IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, *et al.*, *Plaintiffs*, v. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:26-cv-01081-TNM

MOTION TO REVISE AND EXTEND DEADLINES

Pursuant to Federal Rules of Civil Procedure 16(b)(4) and 6(b)(1), Plaintiffs Smart Approaches to Marijuana, et al. ("Plaintiffs"), by and through their undersigned counsel, respectfully move this Court for an order revising and extending the current briefing deadlines governing Plaintiffs' pending Emergency Motion for a Preliminary Injunction and Stay of Agency Action Pending Judicial Review. Defendants oppose this motion.

In support of this Motion, Plaintiffs state as follows:

I. Background

On March 31, 2026, Plaintiffs filed an Emergency Motion for a Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review (the "PI Motion"). On April 1, 2026, this Court denied the Plaintiffs' motion for a temporary restraining order but set briefing deadlines and a hearing for the remainder of the PI Motion. Under the current schedule, Defendants' opposition to the PI Motion is due on April 9, 2026.

On April 6, 2026, Plaintiffs identified three interested parties who seek to join this action on different standing and injury grounds. These new Plaintiffs are a biopharmaceutical corporation and its two subsidiaries: MMJ International Holdings, MMJ BioPharma Labs, Inc., and MMJ BioPharma Cultivation, Inc. (collectively, "MMJ"). For the past eight years, MMJ has been developing cannabinoid-based therapeutics through the Food & Drug Administration ("FDA")'s botanical drug regulatory pathway. The FDA has accepted its Investigational New Drug ("IND") applications, and MMJ has worked with the Drug Enforcement Agency ("DEA") to receive a Schedule I analytical laboratory registration. Its bulk manufacturing application for clinical trials remains pending before the DEA.

MMJ asserts bases for standing and claims of injury that are distinct from those of the existing Plaintiffs. The Substance Access Beneficiary Engagement Incentive ("BEI") harms MMJ by (1) permitting distribution of retail cannabis- and hemp-derived products not approved by the FDA through medical channels while MMJ remains under regulation, (2) distorting the market for cannabinoid-based therapeutics, (3) creating a competitive disadvantage for MMJ by devaluing its investments and undermining its reliance interests and long-term exclusivity expectations, (4) depriving MMJ of due process and the ability to comment on the BEI, and (5) undermining its federally authorized Huntington's disease program by creating uncertainty and increasing development risk.

Accordingly, Plaintiffs intend to file an Amended Complaint adding the new plaintiff and a Supplemental Memorandum of Points and Authorities in support of the

pending PI Motion to address the new plaintiff's standing and the additional grounds for injunctive relief. A declaration from Duane Boise, MMJ's Chief Executive Officer, will accompany the Supplemental Memorandum.

II. Good Cause Exists to Modify the Briefing Schedule

Federal Rule of Civil Procedure 16(b)(4) provides that a scheduling order "may be modified only for good cause and with the judge's consent." Good cause exists where the existing schedule cannot reasonably be met despite the party's diligence in seeking the extension. *See U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 576 F.Supp.2d 128, 133 (D.D.C. 2008). The good cause inquiry focuses primarily on the diligence of the movant. *See id.*

Good cause exists here for three reasons. First, the joinder of a new plaintiff materially changes the scope of this litigation. MMJ asserts distinct grounds for standing and a separate theory of injury that were not part of this case when the current briefing schedule was set and that materially differ from those asserted by current Plaintiffs. The Amended Complaint and Supplemental Memorandum will present new factual and legal bases for the Court's consideration on the PI Motion, including MMJ's independent standing and additional injuries flowing from the BEI and Defendants' failure to follow the law. The current April 9 deadline for Defendants' opposition was set without accounting for these amended pleadings.

Second, Plaintiffs have been diligent in prosecuting this case. Plaintiffs identified MMJ as a proposed new plaintiff on April 6, 2026, learned of their desire to join that same day, and immediately conferred with Defendants' counsel on April 7, 2026 to seek

agreement on a revised schedule. The need for additional time is not the product of delay or neglect but rather the direct and unavoidable consequence of a new plaintiff entering the case with new grounds for relief.

Third, no party will be prejudiced by the requested extension. The proposed revised deadlines add only a modest extension and preserve the orderly and expeditious progression of this emergency matter.

III. Proposed Revised Schedule

Plaintiffs respectfully request that the Court add the following new deadlines and extend the existing PI Motion briefing deadlines as follows:

- Plaintiffs' Amended Complaint: April 13, 2026
- Plaintiffs' Supplemental Memorandum of Points and Authorities in Support of Motion for Preliminary Injunction: April 13, 2026
- Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction: April 20, 2026
- Plaintiffs' Reply in Support of Motion for Preliminary Injunction: April 24, 2026

Plaintiffs further respectfully request that the Court schedule an in-person hearing on Plaintiffs' Motion for a Preliminary Injunction and Stay. Plaintiffs are available on Friday, May 1, 2026 after 1:00 p.m., Monday, May 4, 2026, or Friday, May 8, 2026, and given the urgency of this matter, would prefer the earliest available date.

IV. Conclusion

For the foregoing reasons, Plaintiffs respectfully request that the Court grant this Motion and enter the attached Proposed Order extending the preliminary injunction briefing deadlines as set forth above.

Date: April 8, 2026

Respectfully submitted,

/s/ Connor W. Mighell

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Attorneys for Plaintiffs

CERTIFICATE OF CONFERENCE

Pursuant to Local Civil Rule 7(m), undersigned counsel certifies that on April 7, 2026 counsel for Plaintiffs conferred via email with counsel for Defendants regarding the relief requested herein. On April 8, 2026, counsel for Defendants notified counsel for Plaintiffs that Defendants oppose this Motion.

/s/ Connor W. Mighell
Connor W. Mighell

CERTIFICATE OF SERVICE

I hereby certify that on April 8, 2026, a true and correct copy of the foregoing motion was filed electronically with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record who have registered with the CM/ECF system.

/s/ Connor W. Mighell
Connor W. Mighell

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, *et al.*, *Plaintiffs*, v. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:26-cv-01081-TNM

PROPOSED ORDER

Upon consideration of Plaintiffs' Motion to Revise and Extend Deadlines, and for good cause shown, it is hereby ORDERED that the Motion is GRANTED, and it is further ORDERED that the following deadlines are set:

1. Plaintiffs shall file their Amended Complaint on or before April 13, 2026.
2. Plaintiffs shall file their Supplemental Memorandum of Points and Authorities in Support of the Emergency Motion for Preliminary Injunction and Stay of Agency Action Pending Judicial Review on or before April 13, 2026.
3. Defendants shall file their Opposition to Plaintiffs' Emergency Motion on or before April 20, 2026.
4. Plaintiffs shall file their Reply in Support of the Emergency Motion on or before April 24, 2026.
5. An in-person hearing on Plaintiffs' Emergency Motion is scheduled for [DATE AND TIME].

IT IS SO ORDERED this ____ day of ___________, 2026.

