

No. 26-5205

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

SMART APPROACHES TO MARIJUANA, INC., et al.,

Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human
Services, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia
No. 1:26-cv-01081-TNM (McFadden, J.)

OPENING BRIEF FOR PLAINTIFFS-APPELLANTS

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**CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES
PURSUANT TO CIRCUIT RULE 28(a)(1)**

A. Parties and Amici. Plaintiffs-Appellants are Smart Approaches to Marijuana, Inc. (“SAM”); Cannabis Industry Victims Educating Litigators (“CIVEL”); Hillsborough County Anti-Drug Alliance (“HCADA”); MMJ International Holdings, Inc. (“MMJIH”); MMJ BioPharma Cultivation, Inc. (“MMJBC”); and MMJ BioPharma Labs, Inc. (“MMJBL”). Defendants-Appellees are Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services (“HHS”); Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare & Medicaid Services; the U.S. Department of HHS; and the Centers for Medicare & Medicaid Services. Appellants are aware of no other parties, intervenors, or *amici* who have entered an appearance in this Court as of this filing.

B. Ruling Under Review. Memorandum Opinion of the Honorable Trevor N. McFadden, U.S. District Judge for the District of Columbia, dated May 22, 2026, dismissing the action under Rule 12(b)(1) for lack of Article III standing and denying Plaintiffs’ motion for preliminary injunction and stay under 5 U.S.C. § 705 as moot. ECF No. 38. The opinion is reported at *Smart Approaches to Marijuana, Inc. v. Kennedy*, No. 1:26-cv-01081-TNM (D.D.C. May 22, 2026).

C. Related Cases. Appellants are unaware of any related cases pending in this Court or any other court.

October 5, 2026

/s/ Ilya Shapiro

Ilya Shapiro

Counsel for Plaintiffs-Appellants

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Appellants state as follows:

Appellant Smart Approaches to Marijuana (SAM) is an organization that conducts education and advocacy regarding the public health and safety impact of marijuana and cannabis policy, including public health education campaigns and research and policy analysis programs. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

Appellant Cannabis Industry Victims Educating Litigators (CIVEL) is an organization that educates legal professionals and the public about harms caused by the cannabis industry through legal-education seminars, victim legal-assistance programs, and community outreach. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

Appellant Hillsborough County Anti-Drug Alliance (HCADA) supports law enforcement, the courts, prevention agencies, and substance-abuse-treatment providers through substance abuse education activities, including cannabis awareness. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

Appellant MMJ International Holdings, Inc. (MMJIH) is a private pharmaceutical cannabinoid development company that develops cannabinoid

therapeutics through FDA's botanical drug development framework and is the parent of MMJ BioPharma Cultivation, Inc. and MMJ BioPharma Labs, Inc. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

Appellants MMJ BioPharma Cultivation, Inc. and MMJ BioPharma Labs, Inc. are subsidiaries of MMJIH. No publicly held corporation owns 10% or more of the stock of MMJ BioPharma Cultivation, Inc. or MMJ BioPharma Labs, Inc.

October 5, 2026

/s/ Ilya Shapiro
Ilya Shapiro

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GLOSSARY

AHM – *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024)

APA – Administrative Procedure Act, 5 U.S.C. §§ 551–559, 701–706

BEI – Substance Access Beneficiary Engagement Incentive

CIVEL – Cannabis Industry Victims Educating Litigators

CMMI – Center for Medicare and Medicaid Innovation

CMS – Centers for Medicare & Medicaid Services

DEA – Drug Enforcement Administration

FDA – Food and Drug Administration

HCADA – Hillsborough County Anti-Drug Alliance

HHS – United States Department of Health and Human Services

IND – Investigational New Drug

MMJ – MMJ International Holdings, Inc., including subsidiaries MMJBC and MMJBL, collectively

MMJBC – MMJ BioPharma Cultivation, Inc.

MMJBL – MMJ BioPharma Labs, Inc.

MMJIH – MMJ International Holdings, Inc.

SAM – Smart Approaches to Marijuana, Inc.

THC – Tetrahydrocannabinol

QUESTIONS PRESENTED

1. Whether the District Court erred by dismissing for lack of competitor standing where MMJIH and its subsidiaries have invested more than \$10 million over eight years in federally regulated cannabinoid therapeutics development, are proceeding through the FDA and DEA regulatory process despite DEA's unreasonable delay, and operate in the same market as BEI participants serving the Medicare population.

2. Whether the District Court erred in dismissing for lack of procedural standing by reaching the merits to hold that the BEI falls within the APA's benefits exemption, 5 U.S.C. § 553(a)(2).

3. Whether the District Court erred in dismissing for lack of organizational standing where Plaintiffs-Appellants alleged concrete diversion of resources from ongoing operational services, including pharmaceutical development, legal-education seminars, victim legal-assistance programs, and community outreach, to address harms created by the BEI.

STATEMENT OF THE CASE

I. Nature of the Case

This case challenges the Centers for Medicare & Medicaid Services' (CMS) adoption of the Substance Access Beneficiary Engagement Incentive (BEI), an agency action that created a federally supported pathway for participating Medicare providers to furnish hemp-derived products—including products containing delta-9 tetrahydrocannabinol (THC)—to Medicare beneficiaries. Plaintiffs brought claims under the Administrative Procedure Act, 5 U.S.C. §§ 701–706, challenging both the procedures CMS used to adopt the BEI and CMS's statutory authority to bypass APA rulemaking requirements. The district court dismissed the entire action under Rule 12(b)(1) for lack of Article III standing. In its procedural-standing analysis, it construed the APA's benefits exception. *Op.* at 29.

In 2010, Congress created the Center for Medicare and Medicaid Innovation (CMMI) within CMS through § 1115A of the Social Security Act, 42 U.S.C. § 1315a. CMMI tests “innovative payment and service delivery models” aimed at “reduc[ing] program expenditures . . . while preserving or enhancing the quality of care” for Medicare and Medicaid beneficiaries. *Id.* The Secretary may select models, determine their elements and parameters, and choose participants. 42 U.S.C. § 1315a(b). CMMI has never conducted notice-and-comment rulemaking for a voluntary model component. Fishman Decl. ¶ 5, ECF No. 30-2.

II. Proceedings Below

Plaintiffs-Appellants filed the original complaint on March 28, 2026, along with an emergency motion for a temporary restraining order (TRO), preliminary injunction, and stay under 5 U.S.C. § 705. The district court denied the TRO on March 31, 2026. ECF No. 14.

Plaintiffs-Appellants filed the Amended Complaint on April 13, 2026, adding MMJ International Holdings, Inc. and its subsidiaries as pharmaceutical-company plaintiffs asserting competitor standing. ECF No. 25. They then filed a renewed motion for preliminary injunction and § 705 stay. ECF No. 27.

Defendants-Appellees moved to dismiss under Rule 12(b)(1) and opposed the preliminary injunction. ECF No. 30. The court held oral argument on May 1, 2026.

