[ORAL ARGUMENT NOT SCHEDULED]

Nos. 26-1324, 26-1325 (consol.)

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

STANDARD WELLNESS UTAH, LLC, et al.,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION, et al.,

Respondents.

G.P.M.II, LLC, et al.,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION, et al.,

Respondents.

On Petition for Review of Non-Final Action
by the Drug Enforcement Administration

COMBINED OPPOSITION TO MOTIONS FOR STAY PENDING REVIEW

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Petitioners in No. 26-1324 are Standard Wellness Utah, LLC; Verde Americano, LLC; and NW Confections OK 241AA LLC. Respondents are the Drug Enforcement Administration and Terrance Cole, Administrator.

Petitioners in No. 26-1325 are G.P.M.II, LLC; MLH Explorations LLC; Tri-Mountain Pure, LLC; and Story of PA CR, LLC. Respondents are the Drug Enforcement Administration; Terrance Cole, in his official capacity as Administrator of the Drug Enforcement Administration; the United States Department of Justice; and Todd Blanche, in his official capacity as United States Attorney General.

B. Rulings Under Review

Petitioners seek review of an information document emailed to certain applicants for registration with the Drug Enforcement Administration (DEA) on October 30, 2026. The letter is attached to petitioners' stay motions as Exhibit 2 in No. 26-1324 and Exhibit K in No. 26-1325.

C. Related Cases

The Court *sua sponte* consolidated these two related petitions, which have not previously been before this Court or any other court. Petitioners here challenge a letter DEA issued regarding the registration requirements for schedule III medical marijuana products. This Court is considering a separate challenge to the Attorney General's rescheduling of medical marijuana products from schedule I to schedule III in *SAM, Inc. v. U.S. Department of Justice*, Nos. 26-1106, 26-1130, 26-1136 (D.C. Cir.).

/s/ *J. Kain Day*
J. Kain Day

TABLE OF CONTENTS

Page

GLOSSARY vii

INTRODUCTION 1

STATEMENT 5

A. Legal Framework and Background 5

B. Rescheduling of Medical Marijuana and DEA Registration Requirements 7

C. These Petitions and Motions For Stay 10

ARGUMENT 11

I. Petitioners Are Not Likely To Succeed On The Merits 11

A. The Controlled Substances Act Prohibits Buying Or Selling Controlled Substances Without A Registration 11

B. Petitioners Do Not Challenge A Final Decision Under 21 U.S.C. § 877 And Lack Article III Standing 18

II. The Equitable Factors Disfavor a Stay Pending Review 23

CONCLUSION 26

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF SERVICE

ADDENDUM

TABLE OF AUTHORITIES

Cases: **Page(s)**

Bennett v. Spear,
520 U.S. 154 (1997) 19, 20

California Communities Against Toxics v. EPA,
934 F.3d 627 (D.C. Cir. 2019) 20-21

Canna Provisions, Inc. v. Bondi,
138 F.4th 602 (1st Cir. 2025) 1

Chaplaincy of Full Gospel Churches v. England,
454 F.3d 290 (D.C. Cir. 2006) 23-24

Citizens for Responsibility and Ethics in Washington v. FEC,
993 F.3d 880 (D.C. Cir. 2021) 18

City of Billings v. TSA,
153 F.4th 46 (D.C. Cir. 2025) 14

City of Huntington v. AmerisourceBergen Drug Corp.,
157 F.4th 547 (4th Cir. 2025) 5, 13

Clapper v. Amnesty International USA,
568 U.S. 398 (2013) 21

Coalition for Humane Immigrant Right v. Mullin,
185 F.4th 1275 (D.C. Cir. 2026) 23

Corner Post, Inc. v. Board of Governors of Federal Reserve System,
603 U.S. 799 (2024) 21

Craker v. DEA,
44 F.4th 48 (1st Cir. 2022) 7

Department of Education v. California,
604 U.S. 650 (2025) 24

FCC v. Fox Television Stations, Inc.,
556 U.S. 502 (2009) 14

FCC v. Prometheus Radio Project,
592 U.S. 414 (2021) 17

FDA v. Alliance for Hippocratic Medicine,
602 U.S. 367 (2024) 22

Golden and Zimmerman, LLC v. Domenech,
599 F.3d 426 (4th Cir. 2010) 20

Gonzales v. Raich,
545 U.S. 1 (2005) 5, 6, 13, 22

Holistic Candlers and Consumers Association v. FDA,
664 F.3d 940 (D.C. Cir. 2012) 19-20

Independent Equipment Dealers Association v. EPA,
372 F.3d 420 (D.C. Cir. 2004) 20

