some key facts surrounding the appointment process for the particular Administrative Law Judge who is at the center of this litigation. Accordingly, this amendment seeks to remove all claims, allegations, and references to Appointments Clause issues.

In this specific instance, Counsel for the Defendants has assented to this Motion, as indicated in the Joint Motion for Extension of Time which was filed on or about August 8, 2024.

CONCLUSION

In light of the foregoing, Plaintiffs respectfully request that this court GRANT this Motion to Amend the Complaint and implement the First Amended Complaint as the operative complaint in this matter.

Dated: August 12, 2024

Respectfully submitted,

/s/ Megan E. Sheehan, Esq.

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Counsel for Petitioner
MMJ BioPharma Cultivation, Inc.

EXHIBIT A

PROPOSED AMENDED COMPLAINT

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND**

MMJ BIOPHARMA CULTIVATION INC.,

Plaintiff,

v.

MERRICK B. GARLAND, in his official capacity as U.S. Attorney General, UNITED STATES DEPARTMENT OF JUSTICE, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, ANNE MILGRAM, in her official capacity as Administrator of DEA, TERESA A. WALLBAUM, in her official capacity as an Administrative Law Judge of DEA, and THE UNITED STATES OF AMERICA

Defendants.

Civil Action No. 1:24-cv-00127

FIRST AMENDED COMPLAINT

MMJ BioPharma Cultivation Inc. (“MMJ”) for its complaint against the Defendants, Merrick B. Garland, in his official capacity as Attorney General of the United States, the United States Department of Justice, the United States Drug Enforcement Administration (“DEA”), Anne Milgram, in her official capacity as Administrator of DEA, and the Honorable Teresa A. Wallbaum, in her capacity as an Administrative Law Judge (“ALJ”) of DEA, and the United States of America (collectively, the “Defendants”), hereby alleges, based on knowledge of its own

conduct, and on information and belief as to all other matters, as follows:

NATURE OF ACTION

1. This action arises from DEA's attempt to subject MMJ to an unconstitutional administrative proceeding (the "Administrative Proceeding") before a DEA Administrative Law Judge ("ALJ").
2. Defendants issued an Order to Show Cause in relation to MMJ's application for a manufacturing registration to permit MMJ to cultivate marijuana for research purposes, compelling MMJ to participate in an unlawful adjudicative process before a DEA ALJ is not accountable to President, in violation of the Take Care Clause of Article II, Section 3 of the Constitution.
3. MMJ seeks declaratory and injunctive relief to prevent the irreparable harm it would suffer if subjected to such an unconstitutional proceeding.
4. Statutory restrictions on an ALJ's removal violate the President's Article II executive power.
5. Regardless, DEA attempts to compel MMJ to participate in an unconstitutional DEA administrative proceeding.
6. DEA ALJs are executive "officers." They hold continuing positions, established by law, in which they exercise significant authority and discretion presiding over DEA administrative hearings and adjudicating adversarial enforcement proceedings.
7. The framework for removal of DEA's ALJs is unconstitutional. Article II establishes "[t]he executive Power" in the President, including final authority to remove officers to ensure that the law is "faithfully executed." U.S. Const. art. II, § 1, cl. 1; *id.* § 3.
8. Because the executive power is vested in the President, Article II requires inferior officers, such as ALJs, to be answerable to the President, and not separated from the

President by attenuated chains of accountability. See *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 492-98 (2010) (“*Free Enterprise*”).

9. Statutory prohibitions found in Sections 7521(a) and 1202(d) of Title 5 of the United States Code prevent the President and Attorney General from removing DEA ALJs.
10. Instead, ALJs may be removed only for “good cause” as “determined” by the Merit Systems Protection Board (“MSPB”).
11. Members of the MSPB can only be removed by the President for very limited “good cause” reasons.
12. This structure prevents the President, or even the Attorney General, from performing the required oversight duties. As a result, this violates Article II. *Id.* at 492.
13. This Court provides MMJ its only opportunity for meaningful judicial review that could prevent a deprivation of its constitutional rights.
14. MMJ cannot wait until a DEA ALJ conducts a hearing and reaches a determination before seeking review in an Article III court, because MMJ would then have already suffered a constitutional harm.
15. MMJ thus seeks protection from an “illegitimate proceeding, led by an illegitimate decisionmaker.” *Axon Enter., Inc. v. Fed. Trade Comm’n*, 598 U.S. 175, 191 (2023).
16. Under the Supreme Court’s in *Axon*, MMJ is entitled to seek relief in this Court now to address its constitutional challenges to avoid compounding the “here-and-now injury” from being subjected to this illegitimate proceeding—a harm that is “impossible to remedy once the proceeding is over, which is when appellate review kicks in.” 598 U.S. at 192.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331,

1337, and 1346 because this action arises under the Constitution and laws of the United States concerning commercial regulation. The United States has waived its sovereign immunity from this lawsuit in 5 U.S.C. § 702.

18. Venue is proper in this district under 28 U.S.C. § 1391(e) because (i) one or more Defendants is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or is an agency of the United States, or is the United States and (ii) a substantial part of the events or omissions giving rise to the claim occurred within this venue. Specifically, the applications submitted by MMJ to the DEA were for a manufacturing location in Westerly, RI. In addition, it was the RI DEA office which “investigated” the application, and provided the information for the show cause order, which resulted in MMJ being subjected to the ALJ process. All events which transpired prior to the ALJ hearing took place in Rhode Island. The initial ALJ hearings took place remotely, with MMJ’s participation being in Rhode Island.

THE PARTIES

19. Defendant Merrick B. Garland is the Attorney General of the United States, and the head and principal officer of the United States Department of Justice. He is sued in his official capacity.
20. Defendant United States Department of Justice is an executive department of the United States, headquartered in Washington, D.C.
21. Defendant DEA is a federal government agency tasked with enforcing the controlled substances laws and regulations of the United States and is headquartered in Virginia.
22. Defendant Anne Milgram is the Administrator of DEA. She is sued in her official capacity.
23. Defendant the Honorable Teresa A. Wallbaum is an ALJ of DEA. She is sued in her

official capacity.

24. Defendant United States of America is named in accordance with 5 U.S.C. § 702.

FACTS

Purpose and Initial Application

25. The DEA may register an applicant for pharmaceutical research if it finds that the registration is in the public interest. U.S.C. § 822(a). There has been increased interest in developing pharmaceutical drugs derived from marijuana. The DEA has promulgated regulations for an entity to register for pharmaceutical research using marijuana under 21 C.F.R. § 1301.13 and 21 C.F.R. § 1301.18.
26. For many years, the only registration which has been approved by the DEA has been the University of Mississippi. Amongst the research community it has been a long recognized fact that the marijuana produced by the University of Mississippi was insufficient and of low quality for pharmaceutical research and development, however.
27. In 2015, Congress passed the “Improving Regulatory Transparency for New Medical Therapies Act”, which was enacted on November 15, 2015. The Act amended the CSA to include a requirement that the Attorney General either approve or deny (via a show cause order) an application to cultivate marijuana for research purposes within 90 (ninety) days after the application was submitted. 21 U.S. Code § 823(i)(2)(a).
28. In order to meet the growing demand for pharmaceutical research using marijuana, in 2016 the DEA announced an expansion of the registration program, stating that “[t]o facilitate research involving marijuana and its chemical constituents, DEA is adopting a new policy that is designed to increase the number of entities registered under the

Controlled Substances Act (“CSA”) to cultivate (manufacture) marijuana to supply legitimate researchers in the United States.” 81 Fed.Reg. 53846.

