IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NEW DIRECTIONS ADDICTION RECOVERY SERVICES, et al., *Petitioners*, v. DONALD J. TRUMP, in his official capacity as President of the United States, et al., *Respondents*.	**Case No. 26-1136** Consolidated with Nos. 26-1106 and 26-1130

DECLARATION OF DUANE BOISE

I, Duane Boise, hereby declare under penalty of perjury pursuant to 28 U.S.C. § 1746 as follows:

1. I am over eighteen years of age and am competent to testify to the matters stated herein. I make this declaration based on my personal knowledge, my review of MMJ records, and my review of public agency records, including the official hearing transcripts published by the Drug Enforcement Administration in Hearing Docket No. 26-96.

2. I am the Chief Executive Officer of MMJ International Holdings, Inc. ("MMJIH") and President of its subsidiaries, MMJ BioPharma Cultivation, Inc.

("MMJBC"), and MMJ BioPharma Labs, Inc. ("MMJBL") (collectively, "MMJ"). In that role, I have personal knowledge of MMJ's organizational structure, operations, finances, regulatory history, capital-raising efforts, and the effect of AG Order No. 6754-2026 (the "Rescheduling Order") on MMJ.

3. MMJIH is a Delaware-incorporated life-sciences company formed to develop pharmaceutical cannabinoid therapeutics under the FDA botanical drug development framework. MMJIH oversees regulatory strategy, clinical development planning, chemistry, manufacturing, and controls work, and Investigational New Drug submissions for cannabinoid-based treatments targeting Huntington's disease and multiple sclerosis.

4. MMJBC is a Delaware-incorporated subsidiary formed to cultivate and produce pharmaceutical-grade cannabis plant material required for MMJIH's FDA-authorized clinical trials and drug development. On December 27, 2018, MMJBC submitted DEA applications to import and manufacture marijuana for FDA-authorized clinical trials and research. Thereafter, MMJ obtained authorization from both Health Canada and the DEA to ship pharmaceutical cannabinoid materials into the United States for MMJ's FDA-regulated development program to prove cannabis's therapeutic efficacy through rigorous clinical science.

5. MMJBL is a Delaware-incorporated subsidiary formed to perform analytical testing, formulation support, and regulatory-grade characterization of

botanical extracts used in MMJIH's drug development program. MMJBL was issued a DEA Schedule I analytical laboratory registration issued after DEA inspection and approval of physical security systems, recordkeeping controls, and diversion-prevention safeguards.

6. MMJBC's bulk-manufacturing registration application remains pending before DEA after more than seven years of regulatory process. DEA commenced its pre-registration Section 303 investigation on June 22, 2021. DEA conducted a final on-site visit on October 24, 2021, and a further visit at MMJ's Westerly, Rhode Island facility on October 12, 2022. MMJ provided requested supplemental information in full compliance. After DEA filed a show-cause order on October 3, 2023 and the ALJ recommended that MMJ's application be denied, DEA Administrator Terrance Cole rejected that recommendation and remanded on September 15, 2026. Subsequently, DEA dropped its show-cause proceeding, and has now restarted its inspection process. MMJBC is currently preparing its facility to undergo final inspection in early December 2026.

7. MMJIH initiated formal regulatory engagement with FDA's Center for Drug Evaluation and Research in August 2018 to kick off the Investigational New Drug (IND) process through pre-IND meeting requests for MMJ-001 (to treat Huntington's disease) and MMJ-002 (to treat multiple sclerosis). FDA opened regulatory files including IND 137754 and IND 140712. On January 29, 2019, FDA

granted Orphan Drug Designation for Δ9-tetrahydrocannabinol and cannabidiol for the treatment of Huntington's disease.

8. Consistent with FDA's Botanical Drug Development Guidance, MMJ developed a standardized botanical cannabinoid soft-gel capsule containing defined quantities of cannabis-derived THC and CBD. MMJ evaluated seven prototype formulations, selected a formulation consisting of 5 mg CBD and 2.5 mg THC per capsule, and engaged Catalent Pharma Solutions to develop and manufacture a soft-gel capsule formulation consistent with FDA IND and CMC requirements.

9. MMJ has submitted two IND applications to FDA supporting clinical development for Huntington's disease and multiple sclerosis. FDA has issued clinical holds, including a Full Clinical Hold letter dated February 7, 2025, addressing clinical and chemistry, manufacturing, and controls (CMC) questions associated with IND 140712. MMJ has submitted responses and supporting materials.