John Doe, Inc. v. DEA,
484 F.3d 561 (D.C. Cir. 2007) 4, 19

KalshiEX LLC v. CFTC,
119 F.4th 58 (D.C. Cir. 2024) 23

Make the Road New York v. Mullin,
179 F.4th 16 (D.C. Cir. 2026) 11, 26

Mullin v. Doe,
609 U.S. 324 (2026) 11

Nken v. Holder,
556 U.S. 418 (2009) 11

Trump v. CASA, Inc.,
606 U.S. 831 (2025) 5, 26

Valero Energy Corp. v. EPA,
927 F.3d 532 (D.C. Cir. 2019) 19, 20

Statutes:

21 U.S.C. § 811(a)-(b) 6

21 U.S.C. § 812(a)-(b) 6

21 U.S.C. § 812(c) 6, 7

21 U.S.C. § 822 ..... 1, 21

21 U.S.C. § 822(a)(1)-(2) 6

21 U.S.C. § 822(d) 8, 12, 16

21 U.S.C. § 823(e)(1) 3

21 U.S.C. § 823(e)-(g) 8

21 U.S.C. § 824(a)(4) 6

21 U.S.C. § 877 ..... 4, 17, 18, 19, 20, 21

21 U.S.C. §§ 823(e)(1), 841(a) 21

21 U.S.C. §§ 825-27 6

21 U.S.C. §§ 841(a)(1), 844(a) 5, 6, 12, 13, 17

Rules and Regulations:

21 C.F.R. § 1301.13(a) 2, 8, 12, 15

21 C.F.R. § 1301.13(k)(1) 25

21 C.F.R. § 1301.13(k)(1)(i)-(iii) 3

21 C.F.R. § 1301.13(k)(7) 8, 9, 10, 12, 15

21 C.F.R. § 1301.91 6

21 C.F.R. § 1308.13(c)(7), (c)(9) 8

28 C.F.R. § 0.100 5

91 Fed. Reg. 22714 (Apr. 28, 2026) 1, 2, 3, 7, 8, 14, 17

Other:

Single Convention on Narcotic Drugs, 1961, Mar. 30, 1961, 18 U.S.T. 1407 7

GLOSSARY

The Act	The Controlled Substances Act
DEA	Drug Enforcement Administration
Single Convention	Single Convention on Narcotic Drugs, 1961

INTRODUCTION

Petitioners would like to buy and sell controlled substances without authorization under the Controlled Substances Act (Act), and they essentially ask this Court for an emergency injunction to let them do so. The motions are without merit and should be denied.

Under the Act, anyone seeking to manufacture, distribute, or dispense a controlled substance must be registered with the Drug Enforcement Administration (DEA). 21 U.S.C. § 822. Until recently, all marijuana had been categorized as a schedule I controlled substance, so DEA registrations for marijuana were generally limited to scientific research. Over the last 30 years, states have allowed the manufacture and sale of marijuana under state law for medical or recreational uses, *see Canna Provisions, Inc. v. Bondi*, 138 F.4th 602, 609-10 (1st Cir. 2025), and those activities generally violated federal law, *see id.*

In April, the then-Acting Attorney General rescheduled certain medical marijuana products from schedule I to schedule III. 91 Fed. Reg. 22714, 22714 (Apr. 28, 2026). As with other schedule III controlled substances—like ketamine and anabolic steroids—medical marijuana can now be lawfully manufactured, distributed, and dispensed for medical purposes by entities that are registered with DEA.

In general, entities must have an approved DEA registration before they can "engage in any activity for which registration is required." 21 C.F.R. § 1301.13(a). But in the rescheduling order, the Attorney General provided a cabined exception: If an aspiring manufacturer, distributor, or dispenser of schedule III medical marijuana applied for registration within 60 days of the rescheduling regulation, they could "engage in the manufacture, distribution, and/or dispensing of" medical marijuana while their application was pending so long as their activities were also "in conformity with a state-issued license." 91 Fed. Reg. at 22722. Thus, these early applicants could act as if their registration had been granted "during the pendency" of DEA review, and the Attorney General directed DEA to make every effort to complete its review "within six months." *Id.* at 22720.

DEA received approximately 7,100 applications for registrations to manufacture, distribute, or dispense marijuana within this early 60-day period. Declaration of Megan Almendinger ¶3. All prospective registrants that submitted complete applications within that period may lawfully deal in medical marijuana while their applications are pending.

Petitioners contend that this is insufficient, and that entities who filed outside the 60-day window should be able to freely manufacture, distribute, and dispense a schedule III controlled substance without a registration.

Moreover, entities who did timely file—and who can lawfully manufacture, distribute, or dispense medical marijuana while their application is under review—claim the ability to obtain marijuana from or sell marijuana to entities who lack a DEA registration. Based on these assertions, petitioners ask this Court to enter an emergency order that would effectively enjoin DEA from enforcing the Act's registration requirements.