29. The process for registration is laid out in the DEA regulations, found at 21 C.F.R. § 1301.

30. In addition, 21 C.F.R. § 1318 covers the registration for manufacturing (including cultivation) of marijuana.

31. MMJ and its sister organizations (MMJ BioPharma Labs Inc. and MMJ International Holdings Corp., all three collectively referred to as the “MMJ Group”) collectively look to engage in pharmaceutical research and to produce a gel capsule which contains extracts from the marijuana plant for the purpose of treating those suffering from chronic illnesses such as Multiple Sclerosis and Huntington’s Disease.

32. MMJ’s goal is also to support other researchers performing DEA registered research using marijuana by cultivating specific strains required by researchers in controlled environments and free of contaminants.

33. MMJ International Holdings Copr. is currently in possession of two FDA INDs (IND No. 137754 & IND No.140712). In order to fulfill the purpose of the FDA INDs, MMJ sought two types of registrations from the DEA to ensure the ability to import, grow, extract, and analyze the compounds from marijuana plants.

34. In December 2018, MMJ Biopharma applied to the DEA for an API Bulk Manufacturer (W18134021E) registration to enable them to cultivate and process marijuana for the research and development of the above-mentioned pharmaceutical drug.

35. The MMJ Groups’ overarching purpose of developing pharmaceuticals to reduce symptoms of chronic illnesses such as Multiple Sclerosis and Huntington’s Disease requires careful control of all plant genetics in order to maintain compliance with FDA

requirements regarding the consistent reproducibility of the compounds found in the pharmaceutical. *See generally* 21 CFR 330.10 and the “*Botanical Drug Development Guidance*”, published by the FDA in 2016.

DEA Statutory Requirements

36. The DEA does not have wide latitude in deciding when to issue determinations on pending applications under 21 U.S.C. § 823(j)(2)¹. 21 U.S.C. § 823(j)(2) requires that the government must “issue a notice of application not later than 90 days after the application is accepted for filing.” In addition, it provides “[n]ot later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General ***shall register the applicant, or serve an order to show cause upon the applicant.***” *Id.*

(emphasis added).

37. In addition, on December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act (“MMCREA”) was enacted in an attempt to expedite the approval process for conducting marijuana research. Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. No. 117-215 (2022).

38. The MMCREA mandated that DEA application determination be issued within a 60-day period. The MMCREA directs the DEA to follow procedures specified within the Act to expedite registrations for practitioners and institutions for the purpose of conducting research.

39. Despite their original statutory obligation under 21 U.S.C. § 823(j)(2) and the new expansion act (MMCREA), the DEA chose to not make a determination on MMJ’s

¹ 21 U.S.C. § 823(j)(2) was previously referred to as 21 U.S.C. § 823(i)(2), but was amended in 2022. Any past reference to 21 U.S.C. § 823(i) should be understood as referring to present-day 21 U.S.C. § 823(j)(2).

application prior to the DEA's issuance of an Order to Show Cause on October 31, 2023.

As such, the DEA has flagrantly ignored the deadlines put in place by both the Controlled Substances Act and the MMCREA.

40. MMJ's application for a manufacturing registration was submitted on December 27, 2018. The first Notice of Application regarding the manufacturing registration was not published to the Federal Register until August 27, 2019, eight months later, despite the fact that the government was required to publish the notice of application within 90 days from the date of application. *See* 21 U.S.C. § 823(j)(2). (*See id.*) Nevertheless, the deadline for comment on the notice of application was October 28, 2019. *See* 21 U.S.C. § 823(j)(2). A period of 90 days following *this* deadline for comment would mean the government needed to make a determination on MMJ's application by January 26, 2020. *See id.*
41. However, in addition, an amended Notice of Application regarding the manufacturing registration was published to the Federal Register on October 11, 2019, ten months after the application was submitted.
42. This is, again, in direct contravention to the statutory requirement that the government publish a notice of application within 90 days from the date of application. *See* 21 U.S.C. § 823(j)(2). There was no reason provided to MMJ for the notice of application being amended and re-published to the Federal Register. However, even if using the October 11, 2019 publication date, the deadline for comment would have been December 10, 2019.
43. A period of 90 days following *this* deadline for comment would mean the DEA needed to make a determination on or before March 9, 2020.

44. The DEA violated the express terms of the Controlled Substances Act by failing to submit MMJ's application to the Federal Register within 90 days.
45. The DEA also violated the express terms of the Controlled Substances Act by failing to either issue the registration to MMJ or issue a show cause notice to MMJ within 90 days of the close of the comment period on MMJ's application.
46. Further, the DEA ignored the MMCREA requirement that the DEA make determinations on application for the purpose of research within a 60-day period. Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. No. 117-215 (2022).
47. The MMCREA was designed to create additional time constraints for DEA application processing time in an effort to expedite registrations for practitioners and institutions for the purpose of conducting research. Despite this, however, the DEA *still* failed to expedite MMJ's application and instead left the application "in limbo" until October 31, 2023, when the Order to Show Cause was finally issued.

"Investigation" Process

48. On June 22, 2021, nearly two and a half years after the application manufacturing was submitted, the DEA finally commenced their pre-registration 303 investigation process, and MMJ received the first visit by DEA Diversion personnel that day.
49. The 303 investigation concluded when the final on-site visit took place on October 24, 2021.
50. At the end of the visit, the diversion investigator informed MMJ that they would return to the DEA office, "write up" the report, and submit the report to their group supervisor who would then submit those findings to DEA Headquarters for a final determination.

51. During the 303 investigation inspection, all DEA questions were satisfactorily answered, all security systems and protocols were reviewed, and MMJ demonstrated that all security and diversion conditions were in compliance with the regulations. At no point in time did any DEA personnel inform MMJ or its agents of any issues with the application.
52. Following that investigation, MMJ attempted to follow up with the DEA on several occasions and was met with, at best, blatant indifference and, at worst, callousness.
53. In the time period between the 303 Investigation on October 24, 2021 to October 31, 2023 (over two years) MMJ was unable to receive an approval or denial (via a show cause order) of their application. ***This was almost five years from the date of MMJ's initial applications.***
54. During this time period, and despite numerous attempts to follow-up and check the status of the registration approval determinations for manufacturing and importing, DEA personnel expressed to MMJ that they have not yet made final determinations ***and they have no idea when that determination will be made.*** At one point during this period, DEA personnel responded “why do you want to know?” when MMJ inquired regarding the status of the registrations.
55. In a further attempt to secure information as to the status of the applications, MMJ reached out to Congressman Jim Langevin on February 16, 2022. His office first submitted an informal request for information which was ignored and the Congressional office has now elevated it to a formal inquiry which to date has gone unanswered by the DEA.
56. MMJ's next attempt to gain information was an email followed by a letter to DEA Administrator Ann Milgram dated March 23, 2022 which went unanswered.