____

THE HON. TREVOR N. MCFADDEN
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al., Plaintiffs, v. DR. MEHMET OZ, in his official capacity as CMS Administrator, et al., Defendants.	Civil Action No. 26-1081 (TNM)

DEFENDANTS' OPPOSITION TO PLAINTIFFS'
MOTION TO EXTEND BRIEFING SCHEDULE (ECF NO. 18)

Plaintiffs seek to extend the briefing schedule and postpone the April 20 hearing to accommodate the joinder of MMJ International Holdings and two subsidiaries (collectively, "MMJ"). Defendants do not oppose the joinder of MMJ, as they recognize that Plaintiffs still can amend their Complaint once as a matter of course pursuant to Rule 15(a)(1).[1] But, as regards the pending motion for preliminary injunction, Defendants do oppose extending the schedule this Court set for lack of good cause.

As an initial matter, there is an obvious contradiction between seeking an emergency hearing on one day's notice last week and now insisting that time is not of the essence—based on what Defendants will show is a futile and misleading effort to cure standing deficiencies. The Court should proceed to resolve the preliminary injunction on the existing schedule.

[1] Pursuant to Rule 15(a)(1), a party may amend once as a matter of course within 21 days of filing the lawsuit or within 21 days of a motion filed under Rule 12. As this lawsuit was filed on March 30, 2026, the 21-day period has not yet expired.

Should the Court grant the extension, Defendants request (1) 14 days to oppose any revised motion, which under Plaintiffs' proposed schedule would set a deadline of April 27 rather than April 20; and (2) leave to file under seal with their opposition a declaration and exhibits addressing assertions in the instant motion and anticipated supplemental briefing that Defendants consider materially incomplete but cannot fully address in this filing due to confidentiality constraints.[2]

I. Background on MMJ

MMJ International Holdings is a holding company with two subsidiaries: MMJ BioPharma Labs, Inc. and MMJ BioPharma Cultivation, Inc. MMJ describes itself as "the leading pharmaceutical developer of plant-derived cannabinoid therapeutics."[3] MMJ also notes it has "worked with" the "Drug Enforcement Agency [sic]" to receive an analytical laboratory registration. Mot. (ECF No. 18) at 2. What the Motion means by "worked with" is unclear. What is clear is that MMJ has litigated against the DEA for years over its refusal to grant it a bulk manufacturing registration to cultivate cannabis. *See, e.g.*, Ex. 2 (MMJ Complaint). By MMJ's own account, its inability to procure this registration has significantly hindered progress in its clinical trials. To date, it does not appear to hold anything other than an analytical lab license, which is insufficient to conduct clinical trials.

More recently, MMJ's public record with respect to the BEI is extensive. On March 10, 2026, MMJ issued a press release titled "The $30 Billion CBD Question: Should Medicare

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[2] The Motion asserts that "[t]he FDA has accepted its Investigational New Drug applications," and that MMJ has a "*federally authorized* Huntington's disease program." Mot. (ECF No. 18) at 2 (emphasis added). Defendants raised concerns about the accuracy of these representations on the April 8 meet-and-confer. Plaintiffs chose to nevertheless proceed in making them to the Court. Should the Court permit revised preliminary injunction briefing, Defendants intend to address them through a declaration filed under seal, as doing so requires disclosure of information from confidential regulatory filings.

[3] *See* Ex. 1 (3/31/26 press release).

Reimburse Cannabis Products Without FDA Approval?" opposing the concept of Medicare cannabinoid reimbursement outside the FDA pathway.[4] MMJ issued additional press releases on March 24 and March 27—in the latter, its CEO stated: "A soft-gel is a medicine; a gummy is a snack."[5] And on March 31—the day of the TRO hearing—MMJ issued a fourth press release, proclaiming: "While MMJ International Holdings *is not a party to the litigation*, the company stands as a primary example of why the lawsuit's core argument—that science must precede reimbursement—is a matter of national drug safety."[6] And in it, MMJ linked to the Complaint.

Despite a month of public opposition to the BEI, four press releases, and a statement that it was aware of and aligned with this lawsuit (linking to the Complaint), MMJ did not seek to join this case until Tuesday, April 7, less than 48-hours before Defendants' opposition is due.

II. There is no good cause for the delay.

While Plaintiffs can timely amend their complaint once as a matter of course, modifying a scheduling order requires good cause. Fed. R. Civ. P. 16(b)(4). *See also* Standing Order, No. 9. MMJ offers no good reason let alone "truly exceptional or compelling circumstances" to justify altering the schedule a day before Defendants' response is due.

Plaintiffs filed this motion one day before the affected deadline. Standing Order, No. 9 requires filing at least four days prior. As noted above, MMJ has publicly opposed the BEI since March 10; it publicly commented on this lawsuit on March 31; and even more, on the April 8 conference call, Plaintiffs' counsel conveyed that at least one existing plaintiff discussed this lawsuit with MMJ around the time of the March 31 TRO hearing. Yet, MMJ waited until the eve of the opposition to enter the fray.

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4 Ex. 1 (3/10/26 press release).
5 Ex 1 (3/24/26 and 3/27/26 press releases).
6 Ex. 1 (3/31/26 press release) (emphasis added).

MMJ offers no explanation for *its* delay. The question is not when Plaintiffs identified the need for MMJ, Mot. at 3, but when MMJ knew its interests were at stake—which, by its own public statements, was no later than March 31.

That delay undermines its claim of irreparable harm. The only event between March 31—when MMJ publicly stated it was "not a party to the litigation"—and days later, when it discussed joining with an existing plaintiff, was this Court's TRO hearing, during which the Court raised questions about whether the existing Plaintiffs can establish Article III standing. The Court should not extend the schedule to accommodate a joinder that appears driven not by the urgency of MMJ's claimed injuries but by the standing deficiencies of the parties that initiated this suit.

MMJ, moreover, cannot show irreparable harm. MMJ's claimed injuries—decreased investor confidence, competitive disadvantage, impaired future earnings—are speculative projections about a market MMJ has not entered (and will not enter for years), based on products MMJ has not developed, contingent on authorizations MMJ has not obtained. But even accepting them at face value, they are fully remediable.

Nothing about the pendency of this lawsuit impedes MMJ from resolving its regulatory impediments, obtaining a DEA cultivation registration, or advancing its drug development program. The BEI does not block any of those pathways. If the BEI is set aside, any claimed injury is restored in full. That is the definition of reparable harm. MMJ is years away from market entry—if it ever arrives. There is nothing irreparable about that, and there is no basis for delaying the April 20 hearing to accommodate a party that can show neither standing nor irreparable harm.

In contrast, the motion's assertion that the government and public will not be prejudiced by the requested extension is wrong. Mot. at 4. The proposed schedule would push the hearing from April 20 to May and thus extend the period during which an operational federal program

remains under a cloud of litigation. The program just started, and model participants considering whether to elect the BEI face ongoing uncertainty. The government and public are prejudiced by any extension of a schedule that was expedited for good reason.