Petitioners are wrong on the merits. The entire point of the Controlled Substances Act is to establish a closed system whereby a controlled substance is handled only by DEA-registrants from its manufacture until it reaches the patient. The Attorney General granted a limited waiver of that strict registration requirement for early medical marijuana applicants. But nothing within the Attorney General's order allows other non-registered entities to obtain and sell medical marijuana or allows registered entities to deal with those who lack a DEA registration. *See, e.g.*, 21 U.S.C. § 823(e)(1) (registrants must maintain "effective controls against diversion of" schedule III controlled substances). Thus, as the Attorney General made clear, medical marijuana registrants may only acquire medical marijuana from and sell it to other DEA registrants, "subject to the limitations of its state license." 91 Fed. Reg. at 22722 (promulgating 21 C.F.R. § 1301.13(k)(1)(i)-(iii)). And DEA changed nothing

about this scheme when it emailed a letter to timely applicants with information that summarized these pre-existing statutory and regulatory limits. *See* DEA Medical Marijuana Timely Applicant Information, https://perma.cc/M53X-F65A (DEA Letter).

Petitioners' motions also suffer from threshold defects. Although they seek to enjoin DEA's regulatory authority over medical marijuana by challenging this letter, the letter is not a "final decision" within this Court's jurisdiction under 21 U.S.C. § 877. *See John Doe, Inc. v. DEA*, 484 F.3d 561, 565 (D.C. Cir. 2007). It does not consummate any agency decisionmaking, nor does it result in any new legal consequences. Petitioners lack standing for essentially the same reason. The letter changes none of petitioners' obligations, which were already set by statute and regulation, so the letter did not cause any of petitioners' alleged harm.

The equitable factors likewise disfavor petitioners' extraordinary request. Petitioners complain about an inability to profit from activities—growing and selling medical marijuana—that violate the Controlled Substances Act. Regardless of the extent of those monetary injuries, petitioners have no reliance interests in violating federal law. By contrast, the "Government is likely to suffer irreparable harm" from an injunction that would prohibit it from "effectuating statutes," like the Controlled

Substances Act, "enacted by representatives of its people." *Trump v. CASA, Inc.*, 606 U.S. 831, 860-61 (2025). The motions should be denied.

STATEMENT

A. Legal Framework and Background

1. Congress established a comprehensive regulatory regime in the Controlled Substances Act in 1970. Pub. L. No. 91-513, tit. II, pt. A, 84 Stat. 1236, 1242. The Act "consolidate[d] various drug laws on the books into a comprehensive statute" that would establish regulation for "legitimate sources of drugs" and "prevent diversion into illegal channels." *Gonzales v. Raich*, 545 U.S. 1, 10 (2005). To that end, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by" the Act. *Id.* at 13 (citing 21 U.S.C. §§ 841(a)(1), 844(a)). "Each entity in this closed system, including doctors, is required to register with the DEA, and each manufacturer or distributor is restricted to selling [controlled substances] only to other registered entities." *City of Huntington v. AmerisourceBergen Drug Corp.*, 157 F.4th 547, 554 (4th Cir. 2025).[1]

[1] The Attorney General has delegated his authority to administer the Controlled Substances Act to DEA. 28 C.F.R. § 0.100.

The Act divides controlled substances into five schedules "based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body." *Raich*, 545 U.S. at 13-14 (citing 21 U.S.C. §§ 811, 812). Schedule I substances have "no currently accepted medical use in treatment in the United States" and a high risk for abuse, while schedule II-V substances have currently accepted medical uses and decreasing risks of abuse and dependence. 21 U.S.C. § 812(a)-(b).

Anyone who wishes to manufacture, distribute, or dispense controlled substances must be registered with DEA. 21 U.S.C. § 822(a)(1)-(2). Registrants must comply with numerous statutory and regulatory requirements, *see, e.g.*, *id.* §§ 825-27; 21 C.F.R. § 1301.91, to effectuate the Act's restrictions. Registrants must regularly renew their registrations, 21 U.S.C. § 822(a)(1)-(2), and DEA can suspend or revoke a registration for enumerated reasons including that the person has committed acts that are "inconsistent with the public interest," *id.* § 824(a)(4).

2. Congress originally placed marijuana within schedule I, 21 U.S.C. § 812(c), sch. I (c)(10), but granted the Attorney General authority to reschedule marijuana and any other controlled substance as appropriate, *id.* § 811(a)-(b), (d). Regulation of marijuana under any schedule must also ensure that the United States satisfies its treaty obligations, including

obligations under the Single Convention on Narcotic Drugs, 1961, Mar. 30, 1961, 18 U.S.T. 1407 (Single Convention), which requires the control of cannabis, *id.* arts. 2(1), 28. *See also Craker v. DEA*, 44 F.4th 48, 53 (1st Cir. 2022) (explaining the Single Convention's implementation through the Controlled Substances Act).

Under the Single Convention, the United States has obligations with respect to certain drugs—including marijuana—to require the licensing of manufacturers and distributors, to require prescriptions for dispensing the drugs to patients, to require accurate recordkeeping, and to prohibit "the possession of [such] drugs except under legal authority." Single Convention, arts. 4, 29-30, 33-34.