57. MMJ made multiple calls to DEA headquarters' customer line, and sent multiple emails to DEA DI Thomas Cook. No status update was provided by the DEA.
58. On April 8, 2022, because of an utter lack of communication from the DEA, MMJ filed a Writ of Mandamus with this Court in an attempt to get some kind of determination from the DEA as to the status of their application. Said Writ was dismissed due to a venue issue.
59. In June of 2023 (over four years after submitting their application), DEA personnel informed MMJ that "they will get to it when they get to it" in response to another application status inquiry.
60. On August 18, 2023, MMJ re-filed for a Writ of Mandamus in the United States Court of Appeals for District of Columbia Circuit, again asking that the DEA make *some* determination on their application.
61. Throughout this entire time period, counsel for MMJ and MMJ representatives reached out to the DEA and DEA counsel multiple times, requesting any feedback as to what was still required by the DEA for the registration. This outreach was most often met with silence, or with extremely confusing or contradictory responses from the DEA.
62. On October 31, 2023, facing a looming deadline to respond to MMJ's Writ of Mandamus in the Court of Appeals for District of Columbia Circuit, the DEA finally issued a Show Cause Order to MMJ on the grounds detailed below.

Bona-Fide Supply Agreement

63. On January 19, 2021, the DEA introduced the requirement that applicants for a bulk API Manufacturing registration produce a bona fide supply agreement ("BFSA"). 21 C.F.R.

1318.05(b)(3)(i). No such requirement or equivalent existed prior to this date. *See* 85 FR 82333.

64. Pursuant to the statutory requirements under 21 U.S.C. § 823(j)(2), MMJ's application should have either been granted or issued a show cause order prior to this regulatory change. As such, MMJ argued that the new requirement should still be immaterial to their pending application.
65. From the very beginning, MMJ has made every attempt to comply with the government's ever-increasing and ever-convoluted demands. Countless patients who have been affected by Multiple Sclerosis and Huntington's Disease and are waiting on the potentially life-restoring treatments associated with the development of these pharmaceuticals.
66. Despite the fact that MMJ, should not need to comply with the new requirement to submit a BfSA, MMJ attempted to submit several documents to fulfill this requirement, all of which were rejected. For example, on April 20, 2021, MMJ provided an agreement with the University of Connecticut (UConn) to provide UConn researcher Dr. Stephen Kinsey marijuana on April 20, 2021. MMJ gathered all documentation regarding Dr. Kinsey's Schedule 1 researcher registration and Dr. Kinsey's DEA-approved research protocol and provided it to DEA Diversion Investigator Thomas Cook.
67. For some unintelligible reason, the agreement between MMJ and UConn/Dr. Kinsey was found to not be a valid bona fide supply agreement. The reason later cited by the DEA was that the signature line for UConn's representative was not dated, despite there being no such requirement under 21 CFR 1300 et. seq. nor any such request made by the government in its communications with MMJ prior to the Order to Show Cause.

68. The BFSA requirements were not explained to MMJ by DEA, nor did agents of the DEA (namely, DI Cook) provide any guidance on how to fulfill this requirement upon inquiry by MMJ.
69. The regulations provide that an applicant must produce a bona fide supply agreement, which is defined as “a letter of intent, purchase order or contract between an applicant and a researcher or manufacturer registered under the Act.” See 21 C.F.R. § 1318.02(g); See also 21 C.F.R. § 1318.05(b)(3)(i).
70. However, the DEA attempted to assert a slew of additional requirements (e.g. the requirement that prices be set) in their Order to Show Cause, which do not exist in the regulations.
71. Indeed, if looking at the plain language definition of the term “bona fide supply agreement,” it is patently clear to see that the drafters also intended that they include speculative agreements like letters of intent. See 21 C.F.R. § 1318.02(g). It is either incredibly disingenuous for the DEA to essentially require an ironclad contract for a speculative business relationship based on a license which has not yet been granted, when the regulations permit submission of a mere letter of intent between the parties.
72. Further, it appeared that the DEA instead sought to obfuscate the process and create a target that seemed impossible to hit. Ultimately, the BFSA was deemed insufficient in the Order to Show Cause and DEA refused to provide any explanation as to why it would not be permitted under the DEA regulations.
73. There have been several other instances where the DEA has further obfuscated the process regarding the BFSA. For example, in October 2022, DPM Mark Rubbins suggested that MMJ enter into a BFSA with Dr. Juan Sanchez-Ramos (“Dr. Ramos”), a

researcher with whom MMJ had previously established a relationship with. At that point in time, Dr. Ramos' registration had lapsed. Despite this, DPM Rubbins told MMJ to "just have Dr. Ramos submit his application and we will do a small background check and get it approved." Despite this, however, the DEA ultimately decided to deny Dr. Ramos' registration and, again, leave MMJ in limbo.

74. In a phone call with MMJ shortly after the October 2022 meeting, DEA's Matthew Strait informed MMJ that "the BFSA should be between MMJ and the DEA and this is how the other registrants meet this requirement." Presumably, Mr. Strait's contention is based upon the fact that there exists the international treaty called the Single Convention, which obligates all members of the Convention to appoint a single government agency of the United States to purchase and take possession of all manufactured marijuana. Controls to Enhance the Cultivation of Marihuana for Research in the United States, 85 F.R. 82333. Accordingly, MMJ submitted a BFSA with this arrangement, but this agreement was also denied.

75. Time and time again, the process is obfuscated by the DEA and its agents despite MMJ's obvious desperation to obtain clarity on the alleged "requirements."

Order to Show Cause & ALJ Proceeding

76. Following the Order to Show Cause being served on MMJ on October 31, 2023, MMJ filed a Request for Hearing with the DEA.

77. ALJ Theresa Wallbaum has been assigned for the hearing.

78. Following MMJ's filing the Request for Hearing, but prior to any hearing taking place, and now objects to the Constitutionality of the proceeding.