10. Over about eight years, MMJ has invested more than $10 million in scientific, regulatory, financial, and manufacturing resources to advance pharmaceutical cannabinoid therapeutics through the federal FDA and DEA pathways. These investments include FDA regulatory counsel, clinical development strategy, an investigator's brochure, analytical testing, IND-grade soft-gel

manufacturing, accounting and financial advisory services, and construction of a DEA-compliant cultivation and security facility.

11. In addition, MMJ engaged Seaport Global Securities LLC as lead financial advisor for a proposed $45 million capital raise and proposed public listing. That capital-markets strategy depended on MMJ's position as a federally compliant first mover in FDA-approved cannabinoid pharmaceuticals.

12. MMJ has structured its operations to comply with federal law governing both controlled-substance handling and pharmaceutical drug development. MMJBL obtained a DEA Schedule I analytical laboratory registration after DEA inspection and approval of its physical security systems, recordkeeping controls, and diversion-prevention safeguards; MMJBC applied for DEA bulk-manufacturer registration to cultivate and produce marijuana as its active pharmaceutical ingredient (API) for FDA-authorized clinical trials; and MMJ has used federally supervised import and supply-chain procedures to support its FDA botanical drug development program. These controls are designed so that, once MMJ's product is approved, it can be prescribed by physicians, dispensed through lawful pharmaceutical channels, and used by legitimate patients as medicine according to FDA-approved directions.

13. MMJ competes directly against a burgeoning group of businesses that supply federally unapproved cannabis-based products for therapeutic use under state

medical-marijuana programs. Until the Rescheduling Order, MMJ's critical competitive advantage was its rigorous compliance with federal law: MMJ filed FDA IND applications, obtained orphan-drug designation, pursued DEA registration, constructed DEA-inspected laboratory systems, engaged in rigorous formulation development, undertook stability studies and analytical testing, and instituted full pharmaceutical manufacturing controls—all for the purpose of bringing federally compliant and therapeutically effective cannabis-based medicine to market. Meanwhile, to reach states' medical marijuana markets faster and to secure substantial market share, MMJ's competitors have skipped these important steps: Their products have not undergone the same DEA registration process, FDA IND review, CMC review, clinical trials, stability studies, controlled-formulation analysis, or FDA labeling that MMJ has assiduously pursued.

14. Because MMJ has consistently followed federal law—unlike its corner-cutting competitors—MMJ can deduct business expenses in filing its taxes. This constitutes a substantial advantage over MMJ's competitors, who—until the Rescheduling Order—have not been permitted to deduct business expenses, and were instead taxed on gross profits under Section 280E of the Internal Revenue Code, because their businesses "consist[ed] of trafficking in controlled substances (within the meaning of schedule I … of the Controlled Substances Act) which is prohibited by Federal law." 26 U.S.C. § 280E.

15. The Rescheduling Order directly harms MMJ's competitive advantage by granting legal Schedule III status to state-licensed products without requiring the companies producing them to satisfy the same federal pharmaceutical-development requirements that MMJ has meticulously observed. It eliminates the compliance-based market distinction that MMJ spent more than eight years and $10 million building. It also harms MMJ's competitive advantage by granting MMJ's competitors relief from the Internal Revenue Code's Section 280E deduction disallowance for trafficking in a Schedule I controlled substance. *See* 91 Fed. Reg. at 22720.

16. MMJ competes against companies that market cannabis-based products for therapeutic use under state medical-marijuana programs. State-licensed products can be marketed or dispensed for therapeutic use in capsule, edible, vape, concentrate, flower, and other forms. The Order gives those competitors federal Schedule III legitimacy without requiring them to prove safety, efficacy, formulation consistency, or manufacturing controls through FDA review.

17. MMJ's direct competitors include:

- **Trulieve Cannabis Corp.** (Trulieve), a multistate cannabis operator that markets cannabinoid products for therapeutic use, including its Momenta brand in a soft-capsule (gelcap) format directly analogous to MMJ's soft-gelatin capsule. Trulieve advertises that its "Momenta

Ratio Capsules offer a balanced 1:1 CBN:THC formulation in a simple, familiar capsule format,"[1] sold in 30-count, 300 mg bottles and promoted as "precisely dosed" and offering "consistent, controlled relief."[2] Trulieve is the largest single beneficiary of the tremendous market momentum already generated by the Rescheduling Order: On June 5, 2026, it announced an uplisting to the New York Stock Exchange, and on June 10, 2026, it became the first U.S.-operating cannabis company to trade on a major U.S. exchange, under the ticker symbol "TRLV."[3] Trulieve describes itself as "the largest cannabis retailer in the United States."[4] Shortly after the Order, Trulieve announced that it had filed applications with the DEA to register certain state-licensed medical cannabis operations under the Order's expedited registration pathway,[5] and on November 2, 2026, received DEA

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[1] Trulieve, Momenta Capsules Ratio 30ct 300mg product page, tinyurl.com/Mmenta (last visited Nov. 23, 2026).