B. Rescheduling of Medical Marijuana and DEA Registration Requirements

1. On April 28, 2026, the then-Acting Attorney General rescheduled certain medical marijuana products to schedule III—marijuana products that have been approved by the Food and Drug Administration and those "subject to a state medical marijuana license." 91 Fed. Reg. at 22716. Because the Food and Drug Administration has not yet approved any marijuana products, the rescheduling order's immediate effect is limited to state-licensed medical marijuana, which is now a schedule III substance,

like ketamine, lysergic acid amide, or anabolic steroids. *See* 21 C.F.R. § 1308.13(c)(7), (c)(9), (f).

Anyone seeking to manufacture, distribute, or dispense a schedule III substance must acquire a DEA registration, 21 U.S.C. § 823(e)-(g), and "[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted," 21 C.F.R. § 1301.13(a). But the Attorney General, as a matter of discretion, can "waive [that] requirement" if "he finds it consistent with the public health and safety," 21 U.S.C. § 822(d).

Here, the Attorney General provided a time-limited registration waiver, given that many states had permitted medical marijuana sales "as a matter of state law" and established a state-level licensing regime. 91 Fed. Reg. at 22716. Thus, any state-licensed medical marijuana entities who applied for a DEA registration "within 60 days" of the rescheduling order could continue to "lawfully operate under their state-issued licenses" while DEA reviewed their application. *Id.* at 22720. In other words, these early applicants could act as if they had a DEA registration "during the pendency of [their] application." *Id.* at 22722 (promulgating 21 C.F.R. § 1301.13(k)(7)). The Attorney General further directed DEA to "make

every effort to process all" early applications "within six months," *i.e.*, by October 28. *Id.*

2. Within 60 days of the rescheduling order, DEA received registration applications for schedule III medical marijuana from approximately 2,100 manufacturers, 700 distributors, and 4,300 dispensers. Almendinger Declaration ¶3. Given this volume, DEA continues to process these applications. While these early applications remain pending, the applicants may lawfully engage in the regulated business of medical marijuana as if they had an approved DEA registration. 21 C.F.R. § 1301.13(k)(7).

3. On October 30—just after DEA had originally endeavored to have completed its review—DEA emailed a letter to all early applicants that summarized the regulatory framework. DEA Letter 1-4. DEA explained that, while an application remains pending, the applicant can "distribute schedule III medical marijuana to and obtain schedule III medical marijuana from" entities that either had a DEA registration or similarly had an early application still pending. *Id.* at 1. And as with any other controlled substance, DEA explained that medical marijuana may not be obtained from or sold to entities that lack a DEA registration or applicable waiver. *Id.* at 2. DEA advised that early applicants "should take adequate steps" to

confirm the registration status of the entities in their supply chain and expected that early applicants should be able to confirm "compliant supply chains" by November 29. *Id.* at 2, 4.

C. These Petitions and Motions For Stay

Petitioners deal in state-licensed medical marijuana. Some filed early applications to register as a manufacturer and dispensary. Standard Wellness Mot. 3 (Verde Americano). Some filed early applications to register as a manufacturer, but filed a distributor application after the 60-day window closed. *Id.* at 4 (NW Confections). Others filed early applications to register as a dispenser and filed a manufacturer application after the 60-day window. G.P.M.II Mot. 9-11. And others completely missed the 60-day window. Standard Wellness Mot. 4 (Standard Wellness and The Forest Murray).

"[T]wenty days" after receiving DEA's letter, Standard Wellness Mot. 1, petitioners sought review in this Court and moved for an emergency stay of the letter. On petitioners' view, entities that applied within the 60-day window have "open-ended permission to continue operating" with entities that lack a DEA registration or an applicable waiver. *Id.*; *accord* G.P.M.II Mot. 15 (arguing that any "early applicant[] may continue doing business

with Petitioners' manufacturing divisions," which did not apply for DEA registration within the 60-day window).

ARGUMENT

To secure the extraordinary relief of a stay, petitioners must demonstrate (1) likelihood of success on the merits; (2) irreparable harm absent a stay; (3) that a stay will not harm others; and (4) that the public interest favors a stay. *See Make the Road New York v. Mullin*, 179 F.4th 16, 24-25 (D.C. Cir. 2026). The third and fourth factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009).

I. Petitioners Are Not Likely To Succeed On The Merits

Petitioners fail to establish any likelihood of success on the merits, let alone the "strong showing" necessary to justify what amounts to an injunction against enforcement of the Controlled Substances Act. *See Nken*, 556 U.S. at 426. In addressing the likelihood of success, the Court may consider the issues in any order. *See Mullin v. Doe*, 609 U.S. 324, 345-46 (2026) (plurality op).