III. Conclusion

The Court should deny the motion to extend the schedule and proceed to the April 20 hearing on the preliminary injunction motion as planned. But if the Court is inclined to modify the preliminary injunction schedule as requested by Plaintiffs, it should afford Defendants 14 days—to April 27, 2026—to file an opposition to any revised motion for preliminary injunction and also grant leave to Defendants now to file a portion of their opposition, including declarations and exhibits, under seal. In the event MMJ is permitted to join in the preliminary injunction motion, Defendants also anticipate providing notice pursuant to Local Civil Rule 65.1(d) of their intention to cross-examine any MMJ declarant at the hearing. A proposed order is attached.

Dated: April 9, 2026

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al., Plaintiffs, v. DR. MEHMET OZ, in his official capacity as CMS Administrator, et al., Defendant.	Civil Action No. 26-1081 (TNM)

[PROPOSED] ORDER

UPON CONSIDERATION of Defendants' Opposition to Plaintiffs' Motion to Extend Briefing Schedule (ECF No. 18), and the entire record herein, it is hereby

ORDERED that Plaintiffs' motion is DENIED; [OR]

ORDERED that Defendants' deadline to file an opposition to any revised motion for preliminary injunction is extended to April 27, 2026; and,

ORDERED that Defendants are granted leave to file a portion of their opposition, including declarations and exhibits, under seal.

SO ORDERED:

__________________ Date

____
Trevor N. McFadden
United States District Judge

This is a paid press release. Contact the press release distributor directly with any inquiries.

The $30 Billion CBD Question: Should Medicare Reimburse Cannabis Products Without FDA Approval?

"As CMS Launches its $500 Cannabinoid "Engagement Incentive," MMJ International Holdings Warns of a Regulatory "Double Standard" ... · ACCESS Newswire · MMJ International Holdings

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MMJ International Holdings
March 10, 2026 • 4 min read

"Medicare was built on evidence-based medicine," said Duane Boise, CEO of MMJ International Holdings. "If cannabinoid therapies are going to be reimbursed by federal healthcare programs, they should meet the same scientific standards every other drug must meet-rigorous clinical trials, validated manufacturing, and FDA oversight."

Exhibit 1

WASHINGTON, DC / ACCESS Newswire / March 10, 2026 / Why All CBD Is Not the Same - And Why FDA Standards Matter

As federal policymakers debate the proposed Medicare CBD pilot program, a critical scientific reality is often overlooked: **not all CBD products are the same.**

While cannabidiol (CBD) is a single chemical compound, the products sold across the consumer marketplace vary dramatically in purity, formulation, manufacturing quality, and safety. These differences are precisely why the United States established a rigorous drug approval system administered by the **U.S. Food and Drug Administration**.

Without those standards, two products labeled "CBD" may behave very differently in the body.

This issue becomes particularly significant as policymakers consider reimbursing cannabinoid products for seniors through federal healthcare programs.

Plant Chemistry Is Highly Variable

CBD is derived from *Cannabis sativa*, a plant with thousands of genetically distinct varieties. Each cultivar produces a different chemical profile containing:

- cannabinoids such as CBD, THC, CBG, and CBC
- aromatic terpenes

- flavonoids

- plant waxes and lipids

In consumer products, cannabinoid ratios can vary widely from batch to batch. That variability affects both **therapeutic response and safety**, especially for older adults managing chronic pain, neurological disorders, or multiple medications.

Pharmaceutical drug development requires **genetically stable plant sources and reproducible chemical profiles** so that every batch of medicine is chemically identical.

Manufacturing Methods Matter

CBD products are created by extracting compounds from cannabis plant material. The extraction and purification process determines whether the final product contains unwanted contaminants.

Possible contaminants include:

- pesticides used during cultivation
- residual solvents from extraction processes
- heavy metals absorbed from soil
- microbial contaminants such as mold or bacteria

Pharmaceutical manufacturers must follow **Good Manufacturing Practice (GMP)** standards to ensure contaminants remain below strict safety thresholds.

Many consumer CBD products are not produced under these pharmaceutical controls.

Label Accuracy Is Often Unreliable

Story Continues

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Medicare's Cannabis (CBD) Coverage Plan Sparks Federal Controversy-Is CMS Circumventing FDA Drug Approval Standards?

Provided by ACCESS Newswire • Mar 24, 2026, 4:05:00 PM

Is CMS Circumventing FDA Drug Approval Standards While Congress Moves to Shut the Hemp Market Down?

With Congress tightening federal THC limits and the FDA still evaluating cannabinoid safety standards, critics are asking why Medicare is moving forward with reimbursed CBD products that lack validated dose forms, pharmacokinetic benchmarks, or identified pharmaceutical-grade sources.

WASHINGTON, DC / ACCESS Newswire / March 24, 2026 / A new federal initiative allowing up to **$500 annually in hemp-derived cannabinoid products for Medicare beneficiaries** is raising urgent questions across the pharmaceutical cannabis sector about whether the Centers for Medicare & Medicaid Services (CMS) is moving ahead of the scientific framework traditionally required for medicine in the United States.

"The United States already has a scientific pathway for botanical cannabinoid medicines-it's called the FDA drug approval process," said Duane Boise, CEO of MMJ International Holdings.

"Companies like ours followed that pathway for years under Schedule I restrictions, completed IND submissions, secured orphan drug designation, and developed standardized dose-form cannabinoid capsules specifically to meet federal safety requirements. Now CMS is preparing to reimburse hemp-derived cannabinoid products without identifying a validated formulation, without pharmacokinetic standards, and without an FDA-approved therapeutic profile. That raises serious questions about whether the government is supporting science-or bypassing it."

The pilot program-expected to begin as early as April 1 under Innovation Center care models administered by CMS-would allow participating physicians to furnish orally administered hemp-derived cannabidiol products containing **up to 3 mg of total THC per serving**. But critics warn the initiative risks creating a federally reimbursed cannabinoid category without the scientific safeguards traditionally required for prescription therapies.

A Fundamental Question: Who Approved These Products?

Under longstanding federal law, products intended to diagnose, treat, mitigate, or prevent disease must proceed through the **U.S. Food and Drug Administration's drug approval pathway**.

That process requires:

standardized formulation

pharmacokinetic evaluation

stability testing

clinical trials conducted under Investigational New Drug (IND) authorization

Yet CMS's pilot framework does not identify:

a specific manufacturer

a validated formulation

a defined dosing standard

or any FDA-approved cannabinoid extract beyond existing prescription drugs

Instead, the program references "legally compliant hemp sources" without clarifying whether those extracts meet pharmaceutical-grade botanical drug development standards.

Not All CBD Is the Same

This distinction is central to the controversy.

Cannabidiol is a molecule.

CBD products are not interchangeable medicines.

Products sold in the consumer marketplace vary widely in:

cannabinoid composition

residual solvent levels

pesticide contamination risk

bioavailability

stability

THC exposure

That variability is precisely why the FDA established its **Botanical Drug Development Guidance** framework.

Subsidiaries of MMJ International Holdings-including MMJ BioPharma Cultivation and MMJ BioPharma Labs-have spent years operating within that pathway while developing standardized cannabinoid soft-gel capsules intended for Huntington's disease and multiple sclerosis clinical programs.

