UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

SIMFA ROSE PHARMACEUTICAL SPECIALTY, INC.,

Plaintiff, **Case No. ______________**

v.

MERRICK B. GARLAND, Attorney General of the United States,
ANNE MILGRAM, Administrator of the Drug Enforcement Administration,
DRUG ENFORCEMENT ADMINISTRATION; and
THE UNITED STATES OF AMERICA,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Simfa Rose Pharmaceutical Specialty, Inc. ("Simfarose Pharmacy"), for its complaint against Defendants Merrick B. Garland, in his official capacity as Attorney General of the United States, the United States Department of Justice ("DOJ"), Anne Milgram, in her official capacity as Administrator of the Drug Enforcement Administration, the United States Drug Enforcement Administration ("DEA"), and the United States of America, by and through its Attorney, hereby alleges and states as follows:

NATURE OF THE ACTION

1. This action arises from DEA's attempt to subject Plaintiff to an unconstitutional administrative proceeding before a DEA Administrative Law Judge ("ALJ"). Defendants issued an Order to Show Cause and Immediate Suspension of Registration compelling Simfarose Pharmacy to participate in an unlawful adjudicative process before a DEA ALJ.

2. DEA's scheme subjecting registrants to preliminary and final decisions, penalties, enforcements, and hearings substantially violates Plaintiff's constitutional rights.

3. The pending DEA administrative proceeding against Simfarose violates constitutional separation of powers principles. Plaintiff is subjected to a hearing before a DEA ALJ appointed in violation of Article II of the United States Constitution. The United States Supreme Court in *Lucia* has found that an ALJ appointment process nearly identical to that exercised by the DEA is unconstitutional and DEA has not altered their appointment process consistent with constitutional requirements. *Lucia v. SEC*, 138 S. Ct. 2044 (2018). DEA ALJs are not appointed in accordance with Article II, Section 2, Clause 2 of the United States Constitution ("the Appointments Clause"). Under the Appointments Clause, inferior officers such as DEA ALJs must be appointed by the President or the Head of their Department - the Attorney General of the United States. The DEA ALJs have not been appointed by either. 21 C.F.R. § 1316.52 provides that, "A presiding officer, designated by the Administrator, shall preside over all hearings." The DEA is unable to provide a properly appointed DEA ALJ to preside over the Plaintiff's hearing.

4. Furthermore, the DEA ALJ's dual layer for-cause statutory restrictions violates the President's Article II executive power. This dual-layer removal protection prohibits the President from faithfully executing the law under the Take Care Clause of the United States Constitution. The Court in *Lucia* determined that ALJs, nearly identical to DEA ALJs, are inferior officers and must not be insulated from removal in order to satisfy separation of powers principles. *Lucia,* 138 S. Ct. 2044. The DEA's scheme provides dual layer for-cause protection of both the ALJs and the Board Members of the Merit Systems Protection Board ("MSPB") because both parties are only removable "for-cause", thus insulating the ALJs in

violation of Article II of the United States Constitution. 21 C.F.R. § 1316.52 provides that, "A presiding officer, designated by the Administrator, shall preside over all hearings." The DEA is unable to provide a DEA ALJ that is not subject to removal "for-cause," thus insulating all present DEA ALJs. Therefore, the DEA is unable to provide a constitutionally removable and accountable DEA ALJ to preside over the Plaintiff's hearing.

5. The Court in *Jarkesy* held that an administrative law proceeding was unconstitutional, ruling that "Congress unconstitutionally delegated legislative power to the SEC by failing to give the SEC an intelligible principle by which to exercise the delegated power." *Jarkesy v. SEC*, 34 F.4th 446, 465 (5th Cir. 2022) *cert. granted* 2023 WL 4278448, ____ S.Ct. ____ (June 30, 2023). Congress may not delegate their legislative powers to the DEA and provide the DEA the ability to create laws through enforcement adjudication. The current DEA administrative process is as a subterfuge to legislation through adjudication - creating and enforcing laws through their administrative hearings. Furthermore, "Congress, or an agency acting pursuant to congressional authorization, cannot assign the adjudication of such claims to an agency because such claims do not concern public rights alone." *Id.*

6. The Seventh Amendment ensures the right to a jury trial for all adjudications "analogous to Suits at common law." *See Axon Enter. v. FTC*, 143 S. Ct. 890, 910 (2023).

7. Similarly, Congress's delegation of legislative power to the DEA allows the DEA to choose whether the DEA pursues a matter under their own statutory scheme or in an Article III court. The DEA's success rate is near perfect when pursuing matters under their own watch instead of an Article III court where the registrant is afforded fair, equitable, and hearing before an impartial judge as required by due process.

8. The entire structure of the DEA's administrative enforcement process is constitutionally defective. It violates separation of powers because one agency has been granted the authority to create rules (legislate), enforce them (an executive function), and adjudicate them (judicial power) in their internal administrative enforcement process, all based on the opinions of private citizens DEA hired as "expert" pharmacist and pay handsomely to make up rules to enforce as they go along under DEA's "red flags" concept. The Government cannot deprive citizens private rights to property in this manner. In this case, DEA's flavor-of-the month alleged expert is a competitor of the Plaintiff's. He invented a sweeping, unsupported and absurd new medical standard of treatment (that contradicts the "expert's" prior testimony and every other DEA "expert's" testimony) and a new rule that completely denies patients without insurance access to medications just for DEA to subject Plaintiff to enforcement proceedings in its internal tribunal, where DEA never loses and its experts are always found more reliable and credible than the pharmacies' experts. Specifically, according to DEA's supposed expert, no pharmacy can ever fill (and no doctor can ever prescribe) a prescription for immediate release pain medication to ***any patient, including patients with cancer,*** for more than two (2) to three (3) months and no pharmacy can ever dispense more than one (1) controlled substance prescriptions to ***any*** patient that does not have insurance. This violates due process, equal protection of the law, is an unconstitutional delegation of authority to a private person in the regulated industry who is Plaintiff's competitor, and violates the CSA and constitutional principles federalism as his opinions positively conflict with governing state law.