ALJ Proceeding Unconstitutional

79. ALJs are recognized as officers under Article II of the U.S. Constitution. Their appointments are in accordance with the Administrative Procedure Act (APA). As per the APA and its accompanying regulations, ALJs perform several crucial duties, such as presiding over administrative proceedings and exercising substantial authority. Notably, Sections 1316.52 and 1316.42(f) of Title 21 of the Code of Federal Regulations specifically mandate ALJs to oversee administrative proceedings.
80. According to Section 930.204(a) of Title 5 of the Code of Federal Regulations, DEA ALJs are granted career appointments and are excluded from probationary periods that are applicable to specific government employees.
81. Similar to SEC ALJs, whom the Supreme Court has deemed inferior officers under Article II, DEA ALJs possess wide discretion to wield significant authority in administrative proceedings. According to 5 U.S.C. § 556(c), DEA ALJs have the power to: (1) administer oaths and affirmations; (2) issue subpoenas as authorized by law; (3) rule on offers of proof and admit relevant evidence; (4) conduct or order depositions when necessary for justice; (5) regulate the proceedings; (6) convene conferences to settle issues through consent or alternative dispute resolution methods; (7) inform parties about alternative dispute resolution options and encourage their utilization; (8) compel attendance at conferences; (9) address procedural requests or similar matters; (10) render or recommend decisions; and (11) undertake other actions permitted by agency regulations in line with the APA.

82. DEA regulations bestow authority upon DEA ALJs to conduct adjudicative functions during hearings and resolve adversarial proceedings on behalf of the DEA. According to Section 1316.52 of Title 21 of the Code of Federal Regulations, DEA ALJs are mandated to conduct fair hearings, prevent delays, and maintain order. Additionally, under the same regulation, DEA ALJs possess the following powers: (a) Adjust the date, time, and location of hearings and prehearing conferences, issuing notice accordingly. (b) Convene conferences to resolve, simplify, or determine issues in hearings, or address other matters facilitating prompt resolution. (c) Request parties to submit written statements outlining their positions on various issues in the hearing, and exchange these statements with all other involved parties. (d) Issue subpoenas to ensure witness attendance and document production essential for administrative hearings. (e) Interrogate witnesses and instruct them to testify. (f) Admit, rule on, exclude, or limit evidence. (g) Make rulings on pending procedural matters. (h) Take any action permitted to the presiding officer as stipulated by this regulation or the provisions of the APA.
83. The regulatory and administrative framework governing the removal of DEA ALJs infringes upon Article II. This framework undermines the constitutional responsibilities of the President and the Attorney General to execute executive power and enforce laws faithfully, including overseeing inferior officers like ALJs, including the power to remove them without cause.
84. According to the APA, ALJs, including those within the DEA, can only be removed for good cause as determined by the Merit Systems Protection Board (MSPB). This statutory constraint means that neither the President nor the Attorney General can independently ascertain "good cause" and subsequently remove DEA ALJs without MSPB approval.

However, members of the MSPB themselves cannot be removed except for good cause.

This dual requirement for cause-based removal infringes upon Article II, as interpreted by the Supreme Court in *Free Enterprise*.

85. This convoluted removal structure violates Article II's requirement that inferior executive officers not be protected from removal by their superiors at will, when those superiors are themselves protected from being removed by the President at will.

86. As stated previously, DEA ALJs hold executive positions and exercise significant executive authority. Nonetheless, (a) DEA ALJs are safeguarded from removal by a "good cause" standard outlined in 5 U.S.C. §7521(a), and (b) members of the MSPB responsible for determining this standard are shielded from removal except for reasons of inefficiency, neglect of duty, or malfeasance in office, as per 5 U.S.C. §1202(d). This arrangement impedes the President's Article II executive authority and ensures that neither the President nor the Attorney General, as the Head of Department, can fulfill their duty to faithfully execute laws by independently assessing whether good cause exists to remove inferior officers.

CAUSES OF ACTION

COUNT ONE

(Application for Injunctive Relief)

87. MMJ repeats and incorporates each and every allegation in all preceding paragraphs as if fully set forth here.

88. Without injunctive relief from this Court, MMJ will be required to continue to submit to an unconstitutional proceeding led by an unconstitutional decisionmaker which constitutes a "here-and-now injury" that is "impossible to remedy once the proceeding is over, which is when appellate review kicks in" under *Axon*, 598 U.S. at 191.

89. This, in and of itself, constitutes irreparable harm to Plaintiff unless the Administrative Proceeding is enjoined.

90. If the DEA Administrator, upon recommendation from the presiding DEA ALJ, finds that MMJ's registration is against the public interest, the harm will be severe and irreversible. MMJ's may be forced to close its doors. This comes after years of the DEA's failure to follow the clear requirements under the Controlled Substances Act and general malfeasance. Moreover, Plaintiff could not obtain meaningful judicial review in time to prevent this outcome. Nor can this harm be remedied after-the-fact with money damages, as numerous immunity doctrines would prevent MMJ from obtaining a financial damages award from DEA.

COUNT TWO
(Declaratory Judgment)

91. MMJ repeats and incorporates each and every allegation in all preceding paragraphs as if fully set forth here.

92. MMJ requests a declaratory judgment that the statutes, regulatory provisions, and policies providing for removal of DEA ALJs are unconstitutional as applied by DEA and DOJ.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for an Order and Judgment:

(a) Declaring unconstitutional the statutes, regulatory provisions, and policies providing for the removal of DEA ALJs as applied by DEA and DOJ;

(b) An order and judgment enjoining DEA and DOJ from carrying out an administrative proceeding against MMJ, including on the Order to Show Cause at issue or any other proceedings with regard to MMJ's DEA MMJ's DEA Certificates of Registration unless and until a constitutionally valid system is in place;

(c) Judicial review of the DEA's Order to Show Cause, and finding that MMJ met its burden for issuance of the manufacturer registration under applicable law; and

(c) Such other and further relief as this court may deem just and proper, including reasonable attorneys' fees and costs of this action.

Respectfully submitted,

Dated: August 12, 2024

/s/ Megan E. Sheehan, Esq.

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EXHIBIT B

REDLINE OF CHANGES MADE

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND**

MMJ BIOPHARMA CULTIVATION INC.,

Plaintiff,

v.

MERRICK B. GARLAND, in his official capacity as U.S. Attorney General, UNITED STATES DEPARTMENT OF JUSTICE, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, ANNE MILGRAM, in her official capacity as Administrator of DEA, TERESA A. WALLBAUM, in her official capacity as an Administrative Law Judge of DEA, and THE UNITED STATES OF AMERICA

Defendants.