Those efforts required:

DEA Schedule I research compliance

FDA IND review

orphan drug designation

controlled dose-form development

CMS's pilot proceeds without identifying equivalent scientific benchmarks.

A Policy Collision With Congress

Even more striking is the timing.

The CMS pilot launches just months before a federal statutory change expected to **significantly restrict ingestible hemp-derived cannabinoid products nationwide**.

Congress has already enacted legislation limiting hemp derivatives to approximately **0.4 mg total THC per container**, a threshold many stakeholders believe could eliminate most consumable cannabinoid formulations currently on the market.

Yet CMS's pilot allows:

3 mg of total THC per serving

-more than seven times higher.

That discrepancy raises a fundamental policy question:

Why expand reimbursement for products Congress is preparing to restrict?

No Final Dose Form. No NDA. No IND Disclosure.

Perhaps the most unusual feature of the CMS pilot is what it does not specify.

There is currently:

no named formulation

no pharmacokinetic exposure standard

no validated dosing range

no FDA-approved label

no New Drug Application (NDA) pathway attached to the program

Instead, participating provider organizations must submit internal implementation plans describing product selection and dosing protocols for CMS approval.

This effectively shifts responsibility for therapeutic selection from federal regulators to healthcare networks-an uncommon structure for a federally supported therapeutic access program.

Meanwhile, Companies Following FDA Rules Are Still Waiting

While CMS prepares to distribute hemp-derived cannabinoids through Medicare Innovation Center models, companies that pursued the formal pharmaceutical pathway remain inside the FDA system.

Programs such as **IND 140712**, covering standardized CBD/THC capsule formulations under orphan designation for Huntington's disease, were developed specifically to meet federal drug-approval standards under Schedule I conditions.

Those programs required years of regulatory compliance before reaching the point of clinical advancement.

Critics now ask:

Why does a reimbursement pathway exist before the drug-approval pathway is complete?

Who Benefits From the Pilot?

Another unresolved issue concerns sourcing.

CMS requires that eligible products:

originate from legally compliant farms

meet testing standards

remain within THC thresholds

be physician-distributed through participating organizations

But the agency has not identified:

extract manufacturers

formulation developers

pharmacology datasets supporting dose selection

or standardized exposure targets

At the same time, Congress is tightening hemp definitions in ways expected to reduce the availability of ingestible cannabinoid products nationwide.

That creates a policy paradox:

If the hemp market is contracting, why is Medicare expanding access to it?

A Shadow Regulatory Framework Emerging?

Supporters describe the CMS initiative as a research-driven access pilot designed to generate real-world evidence.

Critics see something different:

a federally supported cannabinoid distribution system developing alongside-but outside-the FDA's botanical drug approval framework.

Because once Medicare reimburses a therapeutic product, it becomes part of the clinical ecosystem regardless of whether the FDA has formally approved it as medicine.

Watch What Happens

The CMS cannabidiol pilot may represent an important experiment in cannabinoid access.

Or it may represent something more consequential:

a reimbursement framework moving ahead of science, ahead of Congress, and ahead of the FDA's established pathway for botanical drug development.

Until CMS identifies the formulations, exposure standards, and evidence supporting its dosing decisions, one question will continue to define the debate:

Is Medicare expanding access to medicine-or redefining what qualifies as medicine without FDA approval?

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SOURCE: MMJ International Holdings

View the original press release on ACCESS Newswire

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Karen Gilchrist • Apr 8, 2026

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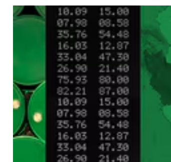

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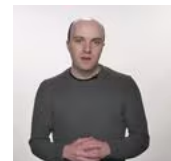

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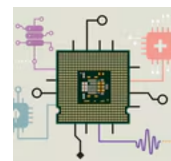

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Bella Albrecht • Apr 6, 2026

United States

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PRESS RELEASE

Medicare CBD Regulatory Cliff: Why FDA Enforcement Must Precede Federal Reimbursement

Published: March 27, 2026 at 12:20 p.m. ET

The MarketWatch News Department was not involved in the creation of this content.

"The CMS pilot program could establish a federally supported cannabinoid treatment category before FDA botanical drug development standards are completed-potentially redefining how medicine enters the U.S. healthcare system, stated Duane Boise, CEO MMJ International Holdings.

As the White House Prepares for Critical April Meetings on CBD Compliance, MMJ International Holdings Warns Against "Policy Moving Faster Than Science."

WASHINGTON, DC / ACCESS Newswire / March 27, 2026 / The federal cannabinoid landscape is approaching a high-stakes "order of operations" crisis. Next week, on April 1 and April 2, the White House Office of Management and Budget (OMB) will hold a series of pivotal meetings to review the FDA's proposed "Cannabidiol (CBD) Products Compliance and Enforcement Policy." These meetings come at a moment of profound internal contradiction within the federal government. While the FDA prepares to tighten its grip on a "Wild West" market characterized by inaccurate labeling and inconsistent manufacturing, the Centers for Medicare & Medicaid Services (CMS) is simultaneously moving to launch a pilot program in April that would reimburse seniors up to $500 annually for these same unvalidated products.

Skip to main content

The Science-First Mandate

For pharmaceutical developers like MMJ International Holdings, the stakes of this regulatory pivot are structural. The company, which has spent nearly a decade adhering to the FDA Botanical Drug Development Guidance, argues that the credibility of cannabinoid medicine depends on maintaining the traditional pharmaceutical sequence: Validation before Reimbursement.

"There is already a clear pathway for botanical cannabinoid medicines in the United States-the FDA created it," stated Duane Boise, CEO of MMJ International Holdings. "Patients with serious neurological diseases, such as Huntington's and Multiple Sclerosis, deserve therapies supported by clinical evidence, standardized manufacturing, and reproducible dosing. Reimbursement policy should strengthen that pathway, not bypass it."

Closing the "Loophole" vs. Expanding Access

The upcoming White House meetings follow a missed February 10 deadline for the FDA to define "containers" and list prohibited synthetic cannabinoids under legislation signed by President Trump in December. That law is set to effectively recriminalize most intoxicating hemp-derived products by mid-November, imposing a strict 0.4 mg THC per container limit.

This creates a looming policy paradox:

Skip to main content

products that have not yet cleared the FDA's drug-approval hurdle.

The Risk of a "Parallel System"

If federal healthcare dollars begin supporting non-standardized cannabinoid products before clinical validation is complete, it risks creating two distinct-and unequal-tracks of medicine:

The Consumer Track: Variable formulations, retail-driven distribution, and limited clinical oversight.

The Pharmaceutical Track: FDA-reviewed dose forms (like MMJ's validated soft-gels), IND-authorized trials, and reproducible pharmacokinetics.

For neurological patients, the difference between these two tracks isn't just regulatory-it's therapeutic. "A soft-gel is a medicine; a gummy is a snack," Boise added. "You cannot build a neurological treatment plan on a product with variable potency and no stability data."

The Bottom Line

As the OMB and OIRA meet with industry stakeholders next week, the fundamental question remains: Will Washington reinforce the FDA's gold standard, or will it allow a "reimbursement-first" model to erode the integrity of the U.S. drug approval system?