9. Defendants served Plaintiff with an Order to Show Cause and an Immediate Suspension Order. The DEA may serve a registrant with an Immediate Suspension Order if

the Attorney General finds "that there is an imminent danger to the public health or safety[….]A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction." 21 U.S.C. § 824(d). The DEA immediately suspended Plaintiff's license, a protected property right, and irreparably harmed Plaintiff's business and has not and cannot provide Plaintiff with a prompt constitutional post-deprivation hearing as demonstrated herein. aThe Due Process clause of the U.S. Constitution protects against property and other rights being taken without notice and an opportunity to be heard, and Plaintiff's due process rights are being violated.

10. The DEA's administration hearing process is unable to provide a constitutionally appropriate judicial review and therefore, Plaintiff's due process rights and Article III have been violated, and Plaintiff is entitled to dissolution by this Court. Plaintiff's fifth and fourteenth Amendment Due Process rights have been and continue to be violated while being subjected to an unconstitutional hearing while their property has been taken and Plaintiff seeks equitable relief.

11. Plaintiff suffers irreparable harm from being subjected to a hearing before a DEA ALJ.

12. Plaintiff suffers irreparable harm from the delay caused by DEA's failure to provide Plaintiff with a constitutional hearing process.

13. Plaintiff's likelihood of success is great because the DEA's hearing process violates multiple constitutional rights.

14. Plaintiff's likelihood of success on the merits, because the decision to immediately suspend its registration was arbitrary and capricious and unconstitutional.

THE PARTIES

15. Plaintiff Simfa Rose Pharmaceutical Specialty, Inc (a/k/a Simfarose Pharmacy) is a Florida corporation with its principal place of business in Pembroke Pines, FL.

16. Simfarose Pharmacy is a family-owned and operated community pharmacy that has been in business since 2007. It is registered with the DEA to dispense controlled substances and its registration number is FS0588004.

17. Defendant Merrick B. Garland is the Attorney General of the United States, and the head of department of the United States Department of Justice. He is sued in his official capacity.

18. Defendant Drug Enforcement Administration is a federal agency, headquartered in Washington, D.C., within the United States DOJ.

19. Defendant Anne Milgram is the Drug Enforcement Administration Administrator. She is sued in her official capacity.

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

JURISDICTION AND VENUE

21. This action arises under the United States Constitution, the Controlled Substances Act, and the Administrative Procedures Act.

22. This Court has subject matter jurisdiction over this action pursuant to 21 U.S.C. § 824(d)(1); 28 U.S.C. § 1131, 1337, 1346. *See also, Axon Enter., Inc.*.

23. The United States has waived its sovereign immunity from this lawsuit in 5 U.S.C. § 702. It has also waived its sovereign immunity through the federal common law principle of non-statutory review. Additionally, this action is not barred by sovereign immunity because the actions challenged were taken by defendants Merrick B. Garland and

Anne Milgram outside the scope of their statutory authority and thus not actions of the sovereign and/or were taken within the scope of their authority in violation of Plaintiff's constitutional rights and the power upon which their conduct is based is unconstitutional.

24. This Court is authorized to issue the non-monetary relief sought herein pursuant to 5 U.S.C. §§ 702, 703, 705, and 706.

25. Venue is proper in this Federal District Court 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. Venue is also proper in this Court under 28 U.S.C. § 1391(e)(1)(B) because a substantial part of the events giving rise to the claim occurred in this District.

BACKGROUND

THE CONTROLLED SUBSTANCES ACT

26. The Controlled Substances Act (CSA or the "Act") creates a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in the manner authorized by the Act. *Gonzales v. Raich*, 545 U.S. 1, 13 (2005); *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823, 827 (11th Cir. 2018). The Act requires pharmacies that dispense prescriptions for controlled substances, to obtain proper registration (i.e., a license) from the Attorney General.

27. The Attorney General has delegated his authority under the CSA, including the authority Congress conferred on him to deny, revoke, or suspend pharmacy registrations, to the Administrator of the DEA. 21 C.F.R. § 0.100.

28. DEA may revoke an existing registration or deny any application for registration if the registration would be "inconsistent with the public interest." 21 U.S.C. §§ 824(a)(4) & 823(f).

29. When the DEA proposes to revoke an existing registration it must serve an order to show cause on the registrant that contains a statement of the basis for the proposed revocation, including specific citations to any laws or regulations alleged to be violated and directs the registrant to appear before the Agency at a time and place not less than thirty (30) days from the date of receipt of the order. 21 U.S.C. § 824(c). Proceedings to revoke a pharmacy's registration shall be conducted in accordance with the APA. 21 U.S.C. § 824(c)(5); 21 C.F.R. 1316.52.