[2] Trulieve, THC Capsules category page, tinyurl.com/TrlvCaps (last visited Nov. 23, 2026).

[3] *See Trulieve Announces Uplist to NYSE*, Investing News (June 5, 2026), tinyurl.com/TRLV-list; *Trulieve Is First US Cannabis Company to Trade on NYSE*, MJBizDaily (June 11, 2026), tinyurl.com/TRLV-nyse.

[4] Trulieve Cannabis Corp., Quarterly Report (Form 10-Q), at 18 (May 7, 2026) (period ended Mar. 31, 2026)

[5] *Trulieve Announces Applications Filed for DEA Registration of State Licensed Medical Marijuana Businesses*, Investing News (Apr. 29, 2026), tinyurl.com/TRLV-dea.

registrations for certain retail facilities.[6] Trulieve's products are dispensed for therapeutic use without IND application and FDA approval; without clinical-trial data; without chemistry, manufacturing, and control (CMC) review; and without demonstrating controlled formulation and stability. Trulieve's products thus do not have proven therapeutic efficacy.

- **Cresco Labs Inc.** (Cresco), a multistate operator whose Remedi brand is expressly positioned as a pharmaceutical-style medical product. In May 2026, Cresco announced that it had registered its state-licensed medical cannabis operations with the DEA under the expedited registration pathway created by the Rescheduling Order.[7] Cresco states that "Remedi products are specifically tailored to meet the needs of medical patients, and they come in precise doses and form factors similar to other health and wellness products," and that "Remedi was originally created for patients with existing medical conditions in medical cannabis states."[8] Remedi's capsule line includes formulations

[6] *Trulieve Receives DEA Registrations for State-Licensed Medical Marijuana Operations*, Cannabis Bus. Times (Nov. 2, 2026), tinyurl.com/TRLV-reg.

[7] *Cresco Labs Marks Historic Step Forward with Medical Cannabis Facility DEA Registration* (May 27, 2026), tinyurl.com/Cresco-dea.

[8] Cresco Labs / Remedi brand materials, crescolabs.com/brands; Leafly, Remedi by Cresco Labs.

comparable to MMJ's, such as Relief 1:1 Capsules (2.5 mg CBD + 2.5 mg THC per capsule) and Rest 1:5 Capsules (1 mg CBD + 5 mg THC per capsule).[9] Cresco's Chief Commercial Officer, Greg Butler, has publicly marketed these "category-specific … capsules" to medical patients.[10] Remedi capsule products are dispensed for therapeutic use without IND application and FDA approval; without clinical-trial data; without chemistry, manufacturing, and control (CMC) review; and without demonstrating controlled formulation and stability. Cresco's products thus do not have proven therapeutic efficacy.

- **Verano Holdings Corp.** (Verano), through its Avexia brand, markets microdosing THC/CBD tablets for "pain relief" and other therapeutic uses. In May 2026, Verano filed applications with the DEA to register its state-licensed medical cannabis operations under the expedited registration pathway created by the Rescheduling Order.[11] Verano's products include 1:1 tablets (2.5 mg THC + 2.5 mg CBD) and 4:1

[9] Leafly, Remedi Relief 1:1 Capsules (last visited Nov. 23, 2026), tinyurl.com/leaflycaps; Remedi Rest 1:5 Capsules (last visited July 2026), tinyurl.com/leaflycaps-2.

[10] Press Release, Cresco Labs, *Cresco Labs Launches Remedi Cannabis Brand Into New York* (Oct. 14, 2020), tinyurl.com/Rmedi-2.

[11] *Verano Submits DEA Registration Applications for State-Licensed Medical Cannabis Businesses Following Landmark Federal Rescheduling Order*, Globe Newswire (May 13, 2026), tinyurl.com/VeranoDEA.

tablets (10 mg CBD + 2.5 mg THC),[12] distributed through Verano and affiliated dispensaries. Avexia tablets are dispensed for therapeutic use without IND application and FDA approval; without clinical-trial data; without chemistry, manufacturing, and control (CMC) review; and without demonstrating controlled formulation and stability. Verano's products thus do not have proven therapeutic efficacy.