A. The Controlled Substances Act Prohibits Buying Or Selling Controlled Substances Without A Registration

1. Petitioners frame their request as a stay of the DEA letter. But to be clear, what petitioners want is an order that allows them to buy and sell

marijuana from entities that lack a DEA registration or a registration waiver. Indeed, Standard Wellness Utah wants to keep buying and selling medical marijuana even though it failed to apply for a DEA registration until just a few days ago. Standard Wellness Mot. 4, 17. At bottom, petitioners want to buy and sell a schedule III controlled substance without any federal interference.

Nothing in the Controlled Substances Act, its regulations, or the rescheduling order supports petitioners' extraordinary demand. If someone wants to deal in controlled substances, they must be federally registered. 21 U.S.C. §§ 822-23. The Attorney General can grant limited waivers of that requirement, *id.* § 822(d), and he did so here. Entities that filed early applications for registration in the 60-day window (*i.e.*, April 28 to June 26) can continue operating as if they had a DEA registration while their application remains pending. 21 C.F.R. § 1301.13(k)(7).

The only question here is whether entities who failed to apply during that window are immune from the Act's requirements. They are not. The Attorney General did not grant them a waiver, and "[n]o person required to be registered" can deal in controlled substances "until [their] application for registration is granted." 21 C.F.R. § 1301.13(a). Nor can registered entities (or the early applicants here) buy controlled substances from

unregistered entities or sell controlled substances to unregistered entities. The Controlled Substances Act establishes "a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by" the Act. *Raich*, 545 U.S. at 13. And "[e]ach entity in this closed system … is restricted to selling [controlled substances] only to other registered entities." *City of Huntington*, 157 F.4th at 554 (discussing the diversion of opioids); *accord* 21 U.S.C. §§ 822, 841(a). A registered manufacturer cannot sell oxycodone to an unregistered gas station, and a registered pharmacy cannot purchase morphine from an unregistered backroom lab.

Indeed, at least one set of petitioners agree that "registered entities" can only "deal[] with specified registrants." G.P.M.II Mot. 15. But they err in asserting that *unregistered* entities can continue manufacturing, distributing, and dispensing medical marijuana even if they did not apply for a registration within the 60-day period. Petitioners' theory seems to be that if an early applicant was already buying and selling from a state-approved medical marijuana entity, then those early applicants can continue to buy and sell from those entities—regardless of whether the entity filed an application within the 60-day window or even filed an application at all. That misconstrues the scope of the Attorney General's

waiver: early applicants can continue as if they had a registration, and they can buy and sell schedule III marijuana with other early applicants and registrants. 91 Fed. Reg. at 22720.

2. Against this backdrop, petitioners' rulemaking challenges fail on the merits. Here, petitioners argue that DEA's letter summarizing the preexisting statutory and regulatory framework is a legislative rule promulgated without notice-and-comment procedures, is contrary to law, and is arbitrary and capricious. Those arguments lack merit.

The motions are premised on petitioners' claim that DEA's letter changed the regulatory framework. But as explained, it merely recounts preexisting requirements and explains that DEA may begin to exercise its enforcement discretion at a later date. Thus, the letter lacks the "force and effect of law" necessary to qualify as a legislative rule, *see City of Billings v. TSA*, 153 F.4th 46, 52 (D.C. Cir. 2025), and is entirely consistent with the Act and the Attorney General's rescheduling order. Nor does the letter reflect any departure from past practice that would need an adequate explanation, *see FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009)—indeed, petitioners agree that for all other controlled substances registered entities may only buy and sell from other registered entities or those with an applicable waiver of the registration requirement.

Petitioners' "adequate notice" arguments, *see* G.P.M.II Mot. 19, fail for similar reasons. Any required notice was already provided by the Controlled Substances Act and its implementing regulations.

The regulatory text allows early applicants to operate as if they were properly registered while DEA reviews their application. 21 C.F.R. § 1301.13(k)(7). In other words, early applicants can perform "activit[ies] for which registration is required." *Id.* § 1301.13(a). But nothing in the text suggests that the Attorney General was granting early applicants the authority to engage in *more* conduct than even a properly registered manufacturer or distributor could perform.

Petitioners' argument primarily rests on the waiver's reference to "manufacture, distribution, and/or dispensing" of medical marijuana "in conformity with a state-issued license." 21 C.F.R. § 1301.13(k)(7). But that reference means that early applicants cannot engage in activities beyond the limitations of their state-issued license. A state-licensed manufacturer cannot start distributing and dispensing medical marijuana if they lack a state license to do so, and the regulation does not permit them to engage in those unlicensed activities even if they filed an early application. The reference to state-issued licenses is in no way a blank check to continue

buying and selling medical marijuana outside the closed system of the Controlled Substances Act.