FIRST AMENDED COMPLAINT

MMJ BioPharma Cultivation Inc. (“MMJ”) for its complaint against the Defendants, Merrick B. Garland, in his official capacity as Attorney General of the United States, the United States Department of Justice, the United States Drug Enforcement Administration (“DEA”), Anne Milgram, in her official capacity as Administrator of DEA, and the Honorable Teresa A. Wallbaum, in her capacity as an Administrative Law Judge (“ALJ”) of DEA, and the United States of America (collectively, the “Defendants”), hereby alleges, based on knowledge of its own conduct, and on information and belief as to all other matters, as follows:

NATURE OF ACTION

1. This action arises from DEA's attempt to subject MMJ to an unconstitutional administrative proceeding (the "Administrative Proceeding") before a DEA Administrative Law Judge ("ALJ").
2. Defendants issued an Order to Show Cause in relation to MMJ's application for a manufacturing registration to permit MMJ to cultivate marijuana for research purposes, compelling MMJ to participate in an unlawful adjudicative process before a DEA ALJ who ~~was appointed in violation of the Appointments Clause of Article II, Section 2, of the Constitution and~~ is not accountable to President, in violation of the Take Care Clause of Article II, Section 3 of the Constitution.
3. MMJ seeks declaratory and injunctive relief to prevent the irreparable harm it would suffer if subjected to such an unconstitutional proceeding.
4. ~~The United States Supreme Court has found that an ALJ appointment process nearly identical to that used by DEA is unconstitutional.~~
5. Statutory restrictions on an ALJ's removal violate the President's Article II executive power. ~~The DEA has done nothing to modify its ALJ appointment process to comply with constitutional requirements.~~
6. Regardless, DEA attempts to compel MMJ to participate in an unconstitutional DEA administrative proceeding.
7. DEA ALJs are executive "officers" ~~for purposes of Article II's Appointments Clause.~~ They hold continuing positions, established by law, in which they exercise significant authority and discretion presiding over DEA administrative hearings and adjudicating adversarial enforcement proceedings.
8. ~~Under the Appointments Clause, inferior Article II "officers" such as DEA's ALJs must be appointed either by the President or the Head of their Department, the Attorney~~

~~General of the United States. U.S. Const. art. II, § 2, cl. 2. ‘~~

9. ~~DEA ALJs are appointed by neither. On information and belief, the DEA ALJ presiding over MMJ’s administrative hearing was selected from a group of candidates provided by the White House Office of Personnel Management (“OPM”) and appointed by the DEA Administrator upon recommendation from DEA’s Chief ALJ.~~
10. ~~In June 2018, the United States Supreme Court held that this ALJ appointment process is unconstitutional in *Lucia v. S.E.C.*, 138 S. Ct. 2044 (2018). The Court’s decision in *Lucia* addressed the appointment of ALJs for the Securities and Exchange Commission (“SEC”), the Court’s exact reasoning applies to the appointment of DEA’s ALJs.~~
11. The framework for removal of DEA’s ALJs is ~~also~~ unconstitutional. Article II establishes “[t]he executive Power” in the President, including final authority to remove officers to ensure that the law is “faithfully executed.” U.S. Const. art. II, § 1, cl. 1; *id.* § 3.
12. Because the executive power is vested in the President, Article II requires inferior officers, such as ALJs, to be answerable to the President, and not separated from the President by attenuated chains of accountability. See *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 492-98 (2010) (“*Free Enterprise*”).
13. Statutory prohibitions found in Sections 7521(a) and 1202(d) of Title 5 of the United States Code prevent the President and Attorney General from removing DEA ALJs.
14. Instead, ALJs may be removed only for “good cause” as “determined” by the Merit Systems Protection Board (“MSPB”).
15. Members of the MSPB can only be removed by the President for very limited “good cause” reasons.
16. This structure prevents the President, or even the Attorney General, from performing the required oversight duties. As a result, this violates Article II. *Id.* at 492.
17. This Court provides MMJ its only opportunity for meaningful judicial review that could

prevent a deprivation of its constitutional rights.

18. MMJ cannot wait until a DEA ALJ conducts a hearing and reaches a determination before seeking review in an Article III court, because MMJ would then have already suffered a constitutional harm.
19. MMJ thus seeks protection from an “illegitimate proceeding, led by an illegitimate decisionmaker.” *Axon Enter., Inc. v. Fed. Trade Comm’n*, 598 U.S. 175, 191 (2023).
20. Under the Supreme Court’s in *Axon*, MMJ is entitled to seek relief in this Court now to address its constitutional challenges to avoid compounding the “here-and-now injury” from being subjected to this illegitimate proceeding—a harm that is “impossible to remedy once the proceeding is over, which is when appellate review kicks in.” 598 U.S. at 192.

JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1346 because this action arises under the Constitution and laws of the United States concerning commercial regulation. The United States has waived its sovereign immunity from this lawsuit in 5 U.S.C. § 702.
22. Venue is proper in this district under 28 U.S.C. § 1391(e) because (i) one or more Defendants is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or is an agency of the United States, or is the United States and (ii) a substantial part of the events or omissions giving rise to the claim occurred within this venue. Specifically, the applications submitted by MMJ to the DEA were for a manufacturing location in Westerly, RI. In addition, it was the RI DEA office which “investigated” the application, and provided the information for the show cause order, which resulted in MMJ being subjected to the ALJ process. All events

which transpired prior to the ALJ hearing took place in Rhode Island. The initial ALJ hearings took place remotely, with MMJ's participation being in Rhode Island.

THE PARTIES

23. Defendant Merrick B. Garland is the Attorney General of the United States, and the head and principal officer of the United States Department of Justice. He is sued in his official capacity.
24. Defendant United States Department of Justice is an executive department of the United States, headquartered in Washington, D.C.
25. Defendant DEA is a federal government agency tasked with enforcing the controlled substances laws and regulations of the United States and is headquartered in Virginia.
26. Defendant Anne Milgram is the Administrator of DEA. She is sued in her official capacity.
27. Defendant the Honorable Teresa A. Wallbaum is an ALJ of DEA. She is sued in her official capacity.
28. Defendant United States of America is named in accordance with 5 U.S.C. § 702.

FACTS

Purpose and Initial Application

29. The DEA may register an applicant for pharmaceutical research if it finds that the registration is in the public interest. U.S.C. § 822(a). There has been increased interest in developing pharmaceutical drugs derived from marijuana. The DEA has promulgated regulations for an entity to register for pharmaceutical research using marijuana under 21 C.F.R. § 1301.13 and 21 C.F.R. § 1301.18.

30. For many years, the only registration which has been approved by the DEA has been the University of Mississippi. Amongst the research community it has been a long recognized fact that the marijuana produced by the University of Mississippi was insufficient and of low quality for pharmaceutical research and development, however.
31. In 2015, Congress passed the “Improving Regulatory Transparency for New Medical Therapies Act”, which was enacted on November 15, 2015. The Act amended the CSA to include a requirement that the Attorney General either approve or deny (via a show cause order) an application to cultivate marijuana for research purposes within 90 (ninety) days after the application was submitted. 21 U.S. Code § 823(i)(2)(a).
32. In order to meet the growing demand for pharmaceutical research using marijuana, in 2016 the DEA announced an expansion of the registration program, stating that “[t]o facilitate research involving marijuana and its chemical constituents, DEA is adopting a new policy that is designed to increase the number of entities registered under the Controlled Substances Act (“CSA”) to cultivate (manufacture) marijuana to supply legitimate researchers in the United States.” 81 Fed.Reg. 53846.
33. The process for registration is laid out in the DEA regulations, found at 21 C.F.R. § 1301.
34. In addition, 21 C.F.R. § 1318 covers the registration for manufacturing (including cultivation) of marijuana.
35. MMJ and its sister organizations (MMJ BioPharma Labs Inc. and MMJ International Holdings Corp., all three collectively referred to as the “MMJ Group”) collectively look to engage in pharmaceutical research and to produce a gel capsule which contains extracts from the marijuana plant for the purpose of treating those suffering from chronic illnesses such as Multiple Sclerosis and Huntington’s Disease.