On May 22, 2026, the district court (McFadden, J.) issued a Memorandum Opinion dismissing the entire action for lack of Article III standing. ECF No. 38. The court denied the preliminary injunction and § 705 stay as moot. The court held that: (1) individual plaintiffs David Evans and Dr. Kenneth Finn failed to show concrete or imminent injury, Op. at 12–15; (2) no organizational plaintiff demonstrated injury-in-fact beyond “mission execution” under the framework of *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), Op. at 15–22; (3) MMJ lacked competitor standing because its competitive injury was “too remote,” Op. at 23–27; and (4) procedural standing failed because no plaintiff showed

concrete injury independent of the procedural violation and because § 553(a)(2) exempted the BEI from notice-and-comment requirements, Op. at 27–30. The court expressly left undecided whether the BEI is a legislative rule requiring notice-and-comment and whether Plaintiffs fall within the zone of interests. Op. at 29 n.8.

Plaintiffs-Appellants filed a Notice of Appeal on June 5, 2026. ECF No. 40. The appeal was docketed on June 8, 2026, as No. 26-5205. A Preliminary Statement of Issues was filed on July 6, 2026, identifying four issues for review.

III. Factual Narrative

A. The Substance Access BEI

In March 2026, CMS announced a new voluntary model component—the Substance Access Beneficiary Engagement Incentive (BEI)—embedded in participation agreements for three existing CMMI models: ACO REACH¹ and the Enhancing Oncology Models (effective April 1, 2026), and the LEAD² Model (effective January 1, 2027). Am. Compl. ¶ 83; Fishman Decl. ¶ 8, ECF No. 30-2. The BEI allows providers who opt in to consult with eligible patients about the possible use of certain hemp products and to furnish up to \$500 per year per beneficiary in eligible products. Am. Compl. ¶ 83.

¹ ACO REACH, which is not used anywhere else in this brief, stands for Accountable Care Organization Realizing Equity, Access, and Community Health.

² LEAD, which is not used anywhere else in this brief, stands for Long-term Enhanced ACO Design.

Products eligible under the BEI must contain no more than 0.3% delta-9 THC and no more than 3 mg per serving of total tetrahydrocannabinols; inhalable products are excluded. *Id.* Medicare does not pay for the products; they are funded at the participant's (provider's) expense. *Id.*

CMS did not publish a Notice of Proposed Rulemaking. It did not solicit or consider public comments. It did not publish the BEI in the Federal Register. And it did not provide any reasoned explanation for its departure from CMS's own April 2025 final rule, which had indicated a materially different position on Medicare-related treatment of cannabis- and hemp-derived products. Am. Compl. ¶¶ 150–159.

B. The Plaintiffs-Appellants

SAM is a 501(c)(3) nonprofit conducting public-health-education campaigns and policy analysis on marijuana and cannabis. Am. Compl. ¶ 6; Niforatos Decl. ¶¶ 5–6, ECF No. 28-1. CIVEL educates legal professionals and the public about harms caused by the cannabis industry through legal-education seminars, victim legal-assistance programs, and community outreach. Am. Compl. ¶ 7. HCADA supports law enforcement, prevention agencies, and substance-abuse-education providers through substance-abuse-education activities. Snelling Decl. ¶¶ 4–5, ECF No. 28-4. Each organizational plaintiff alleges that the BEI required diversion of staff and resources from ongoing programs and that the failure to conduct notice-and-comment rulemaking deprived them of a procedural right. Am. Compl. ¶¶ 6–7, 15.

MMJ International Holdings, Inc. (MMJIH) and its subsidiaries MMJ BioPharma Cultivation, Inc. (MMJBC) and MMJ BioPharma Labs, Inc. (MMJBL) (collectively, “MMJ”) develop cannabinoid therapeutics through FDA’s botanical drug development framework. Since August 2018, MMJ has invested more than \$10 million in regulatory strategy, clinical development planning, chemistry and manufacturing processes, and Investigational New Drug (IND) submissions for cannabinoid-based treatments targeting Huntington’s disease and multiple sclerosis. Boise Decl. ¶¶ 4, 43, ECF No. 28-8.

MMJ has submitted IND applications for Huntington’s disease (IND #140712) and multiple sclerosis (IND #137754). Boise Decl. ¶ 20.³ FDA granted MMJ Orphan Drug Designation for its Huntington’s treatment, recognizing that the treatment targets a rare disease. Boise Decl. ¶ 21. MMJBL obtained a DEA Schedule I analytical-laboratory registration to support MMJ’s cannabis research. Boise Decl. ¶¶ 8, 12. MMJBC has a bulk-manufacturing application that has been pending with DEA for nearly eight years. Boise Decl. ¶¶ 6, 13, 19.

MMJ evaluated seven prototype formulations and scaled one for production, manufacturing softgel capsules with Catalent Pharmaceutical. Boise Decl. ¶ 23. In 2025, however, FDA issued a hold on MMJ’s Huntington’s disease program. Boise

³ The Boise Declaration inadvertently flipped the IND numbers for Huntington’s and multiple sclerosis. The way they appear here is correct.

Decl. ¶¶ 20, 25. Accordingly, MMJ has been unable to complete any clinical trials—and thus has no approved product, revenue, or customers. *See generally* Boise Decl.

IV. The District Court’s Standing Analysis

On competitor standing, the district court found MMJ’s competitive injury “too remote” under *New World Radio, Inc. v. FCC*, 294 F.3d 164 (D.C. Cir. 2002), identifying five contingencies separating MMJ from market entry: (1) DEA approval of bulk-manufacturing registration; (2) FDA lifting the clinical hold; (3) how long clinical trials will run; (4) whether those trials succeed; and (5) FDA approval. Op. at 25–26. The court also questioned market overlap between MMJ’s Huntington’s and multiple-sclerosis therapies and the BEI’s general symptom management products. Op. at 26 n.7.

Regarding organizational standing, the court applied *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), and held that no organization had demonstrated injury beyond “mission execution.” Op. at 18–22. The court found that resource diversion to monitor and respond to the BEI fell within each organization’s existing mission rather than showing that the BEI “directly affected and interfered with” core business activities. Op. at 19.

And as for procedural standing, the court held that even under the relaxed standard for procedural injuries, plaintiffs needed concrete injury independent of the procedural violation itself. Op. at 27–28. The court then reached the merits of the

§ 553(a)(2) benefits exception, holding that the BEI “implicates” Medicare benefits and therefore fell within the exemption—foreclosing the procedural right that underpins procedural standing. Op. at 29. The court cited *Humana of South Carolina, Inc. v. Califano*, 590 F.2d 1070, 1082 (D.C. Cir. 1978), and *Azar v. Allina Health Services*, 587 U.S. 566, 569 (2019).

STANDARD OF REVIEW

This Court reviews the district court’s dismissal under Rule 12(b)(1) for lack of standing de novo. *Arpaio v. Obama*, 797 F.3d 11, 19 (D.C. Cir. 2015); *Mendoza v. Perez*, 754 F.3d 1002, 1010 (D.C. Cir. 2014). At the motion-to-dismiss stage, the court must “treat the Complaint’s factual allegations as true . . . and must grant plaintiff the benefit of all inferences that can be derived from the facts alleged.” *Sparrow v. United Air Lines, Inc.*, 216 F.3d 1111, 1113 (D.C. Cir. 2000). The plaintiff must “clearly allege . . . facts demonstrating each element” of standing. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016).