MMJ International Holdings remains committed to the harder, scientific road, advancing its clinical trials for orphan diseases under the strict federal oversight that ensures patient safety and product consistency.

About MMJ International Holdings MMJ International Holdings is a leading biopharmaceutical company focused on the development of plant-derived, FDA-approved cannabinoid medicines. By prioritizing the FDA's botanical drug pathway, the company is delivering standardized, reproducible therapeutics for patients with unmet medical needs.

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The MarketWatch News Department was not involved in the creation of this content.

Back to the Newsroom

Smart Approach to Marijuana Files Lawsuit to Block Medicare's CBD "Shortcut" - MMJ Moves Forward With FDA Drug Development

Tuesday, 31 March 2026 01:26 PM

Topic: Company Update

"CMS plays an important role in expanding access to healthcare services, but it does not have the legal authority or scientific mandate to approve medicines," said Duane Boise, CEO of MMJ International Holdings.

"In the United States, only the U.S. Food and Drug Administration determines whether a drug is safe, effective, and manufactured to pharmaceutical standards. Reimbursement cannot replace evidence. Coverage is not approval."

WASHINGTON, DC / ACCESS Newswire / March 31, 2026 / MMJ International Holdings, the leading pharmaceutical developer of plant-derived cannabinoid therapeutics, today addressed the filing of a major federal lawsuit by Smart Approaches to Marijuana (SAM) against the Centers for Medicare & Medicaid Services (CMS). The lawsuit, SAM et al. v. Kennedy et al. (Case 1:26-cv-01081), filed in the U.S. District Court for the District of Columbia, seeks to block the April 1 launch of a Medicare pilot program that would reimburse unapproved hemp-derived CBD products.

While MMJ International Holdings is not a party to the litigation, the company stands as a primary example of why the lawsuit's core argument-that science must precede reimbursement-is a matter of national drug safety.

The Lawsuit: Challenging "Access Before Evidence"

The SAM filing argues that CMS, under the direction of Administrator Dr. Mehmet Oz, has bypassed the Administrative Procedure Act (APA) and violated the Federal Food, Drug, and Cosmetic Act (FDCA) by creating a federal reimbursement track for products that have not been proven safe or effective through the FDA's gold-standard approval process.

The lawsuit contends that the CMS "Substance Access" pilot effectively creates a "shadow medical system" where federal healthcare dollars fund retail-grade supplements as if they were validated pharmaceuticals.

The MMJ Standard: Why the FDA Pathway Matters

MMJ International Holdings has spent nearly a decade demonstrating that there are no shortcuts to pharmaceutical legitimacy. Unlike the consumer-grade products targeted by the CMS pilot, MMJ's therapeutic candidates (including MMJ-001 and MMJ-002) have been developed strictly within the FDA's Botanical Drug Development framework.

Why MMJ Followed the FDA Pathway:

Safety for Vulnerable Populations: Patients with Huntington's Disease and Multiple Sclerosis require precise, reproducible dosing. Retail CBD products often suffer from "potency drift" and contamination-risks that are eliminated through FDA-mandated Chemistry, Manufacturing, and Controls (CMC).

Clinical Reproducibility: MMJ has secured Orphan Drug Designations and IND (Investigational New Drug) authorizations. This ensures that every soft-gel capsule produced is identical in its pharmacokinetic profile, a requirement that non-drug "hemp" products cannot meet.

Federal Compliance: MMJ operates under DEA Schedule I research registrations and GMP (Good Manufacturing Practice) standards, ensuring that its medicine is federally defensible and ready for a post-rescheduling environment.

Follow The Money Trail

"The lawsuit filed by SAM highlights a critical policy failure: the attempt to treat cannabinoids as a political commodity rather than a clinical reality. MMJ followed the FDA pathway because we believe that patients deserve medicine, not experiments. We

have done the hard work of stability testing, dose-form validation, and preclinical trial work. By reimbursing unvalidated products, the government is essentially telling companies that scientific rigor is optional. We believe scientific rigor is the only way forward." stated Duane Boise , CEO MMJ International Holdings.

When reimbursement policy moves ahead of scientific validation, the primary beneficiaries are often not patients waiting for clinically tested therapies-but organizations positioned to scale distribution rapidly once federal dollars begin flowing. Transparency regarding the financial and advocacy networks surrounding these developments is essential to ensure national healthcare policy remains grounded in rigorous science rather than profiting.

The Regulatory Crossroads

The April 1 launch of the CMS pilot coincides with a separate White House review of FDA enforcement policies. The contradiction is stark: while one arm of the government seeks to ban high-potency hemp "loopholes," another is preparing to fund them.

MMJ International Holdings remains committed to its mission of providing the first truly validated, FDA-approved botanical cannabinoid medicines for neurological suffering-proving that the highest standard of care is the only standard that matters.

About MMJ International Holdings

MMJ International Holdings is a leading biopharmaceutical company dedicated to the development of plant-derived, FDA-approved cannabinoid medicines. Through its subsidiaries, MMJ BioPharma Cultivation and MMJ BioPharma Labs, the company delivers standardized, reproducible therapeutics for patients with unmet medical needs under full federal oversight.

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SOURCE: MMJ International Holdings

Related Documents:

- 2026.03.30 [Doc 01] Complaint_Redacted

Case 1:26-cv-01081-TNM Document 19-1 Filed 04/09/26 Page 23 of 25

Solutions

Public Companies

Private Companies

Agencies

Legal

Resellers & Market Research

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Media Monitoring

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Investor Relations Products

Access IR Platform

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ADA Compliance

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Earnings Press Releases

Investor Days

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Conference & Event Software

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

MMJ BIOPHARMA CULTIVATION INC.,

Plaintiff,

v.

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

Defendants.

Civil Action No. 1:24-cv-00127

FIRST AMENDED COMPLAINT

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

Exhibit 2

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

NATURE OF ACTION

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

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

9. Statutory prohibitions found in Sections 7521(a) and 1202(d) of Title 5 of the United States Code prevent the President and Attorney General from removing DEA ALJs.

10. Instead, ALJs may be removed only for “good cause” as “determined” by the Merit Systems Protection Board (“MSPB”).

11. Members of the MSPB can only be removed by the President for very limited “good cause” reasons.

12. This structure prevents the President, or even the Attorney General, from performing the required oversight duties. As a result, this violates Article II. *Id.* at 492.

13. This Court provides MMJ its only opportunity for meaningful judicial review that could prevent a deprivation of its constitutional rights.

14. MMJ cannot wait until a DEA ALJ conducts a hearing and reaches a determination before seeking review in an Article III court, because MMJ would then have already suffered a constitutional harm.

15. MMJ thus seeks protection from an “illegitimate proceeding, led by an illegitimate decisionmaker.” *Axon Enter., Inc. v. Fed. Trade Comm’n*, 598 U.S. 175, 191 (2023).

16. Under the Supreme Court’s in *Axon*, MMJ is entitled to seek relief in this Court now to address its constitutional challenges to avoid compounding the “here-and-now injury” from being subjected to this illegitimate proceeding—a harm that is “impossible to remedy once the proceeding is over, which is when appellate review kicks in.” 598 U.S. at 192.