30. The Act grants the Attorney General (delegated to DEA) limited authority to suspend a registration simultaneously with the institution of revocation proceedings and to seize all controlled substances in the registrant's possession at the time of the suspension only in cases where he finds that there is an "imminent danger to the public health and safety" justifying this urgent action without notice and before a hearing. 21 U.S.C. § 824(d)(1);[1] 21 C.F.R. 1301.36(f).

31. Congress was careful to strictly limit the authority to suspend a registration without notice and an opportunity for a hearing only to "emergency situations" where it is necessary to protect genuine "imminent danger to the public health and safety" "to preserve constitutional safeguards with reference to the seizure of property or the deprivation of professional status without notice." *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822,

[1] "Imminent danger to the public health and safety" means that "due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this subchapter or subchapter II, there is a substantial likelihood of an immediate threat of death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registrant." 21 U.S.C. § 824(d)(2).

828-29 (5th Cir. 1976); *Cardinal Health, Inc. v. Holder*, 846 F.Supp.2d 203, 216, 225, 227 & 229-30 (D. D.C. 2012).

32. Additionally, under the statutory framework of the CSA and DEA regulations, and due process requirements, if the DEA issues a pre-hearing suspension order based on a finding of "imminent danger to the public health and safety," it must provide a prompt post-deprivation hearing at the registrant's request. 21 U.S.C. 824(d)(1); 21 C.F.R. 1301.36(h).

33. If the DEA exercises its immediate suspension authority without providing a registrant a prompt constitutional hearing upon request, DEA violates the CSA, its own regulations, and deprives it of protected property interests without due process of law in violation of the Fifth Amendment.

34. Any suspension under 21 U.S.C. 824(d) remains in effect until the conclusion of the administrative hearing proceedings, including judicial review thereof, unless sooner withdrawn by the Administrator or "dissolved by a court of competent jurisdiction." 21 U.S.C. 824(d)(1); 21 C.F.R. 1301.36(h).

THE DEA'S FUNDAMENTALLY FLAWED, INHERENTLY UNFAIR AND CONSTITUTIONALLY DEFECTIVE ADMINISTRATIVE HEARING PROCESS

35. The DEA employs only three ALJs, two are former DEA attorneys.

36. The ALJ ostensibly presides over the hearing and all prehearing matters and offers a mere recommendation to the Administrator, who has the final say and not surprisingly always finds for herself in her own "court," rubber stamping her own ISO/OSC that initiated the proceedings.

37. In the rare event that an ALJ makes a recommendation that is not completely favorable to the DEA, the Administrator overrules the ALJ.

38. Furthermore, Appellate Courts cannot review factual determinations and findings made by the Administrator in their final agency decision, instead they must take the Administrator's findings as conclusive. 21 U.S.C. § 877.

39. The Administrator has complete control over the entire process – from issuing the order to show cause to issuing the final decision.

40. The crushing effect the ISO has on the registrant's business (and livelihood) requires expediency on the registrant's part.

41. The Government often takes years to "investigate" before issuing an OSC/ISO and freely is granted extensions for any reason such as "limited resources" while registrants like doctors and pharmacies are held to stringent deadlines and forced to litigate quickly with very limited information after the ISO/OSC is issued. This is exactly what happened in Plaintiff's proceeding.

42. Under DEA regulations, registrants are only permitted very limited and basic information late in the process after the prehearing conference. There is no right to any discovery beyond this without the permission of the ALJ, which is routinely denied. In Plaintiff's case for example, the ALJ denied Plaintiff's request for subpoenas to health insurers that would have provided Plaintiff with highly relevant and admissible documents on the patients at issue because they ALJ believed they were not "necessary."

43. The Government is aware that immediate suspension orders have a crippling effect on pharmacies' businesses and that judicial review of these orders is extremely limited under current case law and it exploits this and the limited resources small pharmacies have to fight being forced to succumb to DEA's administrative hearing process.

44. As a result, DEA has an almost unbeaten record in its in-house tribunal (but does not fare as well in federal court).

45. Litigating against (and for) the DEA in its home court is so wrought with abuse from the DEA's combined legislative and policy making, executive, and adjudicative power over the entire proceedings that even the DEA's own Chief ALJ publicly acknowledges how unfair it is and questions why respondents dragged before the Agency are not running "to seek redress in federal courts." John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters,* 101 Marquette Law Rev. 333, 450 (2017).

46. In a law review article, DEA Chief ALJ Mulrooney - the only non-former DEA attorney - openly criticized the Administrator and unelected, unappointed members of the Administrator's staff for brazenly violating the APA, DEA's hearing regulations, and due process and provided numerous examples of how DEA wields expansive, unchecked legislative, executive, and judicial powers in its administrative enforcement proceedings to deprive individuals of vested private rights to property (their registrations and in turn livelihoods), including but not limited to:

- Considering evidence that was excluded by the ALJ during the hearing to support the sanction imposed against respondent in derogation of its due process right to respond to the evidence against him, which the D.C. Circuit Court of Appeals also rebuked the Administrator for. *Masters Pharmaceuticals, Inc. v. DEA,* 861 F. 206, 229 (D.C. Cir. 2017).

- Frequently disregarding the "defined structure of adjudicatory duties and insulation Congress provided litigants" in the APA that are "laced into DEA's own regulations" to "ensure a just result and an appearance of fairness" and their case will be decided by an "impartial judge." This includes sua sponte reversals of ALJ decisions on matters exclusively within their authority that deny the respondent's right to due process. Frequently, the Administrator's "anonymous staff members step into the role of pseudo-ALJs and manage contested litigation – without offering any of the protections that the ALJ structure affords to litigants" at the final order stage to help the Government shore up its case or fix its mistakes. This includes directing the Government to cure defects in evidence and resubmit it and then accepting this evidence into the record over respondent's objection gratuitously correcting an important mistake in the Government's charging documents. Mulrooney noted that this violates the APA and "risks a determination that the 'proceedings' were ultra vires and per se violative of due process."