De novo review also extends to the district court’s application of the § 553(a)(2) benefits exception within the procedural-standing analysis, which presents a pure question of law. See *Humana of South Carolina*, 590 F.2d at 1082. The panel owes no deference to the district court’s standing analysis.

Because the parties submitted declarations and the district court considered materials outside the pleadings, this was not a purely facial review. See *Herbert v.*

National Academy of Sciences, 974 F.2d 192, 197 (D.C. Cir. 1992); *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987). Any true jurisdictional fact findings receive clear-error review, but the ultimate standing conclusions and the application of law to the pleaded and record facts remain subject to de novo review. The court did not reject MMJ's regulatory efforts or alleged injuries as false, but instead counted the five regulatory contingencies, questioned market overlap, and folded the § 553(a)(2) merits question into procedural standing. Those are legal conclusions that this Court reviews independently.

INTRODUCTION AND SUMMARY OF ARGUMENT

This appeal concerns the law of standing, not the merits of the BEI. At this juncture, the Court must decide only whether Plaintiffs-Appellants have standing to challenge a program that CMS adopted without notice or comment, without statutory authority, and to the detriment of Plaintiffs-Appellants' concrete interests. If the Defendants-Appellees attempt to shift the discussion toward the program itself, Plaintiffs-Appellants welcome that conversation. The BEI is both procedurally defective in its adoption and materially harmful to market competitors, healthcare providers, and elderly Americans.

But those merits arguments are for proceedings on remand, after this Court vacates the district court's ruling. The district court improperly blended the standards

under Rules 12(b)(1) and 12(b)(6), partially reached the merits, and erred in dismissing on competitor, procedural, and organizational standing for three reasons:

First, the district court erred in holding that MMJ lacks competitor standing. MMJ is not a speculative future entrant. It has invested over \$10 million across more than eight years, obtained Orphan Drug Designation, submitted IND applications for two cannabinoid therapeutics, and holds a DEA Schedule I analytical-laboratory registration. The court’s “five contingencies” framework conflated the motion-to-dismiss standard, which requires only plausible allegations of “actual or imminent” competitive harm, with a summary-judgment demand for certainty. Under *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010), competitor standing does not require an approved product. The district court’s reliance on *New World Radio* was misplaced because MMJ operates in the same regulatory market as the BEI-regulated parties—cannabinoid therapeutics for Medicare users—not a geographically or commercially distinct one. And the Supreme Court’s recent reasoning in *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025) supports a commonsense approach to competitive harm. The government also cannot credibly label MMJ a “speculative future entrant” when the government’s own unreasonable delay of nearly eight years on a bulk-manufacturing application at DEA is the primary cause of MMJ’s pre-approval status. The government should not profit from its own obstruction.

Second, with respect to procedural standing and the § 553(a)(2) benefits exception, the district court erred in two respects. First, the BEI is not a “matter relating to . . . [Medicare] benefits” under § 553(a)(2). The BEI does not establish, modify, or administer a Medicare benefit; it creates a product-distribution pathway funded at participants’ expense. *Humana* involved standard Medicare reimbursement regulations—categorically different from the BEI. Second, the court impermissibly bootstrapped a contested merits question about the scope of § 553(a)(2) into the standing analysis, using it to negate the “procedural right” prong of procedural standing. Exceptions to § 553’s notice-and-comment requirement must be “narrowly construed and only reluctantly countenanced.” *NJ DEP v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980). Additionally, 42 U.S.C. § 1395hh(a)(2) independently requires notice-and-comment for rules that establish or change a substantive legal standard governing the scope of benefits under Medicare.

Third, on organizational standing, the district court misapplied the *Havens Realty* framework after *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024). CIVEL provides concrete operational services including legal-education seminars, victim legal-assistance programs, and attorney retraining; each of these services is directly impaired by the BEI’s creation of a new class of potential cannabis-related injuries. Unlike the advocacy organizations in *Center for Biological Diversity v. DOI*, 144 F.4th 296 (D.C. Cir. 2025), or *Food & Water Watch v. Vilsack*,

808 F.3d 905 (D.C. Cir. 2015), CIVEL’s core activities are not policy advocacy but service delivery that is concretely affected by the challenged action.

The district court also erred in holding that plaintiffs David Evans and Dr. Kenneth Finn lack individual standing, Op. at 12–15, and in rejecting the associational standing that depends on Evans’s injury. Appellants raise this issue as an alternative ground, which the Court need not reach if it reverses on any other.

If this Court reverses on any standing ground (or all), it should vacate the district court’s order, remand for proceedings on the merits, and vacate the mootness ruling on interim relief so the district court may consider Plaintiffs’ motion for a preliminary injunction under Rule 65(a) and a stay under 5 U.S.C. § 705.

ARGUMENT

I. THE DISTRICT COURT ERRED IN HOLDING THAT MMJ LACKS COMPETITOR STANDING

A. The Legal Standard Is That a Plaintiff Must Be a “Direct and Current Competitor” Who Can Suffer Injury Even Before Entering a Market

Competitor standing is a recognized application of the injury-in-fact requirement. “[P]arties suffer constitutional injury in fact when agencies lift regulatory restrictions on their competitors or otherwise allow increased competition.” *La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998). To invoke this doctrine, a plaintiff must be a “direct and current competitor whose bottom line may be adversely affected by the challenged government action.”

New World Radio, Inc. v. FCC, 294 F.3d 164, 170 (D.C. Cir. 2002). The plaintiff need not wait for a completed competitive injury; it suffices to show an actual or imminent increase in competition. *Sherley v. Sebelius*, 610 F.3d 69, 72–73 (D.C. Cir. 2010). A prospective competitor can suffer injury before entering a market, provided it demonstrates “both its intention to enter . . . and its preparedness to do so.” *Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 806–07 (D.C. Cir. 2001).

At the motion-to-dismiss stage, the court must accept the complaint’s factual allegations as true and draw all reasonable inferences in the plaintiff’s favor. *Sparrow*, 216 F.3d at 1113. The plaintiff need only “clearly allege facts demonstrating each element” of standing. *Spokeo*, 578 U.S. at 338. This standard requires plausible allegations, not proof of actual competitive loss. *See also Air Excursions LLC v. Yellen*, 66 F.4th 272, 278 (D.C. Cir. 2023) (synthesizing the two-part inquiry: the challenged action must result in “an actual or imminent increase in competition” in the relevant market, and the plaintiff must be “a direct and current competitor” in that market).

B. MMJ’s Competitive Engagement Satisfies the “Direct and Current” Requirement at the Pleading Stage

MMJ is not a speculative future entrant. The Amended Complaint and Boise Declaration allege: (a) more than \$10 million invested over more than eight years in cannabinoid therapeutics development; (b) IND submissions for Huntington’s disease and multiple sclerosis; (c) Orphan Drug Designation for the Huntington’s

treatment; (d) a DEA Schedule I analytical-laboratory registration held by MMJBL; (e) a bulk-manufacturing application pending with DEA for nearly eight years;⁴ (f) seven prototype formulations evaluated, one scaled for production with Catalent Pharmaceutical; and (g) active regulatory engagement with both FDA and DEA. Am. Compl. ¶¶ 17–21; Boise Decl. ¶¶ 4–43.