<u>JURISDICTION AND VENUE</u>

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

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

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

THE PARTIES

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

official capacity.

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

FACTS

Purpose and Initial Application

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

26. For many years, the only registration which has been approved by the DEA has been the University of Mississippi. Amongst the research community it has been a long recognized fact that the marijuana produced by the University of Mississippi was insufficient and of low quality for pharmaceutical research and development, however.

27. In 2015, Congress passed the "Improving Regulatory Transparency for New Medical Therapies Act", which was enacted on November 15, 2015. The Act amended the CSA to include a requirement that the Attorney General either approve or deny (via a show cause order) an application to cultivate marijuana for research purposes within 90 (ninety) days after the application was submitted. 21 U.S. Code § 823(i)(2)(a).

28. In order to meet the growing demand for pharmaceutical research using marijuana, in 2016 the DEA announced an expansion of the registration program, stating that "[t]o facilitate research involving marijuana and its chemical constituents, DEA is adopting a new policy that is designed to increase the number of entities registered under the

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

29. The process for registration is laid out in the DEA regulations, found at 21 C.F.R. § 1301.
30. In addition, 21 C.F.R. § 1318 covers the registration for manufacturing (including cultivation) of marijuana.
31. MMJ and its sister organizations (MMJ BioPharma Labs Inc. and MMJ International Holdings Corp., all three collectively referred to as the "MMJ Group") collectively look to engage in pharmaceutical research and to produce a gel capsule which contains extracts from the marijuana plant for the purpose of treating those suffering from chronic illnesses such as Multiple Sclerosis and Huntington's Disease.
32. MMJ's goal is also to support other researchers performing DEA registered research using marijuana by cultivating specific strains required by researchers in controlled environments and free of contaminants.
33. MMJ International Holdings Copr. is currently in possession of two FDA INDs (IND No. 137754 & IND No.140712). In order to fulfill the purpose of the FDA INDs, MMJ sought two types of registrations from the DEA to ensure the ability to import, grow, extract, and analyze the compounds from marijuana plants.
34. In December 2018, MMJ Biopharma applied to the DEA for an API Bulk Manufacturer (W18134021E) registration to enable them to cultivate and process marijuana for the research and development of the above-mentioned pharmaceutical drug.
35. The MMJ Groups' overarching purpose of developing pharmaceuticals to reduce symptoms of chronic illnesses such as Multiple Sclerosis and Huntington's Disease requires careful control of all plant genetics in order to maintain compliance with FDA

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

DEA Statutory Requirements

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

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

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

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

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

application prior to the DEA's issuance of an Order to Show Cause on October 31, 2023. As such, the DEA has flagrantly ignored the deadlines put in place by both the Controlled Substances Act and the MMCREA.

40. MMJ's application for a manufacturing registration was submitted on December 27, 2018. The first Notice of Application regarding the manufacturing registration was not published to the Federal Register until August 27, 2019, eight months later, despite the fact that the government was required to publish the notice of application within 90 days from the date of application. *See* 21 U.S.C. § 823(j)(2). (*See id.*) Nevertheless, the deadline for comment on the notice of application was October 28, 2019. *See* 21 U.S.C. § 823(j)(2). A period of 90 days following *this* deadline for comment would mean the government needed to make a determination on MMJ's application by January 26, 2020. *See id.*

41. However, in addition, an amended Notice of Application regarding the manufacturing registration was published to the Federal Register on October 11, 2019, ten months after the application was submitted.

42. This is, again, in direct contravention to the statutory requirement that the government publish a notice of application within 90 days from the date of application. *See* 21 U.S.C. § 823(j)(2). There was no reason provided to MMJ for the notice of application being amended and re-published to the Federal Register. However, even if using the October 11, 2019 publication date, the deadline for comment would have been December 10, 2019.

43. A period of 90 days following *this* deadline for comment would mean the DEA needed to make a determination on or before March 9, 2020.

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

"Investigation" Process

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

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

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

Bona-Fide Supply Agreement

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

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

64. Pursuant to the statutory requirements under 21 U.S.C. § 823(j)(2), MMJ's application should have either been granted or issued a show cause order prior to this regulatory change. As such, MMJ argued that the new requirement should still be immaterial to their pending application.

65. From the very beginning, MMJ has made every attempt to comply with the government's ever-increasing and ever-convoluted demands. Countless patients who have been affected by Multiple Sclerosis and Huntington's Disease and are waiting on the potentially life-restoring treatments associated with the development of these pharmaceuticals.

66. Despite the fact that MMJ, should not need to comply with the new requirement to submit a BFSA, MMJ attempted to submit several documents to fulfill this requirement, all of which were rejected. For example, on April 20, 2021, MMJ provided an agreement with the University of Connecticut (UConn) to provide UConn researcher Dr. Stephen Kinsey marijuana on April 20, 2021. MMJ gathered all documentation regarding Dr. Kinsey's Schedule 1 researcher registration and Dr. Kinsey's DEA-approved research protocol and provided it to DEA Diversion Investigator Thomas Cook.

67. For some unintelligible reason, the agreement between MMJ and UConn/Dr. Kinsey was found to not be a valid bona fide supply agreement. The reason later cited by the DEA was that the signature line for UConn's representative was not dated, despite there being no such requirement under 21 CFR 1300 et. seq. nor any such request made by the government in its communications with MMJ prior to the Order to Show Cause.

68. The BFSA requirements were not explained to MMJ by DEA, nor did agents of the DEA (namely, DI Cook) provide any guidance on how to fulfill this requirement upon inquiry by MMJ.

69. The regulations provide that an applicant must produce a bona fide supply agreement, which is defined as "a letter of intent, purchase order or contract between an applicant and a researcher or manufacturer registered under the Act." See 21 C.F.R. § 1318.02(g); See also 21 C.F.R. § 1318.05(b)(3)(i).

70. However, the DEA attempted to assert a slew of additional requirements (e.g. the requirement that prices be set) in their Order to Show Cause, which do not exist in the regulations.

71. Indeed, if looking at the plain language definition of the term "bona fide supply agreement," it is patently clear to see that the drafters also intended that they include speculative agreements like letters of intent. See 21 C.F.R. § 1318.02(g). It is either incredibly disingenuous for the DEA to essentially require an ironclad contract for a speculative business relationship based on a license which has not yet been granted, when the regulations permit submission of a mere letter of intent between the parties.

72. Further, it appeared that the DEA instead sought to obfuscate the process and create a target that seemed impossible to hit. Ultimately, the BFSA was deemed insufficient in the Order to Show Cause and DEA refused to provide any explanation as to why it would not be permitted under the DEA regulations.

73. There have been several other instances where the DEA has further obfuscated the process regarding the BFSA. For example, in October 2022, DPM Mark Rubbins suggested that MMJ enter into a BFSA with Dr. Juan Sanchez-Ramos ("Dr. Ramos"), a

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

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

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

Order to Show Cause & ALJ Proceeding

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

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

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

ALJ Proceeding Unconstitutional

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

80. According to Section 930.204(a) of Title 5 of the Code of Federal Regulations, DEA ALJs are granted career appointments and are excluded from probationary periods that are applicable to specific government employees.