- Conversely, the Administrator's staff have been "markedly more aggressive" against respondents in applying overly technical bases to disregard issues raised in their filings.

- Expansively taking official notice of facts after the hearing in final orders to exclusively favor the Government without ever giving respondents a real opportunity to contest them.

- The Administrator's staff frequently "drop additional facts" into the record while they are drafting final orders in violation of the APA's prohibition of conducting investigative functions and simultaneously advising on the Agency's final adjudication.

- The Administrator often publicly and gratuitously scolds ALJ's in final orders published in the Federal Register "with increasing aggressiveness" to bully them into deciding for the Agency and develop general bias toward respondents. ALJ Mulrooney also lamented the "increased willingness on the part of the Agency to disregard facts found by impartial ALJs and substitute its own, different facts" and to disregard the legal findings of its ALJs in Agency final orders.

Mulrooney, 101 Marquette Law Rev. at 420-451 ("Agency final orders have more aggressively utilized official notice, summary disposition, and litigation by consent, and have arguably demonstrated a voracious appetite for supplanting the facts and law recommended by its impartial ALJs with the Agency's own facts and law based on its review of the record.")

DEA'S USE OF ADMINISTRATIVE ENFORCEMENT ACTIONS AGAINST PHARMACIES AND WHOLESALERS/DISTRIBUTORS OF CONTROLLED SUBSTANCES

47. Under intense pressure to produce results and make up for its own well-documented failures to address the opioid crisis, DEA invented an amorphous concept of what it calls "red flags" in administrative enforcement actions against pharmacies it began herding through its in-house tribunal in or around 2012.

48. According to the DEA, a "red flag" is a circumstance that does or should raise a reasonable suspicion that a controlled substance prescription may not be for a legitimate

medical purpose. Final Agency decisions in enforcement actions latched on to the general concept of red flags as a means to potentially meet its (own) difficult burden to demonstrate the requisite degree of scienter for a violation of a pharmacist's "corresponding responsibility" by establishing "willful blindness." 21 C.F.R. 1306.06 (a pharmacist may not "knowingly" fill a prescription that was not "issued for a legitimate medical purpose by a [prescriber] in the usual course of his professional practice"). That is, according to DEA's legal reasoning, if a pharmacist does not address an alleged red flag before filling a prescription, this could be some circumstantial evidence that the pharmacist deliberately turned a blind eye to circumstance(s) demonstrating to a high degree of certainty that the prescription lacked a legitimate medical purpose.

49. Red flags - including what is a red flag, what a pharmacist is expected to do when a red flag is present, and given that "all red flags do not have the same hue," which ones and how many must be present and in what combinations to show willful blindness - are not contained in the CSA or DEA's regulations or in any DEA guidance, rule or publication. Despite numerous requests from the regulated community over many years, DEA refuses to issue any formal or informal rules or guidance whatsoever on this controversial policy even though it easily could.

50. Instead, DEA uses its red flags concept to create new broad general standards of pharmacy practice without undergoing APA rulemaking and simultaneously enforce them against select pharmacies arbitrarily targeted for unconstitutional revocation and suspension proceedings before DEA's internal tribunal where it is prosecutor, judge, and jury.

51. When a registrant is subjected to enforcement actions in DEA's home "court' and the results thereof often tend to depend on things like the type and size of the pharmacy, how much money it has, and whether it has influence within the DEA affects the outcome.

52. For example, when DEA claims large national chain pharmacies like Walmart dispensed prescriptions without resolving red flags, it uses the threat of enforcement actions during settlement negotiations to extract exorbitant settlements from them and secondarily an agreement to implement DEA demanded protocols to address red flags. When Walmart (and other large pharmacies with deep pockets) did not agree to DEA's settlement terms, the DOJ sued Walmart in district court for civil penalties and an injunction under the CSA.

53. Other large national pharmacy chains and distributors have effectively bought their way out of ISO's and OSC revocation proceedings by paying the Government hundreds of millions of dollars and agreeing to implement DEA's protocols for resolving alleged red flags.

54. DEA pursues the same red flag allegations against small, independent, non-chain pharmacies by issuing ISO/OSC's that lock them into its internal administrative proceedings. DEA has no real interest in securing or improving any compliance from them or engaging in any cooperative efforts to combat abuse and diversion through these proceedings. Instead, the DEA is out for blood and wants only to put them out of business.

55. Yet other pharmacies within this same class are treated differently and are sued in federal court where they enjoy all the protections of litigation in an Article III court and a fair constitutional hearing before a neutral decision maker that those hauled before DEA can only dream of. There is no legitimate rational basis for this selective enforcement. Rather, the Government funnels what it considers to be a "hard case" to the DEA because it never loses

there and brings easy ones, including cases involving egregious and obviously criminal dispensing, in federal court where things are fair.

56. The most recent DEA scandal involves both a violation of the Appointments Clause and the DEA's fundamentally flawed and inherently unfair administrative hearing process – two (2) of the constitutional violations at issue in this case – and illustrates the real and significant constitutional concerns when executive, legislative, and adjudicative power is consolidated in an agency. DEA evaded the Appointments Clause requirements when re-hiring Louis Milione as DEA's second-in-command because shortly after leaving DEA he went to work for companies that fueled the opioid crisis such as Purdue Pharma as a $600/Hr "consultant" in opioid litigations against them.