These facts establish that MMJ is actively developing cannabinoid therapeutics through FDA’s regulatory pathway and has committed years of effort and millions of dollars of capital to entering the precise market the BEI disrupts—cannabinoid therapeutics for Medicare beneficiaries. Under *Sherley*, that is enough.

Sherley is the controlling D.C. Circuit authority. There, researchers who studied adult stem cells challenged an NIH rule that expanded federal funding for embryonic stem cell research. 610 F.3d at 71. Dr. Sherley had received NIH research grants, and Dr. Deisher planned to seek them. But this Court held they had competitor standing because intensified competition for a fixed pool of funds required additional application-preparation resources and created a sufficiently substantial probability of lost funding. *Id.* at 73–74. The Court explained that a seller

⁴ Pursuant to Federal Rule of Evidence 201, Plaintiffs-Appellants request that the Court take judicial notice of the docket and filings in Case No. 24-13, *In the Matter of MMJ BioPharma Cultivation*, before the DEA Office of Administrative Law Judges, which establishes that MMJ BioPharma Cultivation’s application was recently remanded to an administrative law judge for further consideration. See Applicant’s Motion for Hearing on Remand on an Expedited Schedule, Exhibit A, Case No. 24-13 (DEA Administrator’s Remand Order).

facing increased competition need not wait for a completed competitive injury before challenging the government action that increases competition. *Id.* at 72.

MMJ's competitive engagement with the cannabinoid-therapeutics market is materially stronger than the *Sherley* plaintiffs' position. MMJ has invested \$10 million, not merely applied for grants. MMJ holds Orphan Drug Designation from FDA, a formal agency determination that its product targets a qualifying rare disease. MMJ has two active INDs on file. MMJ holds a DEA laboratory registration. And DEA has sat on MMJ's manufacturing application for nearly eight years. The *Sherley* plaintiffs had none of these indicia of current competitive engagement. If they had competitor standing there, MMJ has it here.

The D.C. Circuit has recognized competitor standing in materially identical circumstances. In *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1499 (D.C. Cir. 1996), a pioneer drug manufacturer challenged an FDA regulation authorizing the manufacture of competing generic drugs. As this Court later explained, "the increase in competing products in the market was a sufficient injury in fact." *Wash. Alliance of Tech. Workers v. DHS*, 892 F.3d 332, 341 (D.C. Cir. 2018) (discussing *Bristol-Myers*). *Bristol-Myers* rejected the argument that FDA was "merely permitting a competitive product to enter the market and leaving the purchasing decision to the consumer." 91 F.3d at 1499. The same reasoning applies here: CMS created a pathway for competing cannabinoid products to enter the Medicare market,

and the fact that providers make the ultimate distribution decision does not negate MMJ's competitive injury.

The district court observed that the *Sherley* plaintiffs “were grant applicants, who sought federal funding for their research,” whereas MMJ “does not gripe that the BEI vests others with funding or other federal benefits at its expense.” Op. at 27. But this distinction is irrelevant. *Sherley* did not limit competitor standing to grant competitions or government disbursements of money; its framework expressly encompasses lifting regulatory restrictions on competitors. 610 F.3d at 72. It applied the general competitor-standing framework of “actual or imminent” competitive harm to researchers competing for NIH grants.

The nature of the competitive benefit (federal funding versus a federal product-distribution pathway) does not change the analysis. What matters is whether the government action bestows a competitive advantage—a benefit—on the plaintiff's competitor and thereby causes an actual or imminent increase in competition in a market where the plaintiff operates. *La. Energy*, 141 F.3d at 367 (parties suffer injury-in-fact “when agencies lift regulatory restrictions on their competitors or otherwise allow increased competition”).

MMJ operates in the cannabinoid-therapeutics market. The BEI introduces a federally supported regulatory path for competitors into that same market. Under *Sherley*'s framework, that establishes competitor standing.

C. The District Court’s “Five Contingencies” Framework Conflated the Motion-to-Dismiss Standard with Summary-Judgment Certainty

The district court identified five “contingencies” separating MMJ from market entry: (1) DEA approval of bulk-manufacturing registration; (2) FDA lifting the clinical hold on the multiple-sclerosis program; (3) how long clinical trials will run; (4) whether trials succeed; and (5) FDA approval. Op. at 25–26. From these contingencies, the court concluded that MMJ’s “alleged competitive injury ‘is too remote to confer standing.’” Op. at 26 (quoting *New World Radio*, 294 F.3d at 172).

This framework is wrong in three respects.

First, the five-contingencies test finds no support in this Court’s competitor-standing doctrine. No ruling has ever required a court to count future regulatory steps and hold that a plaintiff’s competitive injury is “too remote” when the count exceeds some threshold. The governing standard asks whether the plaintiff is a “direct and current competitor” whose competitive interest “may be adversely affected.” *New World Radio*, 294 F.3d at 170. At the pleading stage, the plaintiff need only allege facts making that adverse effect plausible. *Sparrow*, 216 F.3d at 1113. The district court’s five-factor test imposed a burden appropriate for summary judgment, not a motion to dismiss.

Second, the district court misapplied *New World Radio*. There, a broadcaster challenged the FCC’s renewal of a license for a radio station in a different geographic market—a Maryland station, not a Washington, D.C., station. 294 F.3d

at 168–69. The claimed competitive injury depended on the license holder’s “past attempts to relocate” to the D.C. market, which the court found “too remote” because relocation depended on “independent actions of third parties.” *Id.* at 172.

MMJ’s situation is fundamentally different. MMJ does not need a third party to relocate into its market. The BEI itself places competitors into the cannabinoid-therapeutics market serving Medicare beneficiaries, which is the same market MMJ is actively developing products to serve. Unlike the hypothetical geographic relocation in *New World Radio*, the competitive harm here flows directly from the challenged agency action. The BEI, by design, creates a federally supported pathway for hemp-derived products to reach Medicare beneficiaries. That is exactly the population MMJ’s Huntington’s and multiple-sclerosis therapies target. The causal chain runs from the BEI to increased competition. No intermediate third-party decisions are required.

Subsequent courts have confirmed this reading. *New World Radio* applies only “to an agency action that is, at most, the first step in the direction of future competition,” not to an action “that itself imposes a competitive injury, i.e., that provides benefits to an existing competitor or expands the number of entrants in the petitioner’s market.” *Delta Air Lines, Inc. v. Export-Import Bank*, 85 F. Supp. 3d 250, 261 (D.D.C. 2015) (quoting *New World Radio*, 294 F.3d at 172). The BEI is an already-operational program placing competing cannabinoid products into the

Medicare market today—thus making it harder for MMJ to raise capital and otherwise impeding the development of its competing products—not a step towards future competition.

Third, the district court’s reliance on *PSSI Global Services, LLC v. FCC*, 983 F.3d 1 (D.C. Cir. 2020), is misplaced. In *PSSI*, small satellite operators challenged FCC payments to larger operators, but the small operators provided services “almost exclusively” outside the United States and had taken only “a few steps to develop any United States markets.” *Id.* at 11. MMJ, by contrast, has invested \$10 million exclusively in the U.S. regulatory process, holds U.S.-specific FDA and DEA designations, and operates entirely within the domestic cannabinoid-therapeutics market. MMJ is a domestic pharmaceutical developer deep in the FDA regulatory pipeline with \$10 million invested. That is hardly “a few steps.” Even if this Court agrees that MMJ is merely a prospective market entrant, a prospective competitor that demonstrates an intention to enter the market and preparedness to do so may suffer harm sufficient to establish competitive injury before entering the market. *See Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 806–07 (D.C. Cir. 2001).