- **Green Thumb Industries Inc.** (Green Thumb or GTI), a Chicago-based multistate operator, manufactures and sells cannabinoid products for medical and adult use in precisely dosed oral formats. These products include tinctures marketed for therapeutic use under GTI's health-and-wellness brand, Doctor Solomon's.[13] In May 2026, Green Thumb announced that it had filed applications with the DEA to register certain state-licensed medical cannabis operations under the expedited registration pathway created by the Rescheduling Order.[14] None of

[12] Verano/Avexia product listings (last visited July 2026), leafly.com/brands/avexia/catalog; Columbia Care, VE 1:1 Avexia Microdose Tablets (last visited July 2026), tinyurl.com/Avexia; Columbia Care, VE 4:1 Avexia Microdose Tablets (last visited July 2026), tinyurl.com/Avexia-2.

[13] *Our Ingredients*, Green Thumb Industries (last visited July 2026),tinyurl.com/DrSlmn .

[14] Green Thumb Industries Inc., *Green Thumb Industries Files Applications for DEA Registration Following Historic Rescheduling of Medical Cannabis* (May 4, 2026), tinyurl.com/GrnThDEA.

Green Thumb's cannabinoid products has undergone FDA IND review, clinical trials, CMC characterization, or the stability and controlled-formulation requirements MMJ has satisfied, yet its state-licensed products now receive Schedule III treatment and its operations are positioned for expedited federal registration—the same registration that MMJ has diligently sought since December 2018. Green Thumb's products do not have proven therapeutic efficacy.

- **TerrAscend Corp.** (TerrAscend) manufactures and distributes cannabis products for oral administration, including medical-cannabis capsules sold under its Ilera brand.[15] Shortly after the Order, TerrAscend announced that it would be "following all the steps dictated by the DOJ and DEA to register [its] state-licensed medical facilities."[16] TerrAscend's cannabis capsules are dispensed for therapeutic use without IND application and FDA approval; without clinical-trial data; without chemistry, manufacturing, and control (CMC) review; and

[15] Press Release, TerrAscend Corp., *TerrAscend's Award-Winning Apothecarium to Debut Its First Two Pennsylvania Dispensaries* (March 30, 2020),tinyurl.com/Terr-Ilera .

[16] Margaret Jackson, *How Cannabis MSO TerrAscend Is Responding to Federal Marijuana Rescheduling*, MJBizDaily (Apr. 30, 2026), tinyurl.com/TerrAscDEA.

without demonstrating controlled formulation and stability. TerrAscend's products thus do not have proven therapeutic efficacy.

18. Each of these competitors markets a precisely dosed, orally administered cannabinoid product for therapeutic use in the same format that MMJ has developed. Yet none of them has followed the federal pharmaceutical-development pathway that MMJ has pursued: DEA registration, FDA IND application, CMC review, clinical trials, and stability studies. The Rescheduling Order confers Schedule III legitimacy to these competitors' state-licensed products without requiring compliance with this well-established federal pathway.

19. The state-licensed marijuana products covered by the Rescheduling Order include products that have never undergone FDA review, have never been tested in clinical trials to prove efficacy, and lack standardized dosing, validated manufacturing controls, or regulatory-grade characterization. The Order thus opens the floodgates to MMJ's competition: Their products may now be marketed or dispensed for therapeutic use without having followed the same requirements—DEA registration, FDA IND application, CMC review, clinical trials, and stability / controlled-formulation analysis—that MMJ has scrupulously followed. In effect, the Order rewards MMJ's competitors who built their position through federally unsanctioned state medical-marijuana regimes rather than by proceeding through the established federal pharmaceutical pathway. In this way, the Order substantially

erodes the critical market distinction that MMJ carefully built for itself through strict federal compliance.

20. Prior to the Rescheduling Order, many of MMJ's direct competitors candidly acknowledged in filings with the Securities & Exchange Commission that their medical marijuana businesses were subject to substantial legal risk due to marijuana's Schedule I status and their unabashed violation of federal law. These competitors also acknowledged that their illicit trafficking in a Schedule I controlled substance subjected them to a heightened tax burden and a substantial risk-premium to obtain financial services, among other things.