57. When investigation by journalists with the Associated Press exposed Milione's relationship with opioid manufacturers and distributors in May of 2023, they began looking into Milione's position with DEA and whether he used it to improperly influence an administrative enforcement action pending against one of his former clients, Morris & Dickson Co., LLC – the nation's fourth (4th) largest wholesale distributor of pharmaceutical drugs. DEA commenced this proceeding on May 2, 2018 by issuing a combined ISO/OSC to Morris & Dickson. Morris & Dickson then hired Milione as part of a $3 million contract to help persuade DEA it changed its ways and should be allowed to keep its license.

58. DEA voluntarily withdrew the ISO against Morris & Dickson on May 18, 2018, just days after imposing it, thus permitting it to distribute and sell controlled substances until the Administrator made a final decision after the conclusion of the OSC hearing. Upon information and belief, DEA has never voluntarily withdrawn (in 16 days no less) an ISO for any registrant other than Morris & Dickson.

59. In late May 2023, the journalists investigating the story reported that they sought comment from DEA, Milione, and Milgram as to Milione's relationship with Morris & Dickson and why DEA continues to let Morris & Dickson sell drugs even though the ALJ's issued a recommended decision on November 26, 2019 finding that DEA permanently revoke Morris & Dickson's registration for its "cavalier disregard" of 12,000 unusually large suspicious orders of opioid drugs (including 4.5 million hydrocodone and oxycodone pills sold between 2014 and 2017 to a single pharmacy indicted for filling forged prescriptions from pill mill doctors).[2]

60. Milgram, who is at the center of another scandal for allegedly awarding friends and associates $4.7 million in no-bid DEA contracts, has complete and unfettered control over the entire hearing process, including whether and when, if at all, to make her final decision in any given case. Absent mandamus relief from a court, there is nothing in the CSA or DEA's regulations that would prevent Milgram from sitting on the ALJ's recommendation decision in the Morris & Dickson case or any other case for as long as she wants and for any reason or no reason at all.

61. Milione quietly resigned from the DEA four (4) days after they broke the story about his relationship with Morris & Dickson and Perdue. On May 30, 2023, two (2) days after the reporters began questioning DEA about this, a final Agency decision adopting the ALJ's 2019 recommendation and permanently revoking Morris & Dickson's registration suddenly appeared in the Federal Register. 88 Fed. Reg. 34523 (May 30, 2023).

[2] In 2019, Morris & Dickson agreed to pay the Government $22 million dollars in civil penalties to settle a lawsuit the U.S. Attorney's Office filed against it for violating the CSA by failing to report suspicious opioid orders.

DEA'S ADMINISTRATIVE ENFORCEMENT PROCEEDINGS AGAINST SIMFA ROSE PHARMACY

62. Plaintiff was served an Administrative Investigative Warrant ("AIW") on December 17, 2021.

63. As part of the illegal execution of the AIW, the DEA seized the Pharmacy's server. In addition to the server, which is the heart, brain, and blood of the Pharmacy and stores virtually all information about the patients, the DEA seized a litany of other related and unrelated controlled substances documents.

64. Nearly one and a half year later on April 10, 2023, Plaintiff was served an Order to Show Cause ("OSC") and Immediate Suspension Order ("ISO") out of nowhere. (Exhibit A).[3] A true and correct copy of the ISO/OSC DEA issued to Plaintiff is annexed hereto as Exhibit A and incorporated herein by reference.

65. The ISO has irreparably harmed Plaintiff's business. The ISO affects the Pharmacy more than not being able to buy or dispense controlled substances.

66. In order to bring a meritless enforcement proceeding against Plaintiff and deprive it of its license immediately in the interim, DEA failed to conduct a reasonable objective investigation and intentionally, did not disclose all the evidence to their alleged expert and in fact hid documents from him and only provided him with a very limited set of documents it pre-screened for him so that he would give DEA the opinion it wanted - that the alleged expert did not see anything in the documents he reviewed that showed Plaintiff identified, addressed, and resolved alleged red flags. A true and correct copy of the Government's

[3] The Drug Enforcement Administration's Order to Show Cause/Immediate Suspension Order will hereinafter be referred to as "Exhibit A."

Prehearing Statement submitted to the Tribunal and the Government is annexed hereto as Exhibit B and incorporated herein by reference.[4]

67. DEA's alleged expert's opinions are all conclusively refuted by the documents DEA had in its possession but did not disclose to their proposed expert, are completely unfounded, and required Plaintiff to unlawfully discriminate Respondent provided voluminous documents DEA hid from its proposed expert that refutes his unfounded opinions allegations and explained their significance. A true and correct copy of the Respondent's Supplemental Statement submitted to the Tribunal and the Government is annexed hereto as Exhibit C and incorporated herein by reference.[5]

68. The DEA's supposed expert in this case is a competitor of Plaintiff's that stands to benefit further from Plaintiff's registration being suspended and revoked beyond what DEA pays him.

69. After requesting a hearing, the DEA assigned Teresa Wallbaum to preside over the case. ALJ Walbaum represented the DEA for many years in various matters, including the revocation of a pharmacy's registration.

70. Currently, the Pharmacy 's hearing before ALJ Teresa Wallbaum is set to commence on August 21, 2023 and continue at least until August 29, 2023.