Moreover, *PSSI*’s denial of standing rested on the operators’ failure “to connect their competitors’ receipt of payments with a more specific competitive injury.” *Air Excursions*, 66 F.4th at 279. MMJ has made that connection: the BEI creates a federally supported distribution channel for cannabinoid products to the

same Medicare patient population MMJ’s therapeutics target, directly undermining MMJ’s multi-million-dollar investment in the FDA approval pathway. Am. Compl. ¶¶ 17–21; Boise Decl. ¶¶ 34–41.

D. MMJ Targets the Same Regulatory Market as BEI Participants

The district court suggested in a footnote that there may be insufficient “market overlap between MMJ’s marijuana product and the over-the-counter hemp the BEI targets.” Op. at 26 n.7. This suggestion misunderstands the relevant market.

The relevant market is cannabinoid therapeutics for Medicare beneficiaries—not “marijuana” versus “hemp.” Both MMJ’s products and BEI-eligible products are cannabinoid-based therapies designed to address health conditions in the same patient population. The distinction the government draws (marijuana versus hemp) is a regulatory classification based on delta-9 THC concentration (above or below 0.3% on a dry weight basis). 7 U.S.C. § 1639o(1). It is not a market distinction. Hemp is the same plant as marijuana—*Cannabis sativa* L.—and the active compounds are the same tetrahydrocannabinols.

The line between hemp and marijuana is a legal threshold, not a botanical or pharmacological one. Hemp is cannabis with no more than 0.3% delta-9 THC on a dry-weight basis. Marijuana is cannabis above that THC concentration. 7 U.S.C. § 1639o(1). The molecular structure does not magically change at the 0.3% threshold; Delta-9 THC from a plant testing at 0.3% is chemically identical to delta-

9 THC from one testing at 0.4%. Further, cannabinoid content varies with cultivation conditions, extraction methods, and testing practices. Boise Decl. ¶ 36. That variability is why FDA requires a botanical drug sponsor to establish a consistent, reproducible product before giving it to human subjects. *See id.* ¶¶ 22, 25. MMJ has spent years meeting that requirement. BEI-eligible products need not meet it at all.

To put a finer point on it: MMJ develops carefully dosed, purified softgel capsules proceeding through FDA's botanical drug framework, while BEI-eligible products are hemp-derived cannabinoid products distributed without FDA dosing guidance, without the controlled clinical trial process, and without the prescribing information that physicians require for responsible treatment. Both product categories target the same end use: cannabinoid-based treatment of health conditions in Medicare beneficiaries. The government cannot simultaneously maintain that hemp products are appropriate for Medicare beneficiaries (as the BEI presupposes) and that hemp products occupy a different market from FDA-regulated cannabinoid therapeutics. Either cannabinoid products compete with each other in the healthcare market, or they do not. The BEI's very existence demonstrates they do.

This Court has long recognized that competitor standing extends to entities operating under different regulatory frameworks within the same market. In *Associated Gas Distributors v. FERC*, 899 F.2d 1250 (D.C. Cir. 1990), local gas distribution companies had standing to challenge FERC orders opening their markets

to new entrants—even though the new entrants operated under different regulatory authorizations. *Id.* at 1258–59. What mattered was that both sets of competitors operated in the same functional market of gas distribution, not that they held different regulatory classifications. The same principle applies here.

This Court has recognized that competitor standing extends to agency actions that “reimburse[] a firm’s competitor for selling its product or service at discounted rates.” *Air Excursions LLC*, 66 F.4th at 278. The BEI does exactly that. It provides a federal pathway under which providers furnish hemp-derived cannabinoid products to Medicare beneficiaries at the participant’s expense, which subsidizes the distribution of products that compete with MMJ’s FDA-pathway therapeutics.

E. Competitive Injury Is “Certainly Impending” Under Commonsense Causation Principles

The Supreme Court’s recent decision in *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025), reinforces that courts should apply commonsense inferences when evaluating competitive causation. In *Diamond*, the Court held that when third-party behavior in response to a regulation is predictable, plaintiffs may rely on “commonsense inferences” to establish causation and redressability rather than demanding certainty about downstream market effects. *Id.* at 116.

Here, the response to these economic incentives is as predictable as night following day. Subsidizing an activity encourages more of it, while imposing costs discourages it. CMS created a federally supported regulatory pathway for MMJ’s

competitors to distribute competing products unregulated by the FDA to Medicare enrollees—MMJ’s target market. Am. Compl. ¶ 83. Providers who opt into the BEI are reasonably predicted to use that pathway. Those providers will furnish cannabinoid products to the same Medicare population that MMJ’s therapeutics target. The competitive harm to MMJ is transparent to common sense: this CMS-authorized, participant-funded distribution channel for cannabinoid products diverts demand from the regulated pharmaceutical pathway that MMJ has spent over eight years and \$10 million pursuing via its exclusive Orphan Drug Designation.

This Court stated in *Viasat, Inc. v. FCC*, 47 F.4th 769, 778 (D.C. Cir. 2022), that Article III requires an injury that is “actual, imminent, or certainly impending.” That standard is met here. The BEI is already operational. Providers have already opted in. Hemp-derived products are already being furnished to Medicare beneficiaries. MMJ’s competitive injury is happening now, in that the government is diluting MMJ’s orphan-drug market with inferior non-FDA-approved products while blocking MMJ from producing superior products via regulatory delay.

The government may argue that intermediary decisions by individual providers on whether to opt into the BEI and which products to furnish break the causal chain. But this Court has rejected that reasoning as “inconsistent with the competitor standing doctrine.” *Wash. Alliance of Tech. Workers v. DHS*, 892 F.3d 332, 341 (D.C. Cir. 2018). Because “the injury claimed is exposure to competition”

rather than merely “lost sales,” it is “no answer to say that the [agency] is merely permitting a competitive product to enter the market and leaving the purchasing decision to the consumer.” *Id.* (quoting *Bristol-Myers Squibb Co.*, 91 F.3d at 1499); *see also Honeywell Int’l Inc. v. EPA*, 374 F.3d 1363, 1369 (D.C. Cir. 2004) (*per curiam*) (regulation that “legalizes the entry of a product into a market in which [plaintiff] competes” causes injury; rejecting argument that plaintiff could only “speculat[e] about the purchasing decisions of third parties not before the court”).

The district court demanded certainty about MMJ’s future market entry as a prerequisite for standing. But competitor standing has never required the plaintiff to prove it will succeed in the market. It requires only that the plaintiff’s competitive interest “may be adversely affected” by the government action. *New World Radio*, 294 F.3d at 170. MMJ’s competitive interest in the cannabinoid-therapeutics market is real, substantial, and presently affected by the BEI, which is more than enough.