Petitioners also cannot rely on their purported confusion about the registration process for manufacturers and distributors. *See, e.g.*, G.P.M.II Mot. 6-7, 21-22. It was clear from reading the rescheduling order that registration or an early application was required. That is why DEA received thousands of early applications from petitioners' home states of Arizona, Oklahoma, Utah, and Pennsylvania—seeking to register 1,250 manufacturers, 350 distributors, and 1,200 dispensers. Almendinger Declaration ¶4. Petitioners fail to explain why it is unreasonable to expect that they—along with all other early applicants—conform their operations with the Act's registration requirements and the limited waiver for early applicants. Similarly, any reliance interests that petitioners have comes from building a business in a way that violates federal law. That provides no basis for vacating the letter, which simply repeats the Act's longstanding obligations.

Petitioners also mistakenly argue that the government was required to explain why it did not choose another system for expedited review or a different waiver of the registration requirement under 21 U.S.C. § 822(d). That argument cannot justify the request for extraordinary relief. To start,

it amounts to an untimely challenge to the Attorney General's order. *See* 21 U.S.C. § 877 (30-day deadline for petitions); 91 Fed. Reg. at 22720 (promulgated on April 28, 2026). Even setting that point aside, the expedited review system and waiver are eminently reasonable. *See FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021) (agency action need only be "reasonable and reasonably explained"). It offers state-licensed manufacturers, distributors, and dispensers a streamlined process for registration under 21 U.S.C. §§ 822-23, which all agree is required. Moreover, the system allows state-licensed applicants to continue operations pending disposition of their application, so long as they filed the application within 60 days. The Attorney General more than adequately explained the reasons for this system and how it would expeditiously process the many expected applications.

Petitioners also take issue with DEA's statement that it expected early applicants to "establish compliant supply chains no later than November 29, 2026." DEA Letter 4. But early applicants already had that responsibility even before November. In a world where DEA never issued this letter—but where DEA had been able to complete its review of all early applications within six months (by October 28, 2026)—all registered entities would have already been required to buy and sell medical

marijuana only from other registered entities. *See supra* pp.12-13. The only difference here is that DEA's expeditious review still requires additional time. Thus, DEA made clear in the letter that early applicants must still limit their schedule III activities to other early applicants or DEA registrants and provided a November date to allow early applicants to ensure their compliance with the Controlled Substances Act. The letter thus signifies that DEA will not take enforcement action based on supply-chain registration issues that occur before November 29, 2026, and an "agency's exercise of enforcement discretion is unreviewable." *Citizens for Responsibility and Ethics in Washington v. FEC*, 993 F.3d 880, 887 (D.C. Cir. 2021). Petitioners might have preferred a longer reprieve from DEA enforcement, but that does not render DEA's enforcement priorities reviewable or any less reasonable.

B. Petitioners Do Not Challenge A Final Decision Under 21 U.S.C. § 877 And Lack Article III Standing

Petitioners' claims also fail at the threshold because they challenge a letter with no legal effect and which is not the cause of their asserted injuries. The letter is not a "final decision" reviewable under 21 U.S.C. § 877, and petitioners lack Article III standing to challenge it.

1. This Court has jurisdiction only to review *final* DEA decisions. *See* 21 U.S.C. § 877; *John Doe, Inc. v. DEA*, 484 F.3d 561, 565-66 & n.4 (D.C. Cir. 2007). Agency action is final if it both "mark[s] the consummation of the agency's decisionmaking process" and is an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). Neither condition is satisfied here.

First, the letter did not consummate any decisionmaking process. It simply "provide[s] clarity to the public regarding existing requirements under the law or Department of Justice policies," DEA Letter 4, rather than resolving any open questions or initiating any administrative proceeding.

Second, the letter has no legal consequences. It does not require petitioners to do, or refrain from doing, anything. At most, the letter explained the obligations imposed by the Act and the Attorney General's rescheduling order. But in general, "an agency works no legal effect 'merely by expressing its view of the law.'" *Valero Energy Corp. v. EPA*, 927 F.3d 532, 536 (D.C. Cir. 2019). Thus, this Court has repeatedly held that *Bennett*'s second prong is not satisfied where a letter "communicates the agency's position on a matter" but "compels action by neither the recipient nor the agency." *Holistic Candlers and Consumers Association v. FDA*,

664 F.3d 940, 944 (D.C. Cir. 2012); *see also, e.g.*, *Independent Equipment Dealers Association v. EPA*, 372 F.3d 420, 427 (D.C. Cir. 2004) (holding agency "advice letter" nonfinal where it "imposed no obligations and denied no relief").

Nor did the DEA letter here "alter the legal regime" that governs petitioners. *Bennett*, 520 U.S. at 178. The letter was provided "simply to *inform* [petitioners] of what the law, previously enacted or adopted, is." *Golden and Zimmerman, LLC v. Domenech*, 599 F.3d 426, 433 (4th Cir. 2010). It "does not itself *determine* the law or the consequences of not following it," *id.*, nor does it have (or claim to have) any independent legal force, *Valero Energy*, 927 F.3d at 537. Rather, the DEA Letter expressly "leaves the world just as it found it." *Id.* at 536 (citing *Independent Equipment Dealers*, 372 F.3d at 428). Any restrictions on petitioners' ability to deal in medical marijuana flow directly from the Controlled Substances Act.