71. At the prehearing conference, ALJ Wallbaum asked Plaintiff's counsel if Plaintiff would be filing a challenge under the recent Supreme Court case *Axon Enterprises v. SEC* and provided the citation information for this case on her own accord. Plaintiff's counsel responded affirmatively and before filing this action notified her further raised Plaintiff's

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[4] The Government's Pre-Hearing Statement in the Administrative Hearing Process will hereinafter be referred to as "Exhibit B."
[5] The Respondent's Supplemental Statement in the Administrative Hearing Process will hereinafter be referred to as "Exhibit C."

constitutional objections and notified her that Plaintiff will be filing this case in District Court.

72. The ALJ advised that she would rule on Plaintiff's motion for a stay once this case is filed.

SEPARATION OF POWERS ISSUES

I. THE DEA'S ADMINISTRATIVE HEARING PROCESS VIOLATES THE APPOINTMENTS CLAUSE

73. Plaintiff repeats and reiterates each and every allegation contained in Paragraphs 1 through 72 as if fully set forth herein.

74. Inferior officers must be appointed by the President or the Head of the Department - in this case the Attorney General. The Supreme Court held in *Lucia* that administrative law judges of the Securities and Exchange Commission are officers of the United States within the meaning of the Appointments Clause (Art. II, § 2, cl. 2), which describes permissible methods of appointing such officers. *Lucia v. SEC*, 138 S. Ct. 2044, 2046 (2018).

75. DEA ALJ's, including the ALJ presiding over Plaintiff's administrative hearing proceedings, are "Officers of the United States" within the meaning of the Appointments Clause of the United States Constitution (Art II, §2, cl. 2). They exercise significant discretion in presiding over adversarial administrative proceedings such as the enforcement proceedings at issue in this case and in issuing decisions that are the Agency's "last word." *See, 5 U.S.C. 556; 21 U.S.C. 824(c); 21 C.F.R. 1316.42(f), 1316.52, 1316.54-1316.61; 1316.66.*

76. Indeed, DEA ALJ's duties are substantially similar, if not virtually identical in all material respects, to the duties of the ALJ in *Lucia.*

77. The Plaintiff has a right to a hearing before an officer properly appointed in accordance with the Constitution. The DEA however has failed and refused to provide Plaintiff with a constitutionally appointed officer causing Plaintiff actual, continuing, ongoing, here-and-now injury that is redressable in this Court.

78. The ALJ presiding over Plaintiff's matter invited counsel to pursue recourse in a court of competent jurisdiction challenging the DEA's hearing process. The ALJ asked to be notified should counsel choose to do so, because an Article III court could potentially remove the ability for the DEA to hear the case overall, or at a minimum drastically affect the administrative hearing proceeding process.

79. The basic remedy for a plaintiff bringing an Appointments Clause challenge is a new hearing before a constitutionally appointed officer. *Ryder v. United States,* U.S. 177, 188, 115 S. Ct. 2031, 132 L. Ed. 2d 136 (1995). Due to removal issues (discussion below) no other DEA ALJ can preside over the case. The Government cannot provide the basic remedy of a new officer.

II. DEA'S DUAL-LAYER REMOVAL PROTECTIONS OF ALJS VIOLATES ARTICLE II'S VESTING OF EXECUTIVE POWER IN THE PRESIDENT

80. Plaintiff repeats and reiterates each and every allegation contained in Paragraphs 1 through 79 as if fully set forth herein.

81. DEA's administrative hearing proceedings, including the proceedings in Plaintiff's enforcement action, are constitutionally defective because the statutory removal restrictions for DEA ALJ's are unconstitutional.

82. Article II vests all executive power in the President and provides that the President must "take Care that the Laws be faithfully executed." U.S. Const. Art. II, Section 3. The Supreme Court has held that this provision guarantees the President a certain degree

of control over executive officers: the President must have adequate power over officers' appointment and removal and authority over their functions and how they carry them out. *Free Enterprise Fund v. Public Co. Accounting Oversight Board,* 561 U.S. 477 (2010); *Myers v. U.S.,* 272 U.S. 52, 117 (1926).

83. Pursuant to the authority delegated to them by the Agency, DEA ALJ's perform substantial executive functions and exercise considerable power over administrative enforcement proceedings by, among other things, controlling the presentation and admission of evidence and issuing decisions that often become final and binding. Therefore, the President must have sufficient control over the performance of their functions, including who holds the positions.

84. DEA ALJ's have no accountability to the President at all. They are appointed for life and are insulated from Presidential removal with two (2) layers of for-cause restrictions which unconstitutionally impede the President's control of the executive power. For this reason alone, the DEA's hearing process is constitutionally defective. 5 C.F.R. 930.204.

85. Sections 7521(a) and 1202(d) Title 5 of the U.S.C. prevent the President (or Attorney General, the Head of the Department DEA is contained within) from removing DEA ALJ's. ALJ's are only removable for "good-cause" determined by the Merit Systems Protection Board ("MSPB"). Members of MSPB are also only removable for "good cause," thus creating a dual-layer protection from the President or Attorney General from removing the DEA's ALJ's. The dual-layer protections violate Article II by providing an additional barrier between the President (or Attorney General) and the ALJ, prohibiting the President from exercising his executive duties.