81. Similar to SEC ALJs, whom the Supreme Court has deemed inferior officers under Article II, DEA ALJs possess wide discretion to wield significant authority in administrative proceedings. According to 5 U.S.C. § 556(c), DEA ALJs have the power to: (1) administer oaths and affirmations; (2) issue subpoenas as authorized by law; (3) rule on offers of proof and admit relevant evidence; (4) conduct or order depositions when necessary for justice; (5) regulate the proceedings; (6) convene conferences to settle issues through consent or alternative dispute resolution methods; (7) inform parties about alternative dispute resolution options and encourage their utilization; (8) compel attendance at conferences; (9) address procedural requests or similar matters; (10) render or recommend decisions; and (11) undertake other actions permitted by agency regulations in line with the APA.

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

However, members of the MSPB themselves cannot be removed except for good cause. This dual requirement for cause-based removal infringes upon Article II, as interpreted by the Supreme Court in *Free Enterprise*.

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

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

CAUSES OF ACTION

COUNT ONE
(Application for Injunctive Relief)

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

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

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

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

COUNT TWO
(Declaratory Judgment)

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for an Order and Judgment:

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

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

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

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

Respectfully submitted,

Dated: August 12, 2024

/s/ Megan E. Sheehan, Esq.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 26-1081 (TNM)

DEFENDANTS' MOTION TO DISMISS

Defendants Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services ("HHS"), HHS, Dr. Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services ("CMS"), and CMS respectfully move to dismiss this action pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. The grounds for this motion are set forth in Defendants' Memorandum of Points and Authorities (1) In Opposition to Plaintiffs' Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review and (2) In Support of Defendants' Motion to Dismiss. A proposed order is attached.

Dated: April 9, 2026

Respectfully submitted,

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UNITED STATES DISTRICT COURT
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Defendants.

Civil Action No. 26-1081 (TNM)

[PROPOSED] ORDER

UPON CONSIDERATION of Defendants' Motion to Dismiss and Defendants' Memorandum of Points and Authorities (1) In Opposition to Plaintiffs' Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review and (2) In Support of Defendants' Motion to Dismiss, it is hereby

ORDERED that Plaintiffs' motion for a preliminary injunction is DENIED; and it is

ORDERED that Defendants' motion to dismiss is GRANTED; and it is

FURTHER ORDERED that this action is dismissed with prejudice.

SO ORDERED, this _______ day of ______________________, 2026.

____
TREVOR N. McFADDEN
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al., Plaintiffs, v. ROBERT F. KENNEDY, JR., in his official capacity Secretary of Health and Human Services, et al., Defendants.	Civil Action No. 26-1081 (TNM)

DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES (1) IN OPPOSITION TO PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW AND (2) IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

This case begins and ends with *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) (*AHM*). There, the Supreme Court confronted organizations and individuals who challenged FDA's regulatory actions concerning a product they neither prescribed nor used. The Court unanimously held:

> The plaintiffs have sincere legal, moral, ideological, and policy objections to elective abortion and to FDA's relaxed regulation of mifepristone. But under Article III of the Constitution, those kinds of objections alone do not establish a justiciable case or controversy in federal court.

Id. at 396.

Plaintiffs are anti-cannabis advocacy organizations and one Medicare beneficiary. None participates in any Centers for Medicare and Medicaid Services ("CMS") Innovation Center, also known as the Center for Medicare and Medicaid Innovation ("CMMI"), model. None administers the program they challenge. None faces any regulatory obligation from CMS. Their complaint is that CMS announced a voluntary component of existing models allowing willing providers to consult with consenting beneficiaries about eligible hemp products—and they object to it. Under *AHM*, objection is not injury.

The individual Plaintiff, David Evans, receives care from an ACO REACH participant. He opposes hemp products and says he would never use them. His claimed injury is that his provider might someday elect a voluntary program, might someday offer him a product, and he might be upset. That chain of contingencies is not Article III standing. It is speculation about the independent choices of third parties who are not before this Court.

Even if Plaintiffs could establish standing, their claims are barred. Section 1115A(d)(2) of the Social Security Act provides that there shall be "no administrative or judicial review" of "the elements, parameters, scope, and duration" of models tested under CMMI authority. 42 U.S.C.

§ 1315a(d)(2). The Substance Access Beneficiary Engagement Incentive ("Substance Access BEI" or "BEI") is an *element* of existing models. Plaintiffs challenge CMS's decision to include that element. That is exactly what Congress precluded.

On the merits, Plaintiffs' case rests on a fundamental conflation. Congress drew a bright statutory line between hemp and marijuana in the 2018 Farm Bill. Hemp is not a controlled substance. It is not illegal under federal law. The April 2025 CMS rule Plaintiffs invoke addressed "illegal substances under Federal law"—marijuana. *See* TRO Mem. (ECF No. 4) at 12 (citing 90 Fed. Reg. 15792, 15867 (Apr. 15, 2025)). The BEI addresses hemp. There is no inconsistency, no reversal, and no unexplained departure. There is a legal distinction that Congress enacted that Plaintiffs fail to acknowledge.

Plaintiffs cannot satisfy any *Winter* factor. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The BEI is voluntary at every level—for model participants, for providers, and for beneficiaries. The organizational Plaintiffs face no regulatory obligation of any kind. Mr. Evans's provider has not elected the BEI, and even if he or she did, nobody is forcing Mr. Evans to use any product. The notice-and-comment claim flounders because the BEI is not a legislative rule but an optional component of voluntary participation agreements that has been implemented the same way CMMI has implemented every voluntary model for sixteen years. And, hypothetically, even if it were a rule, Section 553(a)(2) of the APA exempts matters relating to benefits from notice-and-comment requirements—and the D.C. Circuit has held that exemption applies to Medicare. *See Humana of S.C., Inc. v. Califano*, 590 F.2d 1070, 1082 (D.C. Cir. 1978).

Therefore, the Court should deny Plaintiffs' motion for preliminary injunctive relief and dismiss this action in its entirety.

BACKGROUND

A. The CMS Innovation Center and Section 1115A

In 2010, Congress enacted Section 1115A of the Social Security Act as part of the Affordable Care Act. *See* 42 U.S.C. § 1315a. Section 1115A established the CMMI within CMS. Its statutory purpose is to "test innovative payment and service delivery models" that are expected to "reduce program expenditures . . . while preserving or enhancing the quality of care" for Medicare and Medicaid beneficiaries. *Id.* § 1315a(a)(1).

Congress gave the Secretary of Health and Human Services (the "Secretary") broad authority to design and implement payment models. The Secretary selects models for testing, determines their elements and parameters, chooses participants, and sets the scope and duration of testing. *Id*. § 1315a(b). Congress required only that the Secretary consider certain statutory factors in selecting models and report periodically to Congress on model performance. *Id.* § 1315a(b)(2), (4). Congress also expressly precluded judicial review of the Secretary's decisions regarding "the selection of models for testing," "the selection of organizations, sites, or participants," and "the *elements*, parameters, scope, and duration of such models." *Id.* § 1315a(d)(2) (emphasis added).