Despite their burden to establish this Court's jurisdiction, petitioners offer only brief arguments that the letter is a final decision under 21 U.S.C. § 877. Standard Wellness Mot. 12; G.P.M.II Mot. 5-6. Petitioners fail to engage with "the specific statutes and regulations" that prevent the DEA Letter from imposing any real "consequences" by itself. *See California*

Communities Against Toxics v. EPA, 934 F.3d 627, 637 (D.C. Cir. 2019). The Act requires registration, 21 U.S.C. § 822, prohibits diversion outside of the Act's closed system, *id.* §§ 823(e)(1), 841(a), and does not allow the agency to establish violations simply by sending a letter to regulated entities. The letter did nothing more than recount long-standing obligations when it explained that petitioners cannot deal with unregistered suppliers or customers.

Of course, petitioners could have challenged the underlying regulations that impose that requirement, but they do not purport to raise such a challenge, and they lost their opportunity to do so long ago. *See* 21 U.S.C. § 877 (30-day deadline). If DEA sought to enforce the Act's prohibitions in a future action, petitioners could challenge "the agency's statutory authority" at that time. *Corner Post, Inc. v. Board of Governors of Federal Reserve System*, 603 U.S. 799, 823 (2024).

2. Separately, petitioners "must establish that they have standing" to challenge the letter. *See Clapper v. Amnesty International USA*, 568 U.S. 398, 408 (2013). Doing so requires showing (1) an injury-in-fact that is (2) traceable to the challenged action and (3) redressable by a favorable judgment. *See id.*

Petitioners fail to establish any injury that is traceable to the letter or that would be redressed through a favorable judgment. These requirements are "often 'flip sides of the same coin,'" directed at whether "the plaintiff's injury likely was caused or likely will be caused by the defendant's conduct." *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 380, 382 (2024).

Here, petitioners' alleged injuries all focus on their inability to deal with entities that lack a registration and did not file early applications with DEA. For example, Verde complains about losing sales to non-registered entities and disruptions to its supply chain. Standard Wellness Mot. Ex. 3, ¶¶20-23, 28-30. And the other petitioners' declarations are similar. *See, e.g.*, Standard Wellness Mot. Exs. 4-5; G.P.M.II Mot., Sheahan Decl. ¶¶21-26, Washington Decl. ¶¶22-29.

Those alleged injuries have no relationship to the letter and instead arise from the Act's registration requirements. A registered distributor has no authority to buy medical marijuana from an unregistered manufacturer or to sell its product to an unregistered dispensary. *See supra* p.12-13. Nothing about the letter alters that longstanding effectuating of the Act's "closed regulatory system." *Raich*, 545 U.S. at 13.

As a corollary, vacating the letter would have no impact on the legal landscape, and petitioners' injuries would not be redressed by their requested relief. This Court's decision in *Coalition for Humane Immigrant Right v. Mullin*, 185 F.4th 1275 (D.C. Cir. 2026), is instructive. There, the plaintiffs challenged a memorandum and email, alleging those documents "led to a rise in" expedited removals, but staying those documents "would not [have] affect[ed] the Government's authority" to initiate such removals. *Id.* at 1282. Thus, even if the Court had granted the stay, the government could still exercise the same authority that caused plaintiffs' alleged injuries. *Id.* Similarly, DEA's enforcement authority rises and falls with the Controlled Substances Act and its implementing regulations because the letter has no legal weight.

II. The Equitable Factors Disfavor A Stay Pending Review

The remaining equitable factors likewise disfavor a stay.

Petitioners fail to show irreparable harm, which is "a necessary prerequisite for a stay." *KalshiEX LLC v. CFTC*, 119 F.4th 58, 64 (D.C. Cir. 2024). Under the "high standard" for irreparable injury, petitioners must establish that, absent relief, they will suffer "certain and great" harm that is "of such *imminence* that there is a 'clear and present' need for equitable relief." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297

(D.C. Cir. 2006). For the same reasons that petitioners lack Article III standing, *supra* pp.21-23, they have not demonstrated irreparable harm.

Fundamentally, petitioners assert irreparable harm based on an asserted threat to the continuing viability of their businesses—businesses they established in buying and selling controlled substances for years without DEA registration under the Controlled Substances Act. When DEA offered an expedited registration system, under which petitioners could work with their customers and suppliers to come into compliance with federal law, petitioners failed to adequately protect their interests by using that process to ensure that their suppliers and customers would all file early applications and qualify for the registration-requirement waiver. Some petitioners even failed to file their own timely application for registration. Thus, the harms that petitioners allege are of their "own making." *Department of Education v. California*, 604 U.S. 650, 652 (2025). And "[s]uch self-imposed costs are not properly the subject of inquiry on a motion for stay." *Id.* The extent of that harm does not matter, nor does petitioners' ability to recover from DEA.