F. *AHM* Does Not Foreclose Competitor Standing

FDA v. Alliance for Hippocratic Medicine, 602 U.S. 367 (2024) (“*AHM*”), does not help the government. *AHM* addressed organizational standing and individual standing. It did not address competitor standing at all. The *AHM* plaintiffs were medical associations and individual doctors who neither manufactured, sold, nor developed a competing pharmaceutical product. 602 U.S. at 386. None “sponsored a competing drug.” *Id.* MMJ, by contrast, is developing a competing

cannabinoid therapeutic through the FDA’s own regulatory framework. The competitor-standing doctrine, which *AHM* did not address, applies to entities that compete in the relevant market—such as MMJ.

Indeed, the term after the Supreme Court decided *AHM*, it confirmed in *Diamond*, 606 U.S. at 120–21, that plaintiffs may rely on “commonsense economic inferences” and a predictable chain of events to establish redressability—without “evidence from expert economists or from directly regulated third parties.” The Court’s standing jurisprudence is not uniformly restrictive. *AHM* tightened organizational and individual standing. *Diamond* later reinforced that competitor-standing claims grounded in economic logic face no comparable barrier.

G. The Government’s Own Delay Bars Its “Speculative Entrant” Defense

The government’s central response below was that MMJ is a “speculative future entrant” because it has no approved product and faces multiple regulatory hurdles. But the government itself is responsible for MMJ’s pre-approval status. This Court should not permit the government to create an obstacle and then invoke that obstacle to defeat standing.

MMJBC submitted its bulk-manufacturing application to DEA nearly eight years ago. Boise Decl. ¶¶ 6, 13, 19. DEA issued an Order to Show Cause and an administrative law judge issued a recommended decision, but DEA has made no final decision. *Id.* ¶ 19. Without bulk-manufacturing registration, MMJ cannot

produce the active pharmaceutical ingredient needed for the clinical trials that FDA approval requires. *Id.* ¶ 13. The first “contingency” the district court identified, DEA approval of bulk-manufacturing registration, is not an independent market barrier. It is a consequence of DEA’s own unreasonable delay.

The significance of this point for standing is direct. The government argues that MMJ’s competitive injury is “too remote” because MMJ faces multiple regulatory steps. But DEA’s response to a pending application, the lengthiest and most uncertain of those steps, is entirely within the government’s control. Under the commonsense causation principles in *Diamond*, this Court need not speculate about whether or when DEA will act. *See Sherley*, 610 F.3d at 72–74. MMJ’s pre-approval status is not evidence of speculative competitive engagement. It is evidence of unreasonable governmental delay.

Nor are the district court’s first two contingencies independent of each other. FDA’s clinical hold rests on chemical, manufacturing, and controls requirements: showing that a botanical drug sponsor has a consistent, reproducible drug substance. *Boise Decl.* ¶ 25. DEA’s delay does not explain why FDA imposed the hold, but does explain why MMJ cannot resolve it. Without bulk-manufacturing registration, MMJ cannot produce its drug substance domestically. *Id.* ¶ 13. The district court counted as two contingencies what is actually one government-created obstacle.

The government should not be heard to argue that MMJ is too far from market entry when the government's own agencies have unreasonably delayed MMJ's path to that market. Accepting this argument would create a perverse incentive: agencies could insulate their own challenged actions from judicial review by simultaneously delaying competitors' regulatory progress and then arguing those competitors are too speculative to have standing. This Court should reject that result.

The district court's competitor-standing holding should be reversed.

II. THE DISTRICT COURT ERRED ON PROCEDURAL STANDING AND THE § 553(a)(2) BENEFITS EXCEPTION

The court below further erred by resolving the benefits exception as part of standing and then by construing that exception to cover the BEI. Those errors independently warrant reversal.

A. The District Court Impermissibly Bootstrapped a Merits Question into Standing Analysis

Procedural standing requires two showings: (1) the defendant violated a procedural right designed to protect the plaintiff's threatened concrete, particularized interest; and (2) that violation resulted in injury to that concrete, particularized interest. *Ctr. for L. & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1157 (D.C. Cir. 2005). *See Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664–65 (D.C. Cir. 1996) (en banc) (requiring a causal connection between the agency action taken without the procedure and injury to the plaintiff's particularized interest). Once the concrete-

interest requirement is satisfied, the standards for imminence and redressability are relaxed, though injury in fact and causation remain necessary. *Ctr. for L. & Educ.*, 396 F.3d at 1157; *Mendoza v. Perez*, 754 F.3d 1002, 1010 (D.C. Cir. 2014).

In applying those requirements at the motion-to-dismiss stage, this Court assumes that the plaintiff states a valid legal claim and accepts the complaint's factual allegations as true. *Mendoza*, 754 F.3d at 1010. That assumption does not dispense with concrete injury: the alleged procedural violation and the plaintiff's concrete interest "are not one and the same." *Ctr. for L. & Educ.*, 396 F.3d at 1159. The standing inquiry therefore asks whether the challenged agency action injures a concrete, particularized interest, while assuming the validity of the claim that the action required the omitted procedure.

The procedural right asserted here is the right to notice and an opportunity to comment before CMS adopts a legislative rule, as provided by 5 U.S.C. § 553(b)–(c). Section 553(a)(2), however, excludes from § 553 a "matter relating to . . . benefits." Whether the BEI is a legislative rule subject to notice and comment, and whether that benefits exception applies, concern whether CMS violated the asserted statutory obligation. *See* 5 U.S.C. § 553(a)(2), (b)–(c); *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 95 (D.C. Cir. 2002) (addressing whether the challenged agency action was a rule as a merits question).

This bootstrapping approach is analytically backwards. If a court must resolve a contested question of statutory interpretation to determine whether a procedural right exists, that question becomes part of the merits analysis and not something to resolve at the standing threshold. Otherwise, the government could defeat standing in any procedural challenge simply by asserting that an exception to the procedural requirement applies—thereby converting every merits defense into a jurisdictional barrier. That cannot be the law.

Once a plaintiff establishes the required concrete interest, procedural standing does not require proof that notice and comment would have changed the agency's decision. A plaintiff “who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered.” *Sugar Cane Growers*, 289 F.3d at 94–95 (further explaining, “All that is necessary is to show that the procedural step was connected to the substantive result.”). Here, the omitted opportunity to comment was directly connected to CMS's adoption of the BEI, the agency action that Plaintiffs challenge.

The district court separately held that Plaintiffs had not shown injury to their concrete interests. Op. at 28–29. Appellants challenge that holding through the competitor and organizational injuries addressed in Parts I and III. Those alleged injuries supply the concrete interests that the notice-and-comment process would protect; the argument does not rest on an interest in commenting alone. With those

interests established, the court should evaluate procedural standing under the standards above and address the scope of § 553(a)(2) on the merits.

B. The BEI Is Not a “Matter Relating to . . . Benefits” Under § 553(a)(2)

Even if the § 553(a)(2) question were proper to consider at the standing stage, the district court answered it incorrectly. Section 553(a)(2) provides that the notice-and-comment requirements of § 553 do not apply to “a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.” 5 U.S.C. § 553(a)(2). The exceptions to § 553 are “narrowly construed and only reluctantly countenanced.” *State of N.J., Dep’t of Env’t Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980). This narrow-construction principle reflects the APA’s fundamental commitment to public participation in rulemaking.