36. MMJ's goal is also to support other researchers performing DEA registered research using marijuana by cultivating specific strains required by researchers in controlled environments and free of contaminants.
37. MMJ International Holdings Copr. is currently in possession of two FDA INDs (IND No. 137754 & IND No.140712). In order to fulfill the purpose of the FDA INDs, MMJ sought two types of registrations from the DEA to ensure the ability to import, grow, extract, and analyze the compounds from marijuana plants.
38. In December 2018, MMJ Biopharma applied to the DEA for an API Bulk Manufacturer (W18134021E) registration to enable them to cultivate and process marijuana for the research and development of the above-mentioned pharmaceutical drug.
39. The MMJ Groups' overarching purpose of developing pharmaceuticals to reduce symptoms of chronic illnesses such as Multiple Sclerosis and Huntington's Disease requires careful control of all plant genetics in order to maintain compliance with FDA requirements regarding the consistent reproducibility of the compounds found in the pharmaceutical. *See generally* 21 CFR 330.10 and the "*Botanical Drug Development Guidance*", published by the FDA in 2016.

DEA Statutory Requirements

40. The DEA does not have wide latitude in deciding when to issue determinations on pending applications under 21 U.S.C. § 823(j)(2)¹. 21 U.S.C. § 823(j)(2) requires that the government must "issue a notice of application not later than 90 days after the application is accepted for filing." In addition, it provides "[n]ot later than 90 days after the date on

¹ 21 U.S.C. § 823(j)(2) was previously referred to as 21 U.S.C. § 823(i)(2), but was amended in 2022. Any past reference to 21 U.S.C. § 823(i) should be understood as referring to present-day 21 U.S.C. § 823(j)(2).

which the period for comment pursuant to such notice ends, the Attorney General *shall register the applicant, or serve an order to show cause upon the applicant.*” *Id.*

(emphasis added).

41. In addition, on December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act (“MMCREA”) was enacted in an attempt to expedite the approval process for conducting marijuana research. Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. No. 117-215 (2022).
42. The MMCREA mandated that DEA application determination be issued within a 60-day period. The MMCREA directs the DEA to follow procedures specified within the Act to expedite registrations for practitioners and institutions for the purpose of conducting research.
43. Despite their original statutory obligation under 21 U.S.C. § 823(j)(2) and the new expansion act (MMCREA), the DEA chose to not make a determination on MMJ’s application prior to the DEA’s issuance of an Order to Show Cause on October 31, 2023. As such, the DEA has flagrantly ignored the deadlines put in place by both the Controlled Substances Act and the MMCREA.
44. MMJ’s application for a manufacturing registration was submitted on December 27, 2018. The first Notice of Application regarding the manufacturing registration was not published to the Federal Register until August 27, 2019, eight months later, despite the fact that the government was required to publish the notice of application within 90 days from the date of application. *See* 21 U.S.C. § 823(j)(2). (*See id.*) Nevertheless, the deadline for comment on the notice of application was October 28, 2019. *See* 21 U.S.C. § 823(j)(2). A period of 90 days following *this* deadline for comment would mean the

government needed to make a determination on MMJ's application by January 26, 2020.

See id.

45. However, in addition, an amended Notice of Application regarding the manufacturing registration was published to the Federal Register on October 11, 2019, ten months after the application was submitted.
46. This is, again, in direct contravention to the statutory requirement that the government publish a notice of application within 90 days from the date of application. *See* 21 U.S.C. § 823(j)(2). There was no reason provided to MMJ for the notice of application being amended and re-published to the Federal Register. However, even if using the October 11, 2019 publication date, the deadline for comment would have been December 10, 2019.
47. A period of 90 days following *this* deadline for comment would mean the DEA needed to make a determination on or before March 9, 2020.
48. The DEA violated the express terms of the Controlled Substances Act by failing to submit MMJ's application to the Federal Register within 90 days.
49. The DEA also violated the express terms of the Controlled Substances Act by failing to either issue the registration to MMJ or issue a show cause notice to MMJ within 90 days of the close of the comment period on MMJ's application.
50. Further, the DEA ignored the MMCREA requirement that the DEA make determinations on application for the purpose of research within a 60-day period. Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. No. 117-215 (2022).
51. The MMCREA was designed to create additional time constraints for DEA application processing time in an effort to expedite registrations for practitioners and institutions for

the purpose of conducting research. Despite this, however, the DEA *still* failed to expedite MMJ's application and instead left the application "in limbo" until October 31, 2023, when the Order to Show Cause was finally issued.

"Investigation" Process

52. On June 22, 2021, nearly two and a half years after the application manufacturing was submitted, the DEA finally commenced their pre-registration 303 investigation process, and MMJ received the first visit by DEA Diversion personnel that day.
53. The 303 investigation concluded when the final on-site visit took place on October 24, 2021.
54. At the end of the visit, the diversion investigator informed MMJ that they would return to the DEA office, "write up" the report, and submit the report to their group supervisor who would then submit those findings to DEA Headquarters for a final determination.
55. During the 303 investigation inspection, all DEA questions were satisfactorily answered, all security systems and protocols were reviewed, and MMJ demonstrated that all security and diversion conditions were in compliance with the regulations. At no point in time did any DEA personnel inform MMJ or its agents of any issues with the application.
56. Following that investigation, MMJ attempted to follow up with the DEA on several occasions and was met with, at best, blatant indifference and, at worst, callousness.
57. In the time period between the 303 Investigation on October 24, 2021 to October 31, 2023 (over two years) MMJ was unable to receive an approval or denial (via a show cause order) of their application. ***This was almost five years from the date of MMJ's initial applications.***

58. During this time period, and despite numerous attempts to follow-up and check the status of the registration approval determinations for manufacturing and importing, DEA personnel expressed to MMJ that they have not yet made final determinations ***and they have no idea when that determination will be made.*** At one point during this period, DEA personnel responded “why do you want to know?” when MMJ inquired regarding the status of the registrations.
59. In a further attempt to secure information as to the status of the applications, MMJ reached out to Congressman Jim Langevin on February 16, 2022. His office first submitted an informal request for information which was ignored and the Congressional office has now elevated it to a formal inquiry which to date has gone unanswered by the DEA.
60. MMJ’s next attempt to gain information was an email followed by a letter to DEA Administrator Ann Milgram dated March 23, 2022 which went unanswered.
61. MMJ made multiple calls to DEA headquarters’ customer line, and sent multiple emails to DEA DI Thomas Cook. No status update was provided by the DEA.
62. On April 8, 2022, because of an utter lack of communication from the DEA, MMJ filed a Writ of Mandamus with this Court in an attempt to get some kind of determination from the DEA as to the status of their application. Said Writ was dismissed due to a venue issue.
63. In June of 2023 (over four years after submitting their application), DEA personnel informed MMJ that “they will get to it when they get to it” in response to another application status inquiry.
64. On August 18, 2023, MMJ re-filed for a Writ of Mandamus in the United States Court of

Appeals for District of Columbia Circuit, again asking that the DEA make *some* determination on their application.