Petitioners' understanding of the regulatory scheme confirms the absence of irreparable injury. Certain petitioners concede that *registered* entities can only deal with other registered entities. *See* G.P.M.II Mot. 15

(citing 21 C.F.R. § 1301.13(k)(1)). Thus, if DEA granted petitioners' applications tomorrow, all would seemingly agree that they could not buy and sell medical marijuana from unregistered entities—the very same harms they now claim are unlawful and irreparable. Petitioners cannot claim a greater right *now* as mere applicants than they could as fully registered manufacturers, distributors, and dispensers under the Controlled Substances Act. And in that way, a stay would not stave off any business risks that petitioners may face from dealing with unregistered entities, as those same risks would persist if their registration applications were granted.

Petitioners suggest that it would be improbable if not impossible for early applicants to only obtain medical marijuana from and sell medical marijuana to other early applicants. Standard Wellness Mot. 14-15. But more than 7,000 manufacturers, distributors, and dispensers all filed early applications and are permitted to buy and sell schedule III marijuana—including thousands in petitioners' home states. *Supra* p.16. Petitioners identify no legal obstacles that prevent them from working with other early applicants and any registrants to ensure that their medical marijuana supply chains are consistent with federal law.

By contrast, the federal government and the public "suffer irreparable harm" when the government is "enjoined by a court from effectuating statutes enacted by representatives of its people." *See CASA*, 606 U.S. at 861; *accord Make the Road*, 179 F.4th at 25. A stay would not only interfere with the DEA's administration of the Controlled Substances Act, but would also limit the government's ability to ensure public safety and comply with its treaty obligations under the Single Convention, including registering manufacturers and distributors, requiring prescriptions for dispensation, and prohibiting unlawful possession. *See supra* pp.6-7.

CONCLUSION

The motions should be denied.

Respectfully submitted,

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NOVEMBER 2026

CERTIFICATE OF COMPLIANCE

This response complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 5,179 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 27(d)(1)(E) because it was prepared using Word for Microsoft 365 in Georgia 14-point font, a proportionally spaced typeface.

/s/ J. Kain Day
J. Kain Day

CERTIFICATE OF SERVICE

I certify that on November 23, 2026, I electronically filed the foregoing response with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system.

/s/ J. Kain Day
J. Kain Day

ADDENDUM

Declaration of Megan Almendinger

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

Standard Wellness Utah, LLC, *et al.*, Petitioners, v. Drug Enforcement Administration, *et al.*, Respondents.	No. 26-1324
G.P.M.II, LLC, *et al.*, Petitioners, v. Drug Enforcement Administration, *et al.*, Respondents.	No. 26-1325

DECLARATION OF MEGAN ALMENDINGER

I, Megan Almendinger, pursuant to 28 U.S.C.§ 1746, and based upon my personal knowledge and information made known to me in the course of my employment, hereby make the following declaration with respect to the above-captioned matter:

1. I currently serve as Staff Coordinator. In my role as Staff Coordinator, I am responsible for assisting with the implementation of AG Order No. 6754-2026. Specifically, I work at DEA Headquarters and one of my responsibilities is assisting with applications received to DEA for the handling of medical marijuana.

2. Earlier this year, the Acting Attorney General issued an order rescheduling certain marijuana products that had been approved by the U.S. Food and Drug Administration, or which were subject to a state medical marijuana license, to schedule III of the Controlled Substances Act. 91 Fed. Reg. 22714 (Apr. 28, 2026). As part of that re-scheduling, persons could apply to DEA for a registration under the Controlled Substances Act to manufacture, distribute, or dispense schedule III marijuana products. *Id.* at 22721-22. The Attorney General directed the DEA Administrator "to process applications submitted within 60 days of publication," April 28, 2026, "within six months, and early applicants may lawfully operate under their state-issued licenses during the pendency of review." *Id.* at 22720.

3. Within 60 days of the Attorney General's rescheduling order, DEA received thousands of applications, which DEA is continuing to process. Based on a preliminary assessment, DEA received approximately 7,100 applications for registration for schedule III medical marijuana products within those 60 days. Those included approximately 4,300 applications for a dispensary registration; approximately 2,100 applications for a manufacturer registration, and approximately 700 applications for a distributor registration.

4. From Arizona, Oklahoma, Pennsylvania, and Utah, collectively, DEA received timely applications for approximately 1,200 dispensary registrations, approximately 1,250 manufacturer registrations, and approximately 350 distributor registrations.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on November 20, 2026

/s/ MEGAN ALMENDINGER Digitally signed by MEGAN ALMENDINGER Date: 2026.11.20 15:42:47 -05'00'

Megan Almendinger
Staff Coordinator