This Court has emphasized that the good-cause exceptions in § 553(b)(B) and (d)(3) “are not escape clauses that may be arbitrarily utilized at the agency’s whim.” *Am. Fed’n of Gov’t Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981) (quoting S. Rep. No. 752, 79th Cong., 1st Sess. (1945)). Rather, “use of these exceptions by administrative agencies should be limited to emergency situations” and “the grounds justifying the agency’s use of the exception should be incorporated within the published rule.” *Id.* CMS invoked no emergency. It published no rule. It incorporated no justification. The § 553(a)(2) exception cannot be deployed as a *post*

hoc defense to litigation when the agency never relied on it at the time of the challenged action.

Also, the BEI does not establish, modify, or administer a Medicare benefit. Medicare “benefits” are the healthcare services for which Medicare provides payment: Part A hospital insurance, Part B supplementary medical insurance, Part C Medicare Advantage plans, and Part D prescription drug coverage. 42 U.S.C. §§ 1395c–1395w-152. The BEI does none of these things. It creates a product-distribution pathway under which participating providers—not Medicare—furnish hemp-derived products to beneficiaries. Medicare does not pay for the products. Am. Compl. ¶ 83. The products are funded at the participant’s expense. *Id.* The BEI is not a reimbursement mechanism, not a coverage determination, and not a payment methodology. It is instead a voluntary model component that permits providers to distribute non-FDA-approved products outside the Medicare benefit structure.

The district court relied on *Humana of South Carolina, Inc. v. Califano*, 590 F.2d 1070 (D.C. Cir. 1978), for the proposition that § 553(a)(2) “prevails when grants, benefits or other named subjects are clearly and directly implicated.” Op. at 29 (quoting *Humana*, 590 F.2d at 1082). But *Humana* involved a standard Medicare reimbursement regulation governing how Medicare would pay for services already covered under the Medicare benefit. 590 F.2d at 1074–75. The challenged action was a regulation governing the return-on-equity allowance for proprietary hospitals.

Id. That is a “matter relating to . . . benefits” in the core sense: it determined how much Medicare would pay for covered services. Medicare does not directly pay for hemp-derived products under the BEI. It allows “participating providers” to do so.

The § 553(a)(2) exception applies only when the named subjects—here, “benefits”—are “clearly and directly implicated.” *Humana*, 590 F.2d at 1082. The BEI does not clearly and directly implicate Medicare benefits. It creates a new, optional, non-reimbursed product-distribution pathway grafted onto Innovation Center models. Medicare *does not pay for the products*. Am. Compl. ¶ 83. No beneficiary receives a Medicare benefit through the BEI. The exception’s language requires a clear and direct connection to the named subject.

The BEI is categorically different than *Humana*’s regulation. It does not set a reimbursement rate. It does not modify a covered service. It does not change a payment method. Instead, it creates a new product-distribution channel funded entirely outside Medicare’s payment structure. The *Humana* court’s language about § 553(a)(2) was addressed to the paradigmatic Medicare benefit question, not to an optional, non-reimbursed distribution pathway grafted onto existing CMMI models.

The district court also cited the Supreme Court’s dictum in *Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019): “While the APA requires many other agencies to offer public notice and a comment period before adopting new regulations, it does not apply to public benefit programs like Medicare.” But this

dictum addressed the general relationship between the APA and Medicare. It did not hold that every action tangentially involving Medicare falls within § 553(a)(2).⁵

The district court's procedural-standing holding should be reversed.

III. THE DISTRICT COURT ERRED IN DISMISSING THE ORGANIZATIONAL PLAINTIFFS FOR LACK OF STANDING

The district court held that no organizational plaintiff demonstrated injury-in-fact under the *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982) framework, as refined by *AHM*, 602 U.S. 367. Op. at 15–22. This was error on the facts presented.

A. The *Havens* Framework Post-*AHM*

Organizational standing under *Havens* requires “concrete and demonstrable injury to the organization’s activities” that is “more than simply a setback to the organization’s abstract social interests.” 455 U.S. at 379. After *AHM*, organizations “cannot spend their way into standing simply by expending money to gather information and advocate against the defendant’s action.” 602 U.S. at 394. The defendant’s actions must have “directly affected and interfered with” the organization’s “core business activities.” *Id.* at 395.

The D.C. Circuit applies a two-part inquiry: (1) whether the agency’s action injured the organization’s interest, and (2) whether the organization used its resources to counteract that harm. *PETA v. USDA*, 797 F.3d 1087, 1094 (D.C. Cir.

⁵ Independently, 42 U.S.C. § 1395hh(a)(2) requires notice-and-comment for rules that establish or change a legal standard governing Medicare benefits.

2015). As the district court itself noted at the hearing on the motion, *AHM* did not overrule *Havens*. It clarified the line between advocacy-driven resource diversion (insufficient) and interference with concrete operational services (sufficient). *PETA* and other standing jurisprudence of this Court remain good law. The key question after *AHM* is whether the organization provides concrete, non-advocacy services that are impaired by the challenged action.

B. CIVEL: Concrete Operational Services Directly Impaired

CIVEL provides concrete operational services that go beyond policy advocacy: legal-education seminars for attorneys, victim legal-assistance programs for individuals harmed by the cannabis industry, and community outreach. Am. Compl. ¶ 7. These are direct service-delivery activities: the organization trains lawyers, assists victims suffering from cannabis-induced psychosis, addiction, and other medical effects of cannabis consumption, and conducts outreach to communities affected by these same harms.

The BEI directly impairs these services. By creating a federally supported pathway for hemp-derived THC products to reach Medicare beneficiaries, it generates a new category of potential cannabis-related injuries. It allows elderly Americans to receive products without FDA dosing guidance, controlled clinical trials, and physician prescribing information. CIVEL's victim legal-assistance programs must now expand to address this new class of potential harms, and its

legal-education seminars must now train attorneys on the legal implications of the BEI for malpractice, product liability, and informed consent. CIVEL will have to develop new procedures for its participating attorneys. This will involve new model BEI complaints and causes of action, litigation strategies, medical and scientific data, demands for production of documents, interrogatories, defense of dispositive motions, and new client-outreach and -vetting procedures. CIVEL will also need to develop new cooperating agreements with ACOs, healthcare providers, and experts. These are concrete operational demands imposed by the BEI, not advocacy choices.

CIVEL's posture here is analogous to the successful standing theory in *PETA*, where that organization challenged the government's refusal to enforce animal welfare regulations for birds. The government's non-enforcement prevented PETA from obtaining agency action on its formal bird-abuse complaints and deprived PETA of reports it had "routinely" used to educate the public. 797 F.3d at 1095–96. This Court held that denial of bird-related inspection information and a means to seek redress for bird abuse impaired PETA's activities, and that PETA expended resources to counter those injuries. *Id.* at 1094–96.

Like PETA, CIVEL does not merely disagree with the BEI. Its concrete operational activities of victim assistance, community outreach, and legal education are directly affected by a government action that expands the distribution of

cannabis-derived products to a vulnerable population. The BEI poses a “concrete obstacle” to CIVEL’s work. *See PETA*, 797 F.3d at 1092.