21. For example, Verano's 2025 Annual Report lists as the company's very first risk factor, "the current illegality of cannabis under federal law, the U.S. federal regulatory landscape and enforcement related to medical … use cannabis." Verano Holdings Corp., Annual Report, at 1, 30 (Form 10-K) (Mar. 12, 2026). Verano also highlighted potential liability under federal "money laundering laws and the Racketeer Influenced and Corrupt Organizations Act" (RICO), "the impact of Section 280E" of the tax code, the "limited intellectual property protection available for cannabis products," their "lack of access to federal bankruptcy protections" as a vendor of contraband under the CSA, and "the difficulties cannabis businesses face accessing and maintaining banking or financial services due to federal regulations," among other things. *Id.* at 1–2, 30–33, 53–54, 56, 58–59, 67. Trulieve's 2025

Annual Report identified the same Schedule I related risks. *See* Trulieve Cannabis Corp., Annual Report, at 18–19, 22–25, 27 (Form 10-K) (Feb. 26, 2026). Similarly, Cresco's 2025 annual SEC filing (as a foreign private issuer) likewise identified risks flowing from its trafficking in a Schedule I substance. *See* Cresco Labs Inc., Annual Information Form, at 82–88, ex. 99.4 to Form 40-F (Mar. 14, 2025). Cresco also warned that cannabis businesses like it had "limited, if any, access to credit card processing services" and therefore were "largely cash-based," which "complicates the implementation of financial controls and increases security issues." *Id.* at 27, 36.

22. The Rescheduling Order relieves MMJ's competitors like Verano, Trulieve, and Cresco of these serious risks attendant to their marketing of non-FDA-approved cannabis-therapeutics through state medical marijuana programs. The Order absolves these competitors of falsely marketing their products as having proven medical benefits despite lacking any clinical-trials proof of efficacy. And already, these competitors have begun to reap the substantial financial benefits of the Order's tax relief under Section 230E. *See, e.g.*, Trulieve Cannabis Corp., Quarterly Report, at 25 (Form 10-Q) ("The decrease in provision for income taxes was primarily driven by the Company not applying IRC Section 280E for the 2026 taxable year, where the prior period included the impact of IRC Section 280E.").

23. MMJ's injury is immediate and compounding. Every day the Order remains in effect, state-licensed marijuana products gain market access, consumer acceptance, provider familiarity, investor confidence, and perceived federal legitimacy. That erodes the market position and capital-raising value MMJ built by pursuing FDA approval and DEA compliance. MMJ estimates the economic damage to its business totals $38 million, based on pro-rated sales data in cannabis capsule-category sales.[17]

24. The Order has already harmed MMJ's access to capital. In February 2026, a long-time investor who had previously invested approximately $1 million in MMJ advised me that he would not invest further because of uncertainty created by federal rescheduling efforts and the resulting competitive harm to MMJ. Prospective institutional investors have questioned why Schedule III economic benefits and federally recognized market access are being extended to state-licensees while MMJ's federally compliant pharmaceutical program remains delayed by agency processes.

25. MMJ cannot avoid this injury by abandoning its federal pathway. MMJ has sunk substantial investment into FDA and DEA compliance, its DEA bulk-

[17] *See* Headset, *Cannabis Capsules Product Category*, tinyurl.com/HdstCaps (last visited Nov. 23, 2026) (reporting approximately $72.3 million in U.S. cannabis capsule-category retail sales for October 2025 through September 2026); *see also* Headset, *Insights Sampling Process & Analytical Methods*, tinyurl.com/HdstMthd (last updated Mar. 4, 2024).

manufacturer application remains pending, and the new Schedule III state-licensee pathway is directed to operators holding state medical-marijuana licenses rather than to an applicant already awaiting action under DEA's existing registration process.

26. The Order also injured MMJ procedurally. If MMJ had had the opportunity to participate in a formal rulemaking on the record or otherwise offer comment on the Order before it took effect, MMJ would have submitted evidence that, among other things, reproducible chemistry, standardized dosing, CMC manufacturing controls, stability data, FDA clinical review, DEA registration, and FDA labeling are critical controls for drugs available for medical use outside of Schedule I. These controls, MMJ would have explained, distinguish legitimate, scientifically-grounded pharmaceutical products from merely state-licensed retail products, which do not bear any of the hallmarks of science-based medicine, and so, do not deserve the federal imprimatur conveyed by this Order.

27. A favorable decision vacating the Order would redress MMJ's injury by removing Schedule III status from state-licensed products unless and until the agency lawfully completes the required process. That relief would restore the regulatory distinction between FDA-DEA compliant pharmaceutical development and state-licensee products that have not undergone that process.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November ___, 2026 _____

Duane Boise
Chief Executive Officer
MMJ International Holdings, Inc.