86. These statutory removal restrictions violate the separation of powers in Article II of the Constitution. The Supreme Court imposed a bright-line limit on Congress's power to interfere with the President's removal authority, holding in *Free Enterprise* that "dual for-cause limitations" on removal of officers violate the separation of powers. The Court held that such insulated protection from removal is contrary to the President's executive authority. *Free Enterprise,* 561 U.S. 477. *See also, Collins v. Yellen,* 141 S. Ct. 1761 (2021); *Seila Law LLC v. CFBP,* 591 U.S. ___, 140 S.Ct. 2183 (2020); *Jarkesy v. SEC*, 34 F.4th 446 (5th Cir. 2022) *cert. granted* 2023 WL 4278448, ___ S.Ct. ___ (June 30, 2023) (holding that the SEC's use of in-house ALJ's under a similar structure violated the Take Care Clause of U.S. Const. Art. II).

87. For this reason alone, DEA's entire administrative hearing process and the unaccountable ALJs it employs is unconstitutional.

III. CONGRESS FAILED TO GIVE THE DEA AN INTELLIGIBLE PRINCIPLE BY WHICH TO EXERCISE THE DELEGATED POWER

88. Plaintiff repeats and reiterates each and every allegation contained in Paragraphs 1 through 87 as if fully set forth herein.

89. Congress must give "intelligible principles" to its delegee in accordance with Article I, Section I of the Constitution known as the "nondelegation doctrine."

90. Congress delegates its legislative Powers of the United States to the DEA.

91. Congress unconstitutionally delegated legislative power to the DEA when it gave the DEA unfettered authority to choose whether to bring enforcement actions in Article III courts or within the agency. *Jarkesy,* 34 F.4th at 459.

92. The DEA is legislating through adjudication and law-making in the process during their administrative hearings. The DEA creates laws through their paid "experts'"

opinions under the guise of adjudication to evade the APA's rulemaking requirements and targets whoever it wants through enforcement proceedings in its internal tribunal, their ALJ preliminary decisions, and through the final decision and order signed off by the Administrator. The DEA's "case law" is written by their own experts, supported by their own experts, and finds registrants in violation of their own decisions, in effect giving the DEA unfettered authority to create their own laws.

93. Subjecting and punishing all registrants for failing to abide by their own secret and unguided laws violates the non-delegation doctrine in Article I, Section I of the U.S. Constitution.

94. Congress has delegated power into one agency - the DEA - which uses its authority to deprive private citizens of their private right to property.

95. The construction and expansion of the administrative hearing process means that the DEA's administrative hearing process stands in the shoes of the district court. This regime allows an executive agency - the DEA, legislate and make laws through agency adjudication.

96. A litigant may appeal their final agency decision to a federal appellate court. However, a litigant receiving limited deferential judicial review, such as Plaintiff, is impermissible.

97. Congress has taken a hands off approach, leaving all vested power in the DEA without providing the DEA with an intelligible principle in which to follow.

IV. DUE PROCESS

98. Plaintiff repeats and reiterates each and every allegation contained in Paragraphs 1 through 97 as if fully set forth herein.

99. The ISO is an informal agency action made reviewable by 21 U.S.C. § 824(d).

100. Plaintiff is adversely affected and aggrieved by the ISO.

101. Plaintiff is suffering a here and now injury by having its registration immediately suspended without an opportunity to be heard.

102. The ISO denied Plaintiff prior notice of the allegations against it and the opportunity to be heard and dispute the allegations included in the OSC/ISO.

103. Notice and an opportunity to be heard are essential where "a person's good name, reputation, honor, or integrity was at stake because of government action." *Wisconsin v. Constantineau*, 400 U.S. 433, 434, 91 S. Ct. 507, 508 (1971).

104. Plaintiff has a property right in its DEA registration and "when private rights are at stake, full Article III adjudication is likely required." *Wellness Int'l Network,* 575 U.S., at 713-714, 135 S. Ct. 1932, 191 L. Ed. 2d 911.

105. Plaintiff's property right was taken without being provided a court of competent jurisdiction, which deprived Plaintiff's core private right. *B&B Hardware,* 575 U.S. at 164, 135 S. Ct. 1293, 191 L. Ed. 2d 222.

106. Depriving Plaintiff of prior notice of the allegations against it and the opportunity to dispute the allegations prior to the suspension of its DEA Registration was not necessary to further any governmental interest, deprived Plaintiff's due process rights afforded by law and the Fifth and Fourteenth Amendments of the U.S. Constitution, and impaired Plaintiff property interest in its DEA Registration.

107. The ISO is contrary to constitutional rights, power, and privilege in violation of 5 U.S.C. § 706(2)(B).

108. The DEA cannot provide Plaintiff with a fair, meaningful and constitutionally valid hearing in a fair tribunal and detached, impartial, independent, and neutral judge in the first instance, thus violating Plaintiff's procedural due process rights.

109. The DEA's use of its red flags concept in individual, ad hoc litigation to formulate entirely new standards of conduct through general, hard and fast rules of broad application announced in constitutionally defective administrative enforcement proceedings where they are applied both retroactively and prospectively is an abuse of discretion, an effort to avoid the rulemaking prescribed by the APA, and violates Plaintiff's due process requirements.

V. EQUAL PROTECTION OF THE LAW

110. Plaintiff repeats and reiterates each and every allegation contained in Paragraphs 1 through 109 as if fully set forth herein.

111. The DEA is prohibiting a class of individuals from obtaining legitimate medical care.

112. The DEA is discriminating against chronic pain patients.

113. The DEA is discriminating against individuals in a low socioeconomic class.

114. The DEA is discriminating against patients without insurance, preventing patients without insurance from paying for their prescriptions at the same pharmacy after the second fill.