The district court characterized CIVEL’s theory as requiring “multiple levels of speculation about injuries hemp may cause, and litigation those hypothetical injuries may generate.” Op. at 20. This characterization collapses the distinction between advocacy (studying and opposing the BEI) and service delivery (assisting victims whose injuries are caused or exacerbated by the BEI). The court also stated that even if CIVEL “dedicates more resources ‘to handle those cases,’ doing so serves its aim of supporting ‘legal professionals.’” Op. at 20. But that reasoning would eliminate organizational standing for any service-delivery organization: an increase in demand for an organization’s services always “serves” the organization’s mission in some abstract sense. The relevant question under *Havens* and *PETA* is whether the challenged action concretely impairs the organization’s ability to deliver those services—and it does. CIVEL must now divert its limited resources from existing victim-assistance and legal-education programs, including its efforts to oppose the government’s foolhardy and unlawful rescheduling of cannabis to Schedule III, to address a new category of harms the BEI creates.

C. SAM and HCADA

SAM operates patient- and provider-education programs directed at healthcare providers and patients. Niforatos Decl. ¶¶ 5–6, 9, ECF No. 28-1. The BEI

required SAM to redirect staff from these programs to monitor and explain the BEI to stakeholders. *Id.* ¶ 9. SAM’s programmatic activities—“research and policy analysis” and “public health education campaigns”—are closer to the advocacy activities that *AHM* found insufficient. Am. Compl. ¶ 6. But SAM’s specific patient-education and provider-education programs are concrete services that were impaired by the BEI, and do not constitute advocacy. Instead, SAM’s educational and analytical efforts focus on monitoring government regulation of cannabis. The district court’s premature dismissal of SAM’s claims prevented it from developing record details regarding these efforts, and Appellants request remand so that the district court can adequately address SAM’s standing on the merits.

HCADA supports law enforcement, prevention agencies, and substance abuse education providers through educational activities and community events. Snelling Decl. ¶¶ 4–5. HCADA’s substance-abuse education and community outreach are concrete services that it must divert its limited resources from pursuing in order to oppose the BEI, which will make its programmatic activities harder by shifting the burden to respond to the BEI’s effects on the elderly to community organizations like HCADA. This is grounds for standing. *See PETA*, 797 F.3d at 1091.

D. Adverse Authority Is Distinguishable

Center for Biological Diversity v. DOI, 144 F.4th 296 (D.C. Cir. 2025), rejected an information-gathering theory of organizational injury. The organization

there challenged the government's failure to produce biological opinions and claimed it had to file FOIA requests for information useful to its mission. *Id.* at 315. This Court held that merely having to "work harder" to gather mission-relevant information was insufficient. *Id.* Appellants' theory is different. CIVEL provides victim assistance, not information-gathering. HCADA provides community programs and other outreach efforts. SAM constantly monitors federal regulations related to cannabis. The BEI does not deprive Appellants of information; it creates new victims, new societal harms, new regulatory structures, and new legal issues that their programs must address.

Food & Water Watch v. Vilsack, 808 F.3d 905 (D.C. Cir. 2015), is similarly distinguishable. There, a food-safety advocacy organization claimed it would have to "spend resources educating its members and the public" about loosened poultry inspection rules. *Id.* at 921. But the group's "activities [had not] been perceptibly impaired in any way." *Id.* CIVEL's victim-assistance and legal-education services and HCADA's community-support efforts are perceptibly impaired: the BEI creates a new class of cannabis-related injuries that CIVEL and HCADA's programs must now address, diverting resources from ongoing service delivery. CIVEL also faces a threatened increase in logistical and financial burdens, apart from resources already diverted to respond to the BEI. Plaintiff Evans explained that the BEI will increase

cannabis-related injuries and resulting litigation, enlarging the population CIVEL's victim-assistance and legal-education programs must serve. Evans Decl. ¶¶ 22–23.

The organizational-standing dismissal should be reversed.

IV. THE PLAINTIFFS ALSO HAVE ASSOCIATIONAL AND INDIVIDUAL STANDING

Appellants preserve as an alternative ground for reversal the associational standing claims of the organizational Plaintiffs under *Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333, 343 (1977), and the individual standing claims of David Evans and Dr. Kenneth Finn. The district court held that Evans lacked injury-in-fact because his provider had not yet opted into the BEI and his claimed harms were conjectural. Op. at 12–13. Because associational standing requires at least one member with individual standing, and Evans was the sole identified member, the associational theory rises or falls with Evans. If this Court reverses on any other standing ground, these issues need not be reached. Appellants include this point solely to protect against waiver in any subsequent proceedings.

V. THIS COURT SHOULD VACATE THE DISMISSAL ORDER, VACATE THE DENIAL OF A PRELIMINARY INJUNCTION/STAY, AND REMAND FOR EXPEDITED PROCEEDINGS

If this Court reverses the district court's standing determination on any ground, the appropriate remedy is threefold.

First, this Court should vacate the district court's order dismissing the action for lack of standing. The case should be remanded for proceedings on the merits of

Plaintiffs’ APA claims that remain unresolved—including whether the BEI is a legislative rule requiring notice-and-comment, whether it is arbitrary and capricious, and whether CMS exceeded its statutory authority under Section 1115A. Op. at 29 n.8 (reserving the legislative-rule question).

Second, the Court should vacate the district court’s ruling denying the preliminary injunction and § 705 stay as moot. The district court denied interim relief solely because it dismissed the case on standing grounds and never reached the merits of Plaintiffs’ motion. Op. at 30. On remand, the district court should be directed to consider Plaintiffs’ motion for a preliminary injunction under Rule 65(a) and a stay under 5 U.S.C. § 705 under the applicable standards: likelihood of success, irreparable harm, balance of equities, and public interest.

Third, the Court should preserve Plaintiffs’ ability to seek expedited proceedings on remand. The BEI remains operational. Under 5 U.S.C. § 705, the district court may “issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.” That authority reaches agency action already in effect. *See, e.g., Ohio v. EPA*, 603 U.S. 279 (2024) (staying enforcement of an EPA rule already in effect pending judicial review); *see also Nken v. Holder*, 556 U.S. 418, 428–29 (2009) (a stay operates by “temporarily suspending the source of authority to act”). The merits of that request have never been adjudicated. Plaintiffs

respectfully request that the Court make clear in its mandate that the district court should promptly consider Plaintiffs' motion for interim relief on remand.

CONCLUSION

For the foregoing reasons, Appellants respectfully request that this Court (1) reverse the district court's order dismissing this action for lack of Article III standing; (2) vacate the district court's denial of Plaintiffs' motion for preliminary injunction and stay of agency action under 5 U.S.C. § 705 as moot; and (3) remand for proceedings on the merits of Plaintiffs' APA claims and for consideration of Plaintiffs' motion for interim relief under Rule 65 and 5 U.S.C. § 705.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 9,067 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1), as determined by the word counting feature of the software (Microsoft Office 365) used to prepare this brief.

This brief complies with the typeface requirements of FRAP 32(a)(5) and the type-style requirements of FRAP 32(a)(6) because this brief has been prepared in a proportionally spaced typeface, 14-point Times New Roman.

/s/ Ilya Shapiro

Counsel for Plaintiffs-Appellants

Dated: October 5, 2026

CERTIFICATE OF SERVICE

I hereby certify that on October 5, 2026, I electronically filed the above with the Clerk of Court using the CM/ECF system which will send notification of this filing to counsel for all parties.

/s/ Ilya Shapiro

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