65. Throughout this entire time period, counsel for MMJ and MMJ representatives reached out to the DEA and DEA counsel multiple times, requesting any feedback as to what was still required by the DEA for the registration. This outreach was most often met with silence, or with extremely confusing or contradictory responses from the DEA.
66. On October 31, 2023, facing a looming deadline to respond to MMJ's Writ of Mandamus in the Court of Appeals for District of Columbia Circuit, the DEA finally issued a Show Cause Order to MMJ on the grounds detailed below.

Bona-Fide Supply Agreement

67. On January 19, 2021, the DEA introduced the requirement that applicants for a bulk API Manufacturing registration produce a bona fide supply agreement ("BFSA"). 21 C.F.R. 1318.05(b)(3)(i). No such requirement or equivalent existed prior to this date. *See* 85 FR 82333.
68. Pursuant to the statutory requirements under 21 U.S.C. § 823(j)(2), MMJ's application should have either been granted or issued a show cause order prior to this regulatory change. As such, MMJ argued that the new requirement should still be immaterial to their pending application.
69. From the very beginning, MMJ has made every attempt to comply with the government's ever-increasing and ever-convoluted demands. Countless patients who have been affected by Multiple Sclerosis and Huntington's Disease and are waiting on the potentially life-restoring treatments associated with the development of these pharmaceuticals.

70. Despite the fact that MMJ, should not need to comply with the new requirement to submit a BFSA, MMJ attempted to submit several documents to fulfill this requirement, all of which were rejected. For example, on April 20, 2021, MMJ provided an agreement with the University of Connecticut (UConn) to provide UConn researcher Dr. Stephen Kinsey marijuana on April 20, 2021. MMJ gathered all documentation regarding Dr. Kinsey's Schedule 1 researcher registration and Dr. Kinsey's DEA-approved research protocol and provided it to DEA Diversion Investigator Thomas Cook.
71. For some unintelligible reason, the agreement between MMJ and UConn/Dr. Kinsey was found to not be a valid bona fide supply agreement. The reason later cited by the DEA was that the signature line for UConn's representative was not dated, despite there being no such requirement under 21 CFR 1300 et. seq. nor any such request made by the government in its communications with MMJ prior to the Order to Show Cause.
72. The BFSA requirements were not explained to MMJ by DEA, nor did agents of the DEA (namely, DI Cook) provide any guidance on how to fulfill this requirement upon inquiry by MMJ.
73. The regulations provide that an applicant must produce a bona fide supply agreement, which is defined as "a letter of intent, purchase order or contract between an applicant and a researcher or manufacturer registered under the Act." See 21 C.F.R. § 1318.02(g); See also 21 C.F.R. § 1318.05(b)(3)(i).
74. However, the DEA attempted to assert a slew of additional requirements (e.g. the requirement that prices be set) in their Order to Show Cause, which do not exist in the regulations.

75. Indeed, if looking at the plain language definition of the term “bona fide supply agreement,” it is patently clear to see that the drafters also intended that they include speculative agreements like letters of intent. See 21 C.F.R. § 1318.02(g). It is either incredibly disingenuous for the DEA to essentially require an ironclad contract for a speculative business relationship based on a license which has not yet been granted, when the regulations permit submission of a mere letter of intent between the parties.
76. Further, it appeared that the DEA instead sought to obfuscate the process and create a target that seemed impossible to hit. Ultimately, the BFSAs were deemed insufficient in the Order to Show Cause and DEA refused to provide any explanation as to why it would not be permitted under the DEA regulations.
77. There have been several other instances where the DEA has further obfuscated the process regarding the BFSAs. For example, in October 2022, DPM Mark Rubbins suggested that MMJ enter into a BFSAs with Dr. Juan Sanchez-Ramos (“Dr. Ramos”), a researcher with whom MMJ had previously established a relationship with. At that point in time, Dr. Ramos’ registration had lapsed. Despite this, DPM Rubbins told MMJ to “just have Dr. Ramos submit his application and we will do a small background check and get it approved.” Despite this, however, the DEA ultimately decided to deny Dr. Ramos’ registration and, again, leave MMJ in limbo.
78. In a phone call with MMJ shortly after the October 2022 meeting, DEA’s Matthew Strait informed MMJ that “the BFSAs should be between MMJ and the DEA and this is how the other registrants meet this requirement.” Presumably, Mr. Strait’s contention is based upon the fact that there exists the international treaty called the Single Convention, which obligates all members of the Convention to appoint a single government agency of the

United States to purchase and take possession of all manufactured marijuana. Controls to Enhance the Cultivation of Marijuana for Research in the United States, 85 F.R. 82333. Accordingly, MMJ submitted a BfSA with this arrangement, but this agreement was also denied.

79. Time and time again, the process is obfuscated by the DEA and its agents despite MMJ's obvious desperation to obtain clarity on the alleged "requirements."

Order to Show Cause & ALJ Proceeding

80. Following the Order to Show Cause being served on MMJ on October 31, 2023, MMJ filed a Request for Hearing with the DEA.

81. ALJ Theresa Wallbaum has been assigned for the hearing.

82. Following MMJ's filing the Request for Hearing, but prior to any hearing taking place, ~~MMJ has reviewed the appointment of ALJ Wallbaum, and~~ now objects to the Constitutionality of the proceeding.

ALJ Proceeding Unconstitutional

83. ALJs are recognized as officers under Article II of the U.S. Constitution. Their appointments are in accordance with the Administrative Procedure Act (APA). As per the APA and its accompanying regulations, ALJs perform several crucial duties, such as presiding over administrative proceedings and exercising substantial authority. Notably, Sections 1316.52 and 1316.42(f) of Title 21 of the Code of Federal Regulations specifically mandate ALJs to oversee administrative proceedings.