115. The DEA is discriminating against individuals from traveling certain distances to obtain medical care.

116. The DEA is discriminating against independent pharmacies and their owners, using ISOs as a device to strip independent pharmacies and their owners of their licenses/registrations.

OTHER CONSTITUTIONAL ISSUES

VI. PRIVATE RIGHTS REQUIRE ARTICLE III COURT & SEVENTH AMENDMENT RIGHT TO JURY TRIAL

117. Plaintiff repeats and reiterates each and every allegation contained in Paragraphs 1 through 116 as if fully set forth herein.

118. The DEA's adjudication of administrative enforcement proceedings against Plaintiff that deprives it of private rights such as its registration is an exercise of judicial power by an executive agency that violates due process and Article III of the United States Constitution.

119. Government deprivations of property such as DEA's suspension and attempted permanent revocation of Plaintiff's registration can only be adjudicated by Article III courts and not executive agencies.

120. Furthermore, vesting primary authority to adjudicate in the DEA the deprivation of vested private rights, Plaintiff's property rights with only deferential judicial review in the United State Court of Appeals on the back end where the Agency's factual findings are conclusive is unconstitutional.

121. The CSA is unconstitutional because congress granted authority to executive agencies such as the DEA and the Attorney General to perform lawmaking functions that the constitution vests exclusively in congress itself.

CAUSES OF ACTION

COUNT ONE
(Dissolution of OSC/ISO)

122. Plaintiff repeats and reiterates each and every allegation contained in Paragraphs 1 through 121 as if fully set forth herein.

123. Without the dissolution of the OSC/ISO, Simfa Rose will be subjected to an unconstitutional administrative proceeding before a DEA ALJ. The Plaintiff will be irreparably harmed and injured if the OSC/ISO is not dissolved.

124. The harm done to Plaintiff by not dissolving the OSC/ISO is severe and irreversible.

125. Without a DEA registration, the Plaintiff's business will be required to cease operations.

126. Under the current scheme, the Plaintiff is not afforded meaningful judicial, especially not before the business being required to cease operations.

127. No remedy after the fact, including monetary damages, are sufficient to redress the Plaintiff's injuries.

128. Plaintiff has a substantial likelihood of success on the merits of its various claims, including constitutional challenges regarding the entire structure of the DEA.

129. The dissolution helps restore faith in the community that constitutional rights trump whim decisions that destroy small businesses and livelihoods.

130. The dissolution of the OSC/ISO helps protect Plaintiff's and other DEA registrants' constitutional rights.

131. Finally, the dissolution of the OSC/ISO allows (1) the pharmacy to serve and provide medicine to their patients and (2) the patients to exercise their constitutional rights and return to the pharmacy of their choice.

COUNT TWO
(Declaratory Judgment)

132. Plaintiff repeats and reiterates each and every allegation contained in Paragraphs 1 through 131 as if fully set forth herein.

133. Plaintiff requests a declaratory judgment that the DEA's entire administrative hearing procedure is unconstitutional.

134. Plaintiff requests a declaratory statement that the statutes, regulatory provisions, and policies providing for the appointment of DEA ALJs are unconstitutional.

135. Plaintiff requests a declaratory statement that the statutes, regulatory provisions, and policies providing for the removal of DEA ALJs is unconstitutional.

136. Plaintiff requests a declaratory statement that the administrative hearing process violates Plaintiffs due process rights.

137. Plaintiff requests a declaratory statement that the administrative hearing process violates Plaintiff equal protection of the law.

138. Plaintiff requests a declaratory statement that Congress granting power to the DEA violates the non-delegation doctrine in the DEA's current scheme.

DEMAND FOR TRIAL BY JURY

139. Plaintiff demands a trial by jury on all issues that are so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for an Order and Judgment

140. Declaring unconstitutional the entire DEA hearing process;

141. An order and judgment enjoining DEA and DOJ from carrying out any administrative proceeding against Plaintiff, including on the Order to Show Cause until a constitutionally valid DEA hearing system is in place;

142. An order and judgment enjoining the DEA from issuing an OSC or ISO on the Plaintiff until a constitutional hearing system is established.

143. Declaring unconstitutional the statutes, regulatory provisions, and policies providing for the appointment of DEA ALJs as applied to the DEA and DOJ;

144. Declaring unconstitutional the statutes, regulatory provisions, and policies providing for the removal of DEA ALJs as applied to the DEA and DOJ;

145. Declaring unconstitutional the delegation of duties from the Congress to the DEA, resulting in an un-intelligible principle;

146. An order and judgment dissolving the Immediate Suspension Order to restore Plaintiff's due process rights;

147. Declaring unconstitutional the statutes, regulatory provisions, and policies providing for unequal protection of the laws, in violation of the Equal Protections Clause.

148. An order and judgment declaring Florida State Statute 64B16-27.831 as the governing law regarding a Florida Pharmacist's standard of care when filling Controlled Substance Prescriptions and that the standards invented by DEA's alleged expert positively conflict with state laws including this statute in violation of the CSA and federalism principles;

149. Declaring unconstitutional that a pharmacist may not fill a third prescription for cash for a patient;

150. Declaring unconstitutional that a pharmacist may not fill non-insurance patients' prescriptions;

151. An order enjoining enforcement of DEA's "red flags" policies as unconstitutional and violative of the APA, and;

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

Dated: August, 8, 2023

Respectfully submitted,

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