84. According to Section 930.204(a) of Title 5 of the Code of Federal Regulations, DEA ALJs are granted career appointments and are excluded from probationary periods that are applicable to specific government employees.
85. Similar to SEC ALJs, whom the Supreme Court has deemed inferior officers under Article II, DEA ALJs possess wide discretion to wield significant authority in administrative proceedings. According to 5 U.S.C. § 556(c), DEA ALJs have the power to: (1) administer oaths and affirmations; (2) issue subpoenas as authorized by law; (3) rule on offers of proof and admit relevant evidence; (4) conduct or order depositions when necessary for justice; (5) regulate the proceedings; (6) convene conferences to settle issues through consent or alternative dispute resolution methods; (7) inform parties about alternative dispute resolution options and encourage their utilization; (8) compel attendance at conferences; (9) address procedural requests or similar matters; (10) render or recommend decisions; and (11) undertake other actions permitted by agency regulations in line with the APA.
86. DEA regulations bestow authority upon DEA ALJs to conduct adjudicative functions during hearings and resolve adversarial proceedings on behalf of the DEA. According to Section 1316.52 of Title 21 of the Code of Federal Regulations, DEA ALJs are mandated to conduct fair hearings, prevent delays, and maintain order. Additionally, under the same regulation, DEA ALJs possess the following powers: (a) Adjust the date, time, and location of hearings and prehearing conferences, issuing notice accordingly. (b) Convene conferences to resolve, simplify, or determine issues in hearings, or address other matters facilitating prompt resolution. (c) Request parties to submit written statements outlining their positions on various issues in the hearing, and exchange these statements with all

other involved parties. (d) Issue subpoenas to ensure witness attendance and document production essential for administrative hearings. (e) Interrogate witnesses and instruct them to testify. (f) Admit, rule on, exclude, or limit evidence. (g) Make rulings on pending procedural matters. (h) Take any action permitted to the presiding officer as stipulated by this regulation or the provisions of the APA.

~~87. Section 3105 of Title 5 of the United States Code outlines the procedure for appointing ALJs across all federal agencies, including those within the DEA. This legislation stipulates that each federal executive agency is obligated to appoint a sufficient number of ALJs to facilitate its administrative proceedings.~~

~~88. Upon information and belief, DEA ALJs are appointed by the DEA Administrator. The process entails the DEA Administrator selecting ALJs from a candidate pool that submits applications to the Office of Personnel Management (OPM). Subsequently, the DEA Chief ALJ assesses these applications and recommends certain ALJ candidates for the DEA Administrator's consideration and appointment.~~

~~89. Similarly, it is believed that ALJ Wallbaum, who presides over MMJ's Administrative Proceeding within the DEA, was chosen from a pool of candidates provided by OPM. Based upon information and belief, following this selection process ALJ Wallbaum was appointed by the DEA Administrator, based on the recommendation from the DEA's Chief ALJ.~~

~~90. The appointment of DEA ALJs by the DEA Administrator raises concerns regarding compliance with Article II's Appointments Clause. This clause specifies that appointments must be made by the "head" or "principal officer" of an executive department. However, the DEA Administrator does not hold such a position within an~~

~~executive department. Instead, the DEA operates as an agency within and subordinate to the Department of Justice, which is an executive department under Article II of the Constitution.~~

91. ~~The Attorney General of the United States serves as the primary official of the Department of Justice. Being the head of the Department under which the DEA operates, the exclusive authority to appoint DEA ALJs lies with the Attorney General, in addition to the President. The DEA Administrator does not possess the constitutional mandate or authority to appoint an ALJ.~~
92. ~~Neither the President nor the Attorney General appoints ALJs to serve within the DEA. Consequently, the appointment process for DEA ALJs violates the Appointments Clause, representing a fundamental flaw in the DEA's administrative enforcement procedures.~~
93. ~~Moreover,~~ the regulatory and administrative framework governing the removal of DEA ALJs ~~also~~ infringes upon Article II. This framework undermines the constitutional responsibilities of the President and the Attorney General to execute executive power and enforce laws faithfully, including overseeing inferior officers like ALJs, including the power to remove them without cause.
94. According to the APA, ALJs, including those within the DEA, can only be removed for good cause as determined by the Merit Systems Protection Board (MSPB). This statutory constraint means that neither the President nor the Attorney General can independently ascertain "good cause" and subsequently remove DEA ALJs without MSPB approval. However, members of the MSPB themselves cannot be removed except for good cause. This dual requirement for cause-based removal infringes upon Article II, as interpreted by the Supreme Court in *Free Enterprise*.

95. This convoluted removal structure violates Article II's requirement that inferior executive officers not be protected from removal by their superiors at will, when those superiors are themselves protected from being removed by the President at will.
96. As stated previously, DEA ALJs hold executive positions and exercise significant executive authority. Nonetheless, (a) DEA ALJs are safeguarded from removal by a "good cause" standard outlined in 5 U.S.C. §7521(a), and (b) members of the MSPB responsible for determining this standard are shielded from removal except for reasons of inefficiency, neglect of duty, or malfeasance in office, as per 5 U.S.C. §1202(d). This arrangement impedes the President's Article II executive authority and ensures that neither the President nor the Attorney General, as the Head of Department, can fulfill their duty to faithfully execute laws by independently assessing whether good cause exists to remove inferior officers.

CAUSES OF ACTION

COUNT ONE

(Application for Injunctive Relief)

97. MMJ repeats and incorporates each and every allegation in all preceding paragraphs as if fully set forth here.
98. Without injunctive relief from this Court, MMJ will be required to continue to submit to an unconstitutional proceeding led by an unconstitutional decisionmaker which constitutes a "here-and-now injury" that is "impossible to remedy once the proceeding is over, which is when appellate review kicks in" under *Axon*, 598 U.S. at 191.
99. This, in and of itself, constitutes irreparable harm to Plaintiff unless the Administrative Proceeding is enjoined.

100. If the DEA Administrator, upon recommendation from the presiding DEA ALJ, finds that MMJ's registration is against the public interest, the harm will be severe and irreversible. MMJ's may be forced to close its doors. This comes after years of the DEA's failure to follow the clear requirements under the Controlled Substances Act and general malfeasance. Moreover, Plaintiff could not obtain meaningful judicial review in time to prevent this outcome. Nor can this harm be remedied after-the-fact with money damages, as numerous immunity doctrines would prevent MMJ from obtaining a financial damages award from DEA.

COUNT TWO
(Declaratory Judgment)

101. MMJ repeats and incorporates each and every allegation in all preceding paragraphs as if fully set forth here.

102. ~~MMJ requests a declaratory judgment that the statutes, regulatory provisions, and policies providing for the appointment of DEA ALJs are unconstitutional as applied by DEA and DOJ.~~

103. MMJ further requests a declaratory judgment that the statutes, regulatory provisions, and policies providing for removal of DEA ALJs are unconstitutional as applied by DEA and DOJ.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for an Order and Judgment:

(a) Declaring unconstitutional the statutes, regulatory provisions, and policies providing for the ~~appointment and~~ removal of DEA ALJs as applied by DEA and DOJ;

(b) An order and judgment enjoining DEA and DOJ from carrying out an administrative proceeding against MMJ, including on the Order to Show Cause at issue or any other

proceedings with regard to MMJ's DEA MMJ's DEA Certificates of Registration unless and until a constitutionally valid system is in place;

(c) Judicial review of the DEA's Order to Show Cause, and finding that MMJ met its burden for issuance of the manufacturer registration under applicable law; and

(c) Such other and further relief as this court may deem just and proper, including reasonable attorneys' fees and costs of this action.

Respectfully submitted,

Dated: April 5, 2024

/s/ Megan E. Sheehan, Esq.

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