Since its creation, CMMI has tested dozens of models. These include ACO REACH, the Enhancing Oncology Model ("EOM"), Bundled Payments for Care Improvement Advanced, Primary Care First, the Making Care Primary Model, and others.

CMS implements a voluntary model and model components through participation agreements between CMS and model participants. Participation agreements define model requirements including quality benchmarks, spending targets, reporting obligations, beneficiary engagement incentives, payment methodologies, and other conditions. CMS has added, modified, and removed model components throughout CMMI's sixteen-year history. It has never conducted

notice-and-comment rulemaking for any voluntary model component. Fishman Decl. ¶ 5 (copy attached as Ex. 1)

B. Hemp and Marijuana Under Federal Law

The Agriculture Improvement Act of 2018 (2018 Farm Bill) established a statutory line between hemp and marijuana. Congress defined "hemp" as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers," with "a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. § 1639*o*(1) (italicization original). It simultaneously amended the Controlled Substances Act (CSA) to exclude hemp from the definition of "marihuana." *See* Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 12619, 132 Stat. 4490, 5018.

The legal consequence is that hemp is not a Schedule I controlled substance and is not illegal under federal law. Marijuana—cannabis above the 0.3% delta-9 THC threshold—remains a Schedule I substance. *See* 21 U.S.C. § 812 sched. I(c)(10).

C. The Substance Access Beneficiary Engagement Incentive

On March 20, 2026, CMS announced the Substance Access Beneficiary Engagement Incentive, an optional component available to participants in three existing Innovation Center models: ACO REACH, EOM, and (beginning January 1, 2027) the Long-term Enhanced ACO Design Model (LEAD). The BEI allows model participants that affirmatively elect it to consult with eligible beneficiaries about the possible use of eligible hemp products to improve symptom control and, if appropriate, to furnish such products up to $500 per year per eligible beneficiary. Fishman Decl. ¶ 8.

The BEI is voluntary at every level. Model participants are not required to elect it. Participants that do elect the BEI must submit an implementation plan for CMS approval. CMS retains authority to reject or suspend participation.

The BEI adopts the 2018 Farm Bill's definitional threshold: eligible products must contain no more than 0.3% delta-9 THC by weight. 7 U.S.C. § 1639*o*(1) (italicization original). Products above that threshold are marijuana and are ineligible. Physicians must determine beneficiary eligibility, including that the beneficiary is over 18 and does not have a disqualifying condition. Beneficiaries must consent through shared decision-making. Participants must report to CMS quarterly. No provider is compelled to offer hemp products. No beneficiary is compelled to accept them. Fishman Decl. ¶ 6.

CMS does not pay for hemp products under the BEI. The participating provider furnishes eligible products at its own cost, subject to the $500 annual cap per beneficiary. The BEI operates within the shared-savings framework that defines the underlying models. If a provider's investment in beneficiary engagement reduces the beneficiary's total cost of care, the provider and CMS share in the resulting savings. If it does not, the provider absorbs the loss. No new federal appropriation is involved. No new entitlement is created. The BEI is, at its core, a decision by willing providers that a particular intervention can reduce downstream claims. Fishman Decl. ¶ 4-6.

D. Plaintiffs

Plaintiffs are ten organizations and one individual. *See* Compl. (ECF No. 8) ¶¶ 8–18. The organizational Plaintiffs are advocacy organizations whose missions involve opposing the expansion of access to cannabis and hemp-derived products. *Id.* ¶¶ 8–17. None is a participant in ACO REACH, EOM, or LEAD. Fishman Decl. ¶ 10. None administers or is subject to the BEI. *Id.* None is regulated by CMS in any respect relevant to this case. *Id.*

The individual Plaintiff, David Evans, is a 78-year-old Medicare beneficiary who receives care from Hopscotch Primary Care, an ACO REACH participant. Evans Decl. (ECF No. 4-2) ¶¶ 4, 6. Mr. Evans alleges he is "opposed to expanded access to cannabis and hemp-derived products" and does "not want them provided by or through [his] Medicare provider." *Id.* ¶ 7. Plaintiffs make no allegation that Hopscotch Primary Care has elected the BEI, submitted an implementation plan, or offered Mr. Evans any hemp product.

LEGAL STANDARD

A preliminary injunction is an "extraordinary remed[ies] never awarded as of right." *Winter*, 555 U.S. at 24. A plaintiff seeking such relief "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Id.* at 20. The plaintiff bears the burden on each factor. *Id.* Where the government is a party, the balance of equities and public interest factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

Before the Supreme Court's decision in *Winter*, courts weighed these factors on a "sliding scale," allowing "an unusually strong showing on one of the factors" to overcome a weaker showing on another. *Damus v. Nielsen*, Civ. A. No. 18-0578 (JEB), 2018 WL 3232515, at *4 (D.D.C. July 2, 2018) (quoting *Davis v. Pension Ben. Guar. Corp.*, 571 F.3d 1288, 1291–92 (D.C. Cir. 2009)). The Supreme Court overruled the sliding scale approach, holding that "a plaintiff seeking a preliminary injunction must make a clear showing that 'he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.'" *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024) (quoting *Winter*, 555 U.S. at 20).

Before reaching these factors, however, the Court must satisfy itself that it has subject matter jurisdiction. A court may not "assume jurisdiction for the purpose of deciding the merits"

when Article III standing is in doubt. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998). And where Congress precludes judicial review, the Court lacks jurisdiction. *See Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 353 n.4 (1984) (preclusion is jurisdictional).[1]

ARGUMENT

I. Plaintiffs Lack Article III Standing.

A plaintiff must show "(i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief." *AHM*, 602 U.S. at 380 (citing *Summers v. Earth Island Institute*, 555 U.S. 488, 493 (2009); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992)). Where, as here, "a plaintiff challenges the government's 'unlawful regulation (or lack of regulation) of someone else,' 'standing is not precluded, but it is ordinarily substantially more difficult to establish.'" *Id.* at 382 (quoting *Lujan*, 504 U.S. at 562). That is because "unregulated parties may have more difficulty establishing causation—that is, linking their asserted injuries to the government's regulation (or lack of regulation) of someone else." *Id.* (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 413-414 (2013); *Lujan*, 504 U.S. at 562; *Duke Power Co. v. Carolina Env't Study Grp, Inc.*, 438 U.S. 59, 74, 98 (1978); *Simon v. Eastern Ky. Welfare Rights Organization*, 426 U.S. 26, 41-46 (1976); *Warth v. Seldin*, 422 U.S. 490, 504-508 (1975)).

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[1] Local Civil Rule 7(n)(1) provides that "[i]n cases involving the judicial review of administrative agency action, unless otherwise ordered by the Court, the agency must file a certified list of the contents of the administrative record with the Court within 30 days following service of the answer to the complaint *or simultaneously with the filing of a dispositive motion, whichever occurs first*." (Emphasis added.) Consistent with paragraph 13(B) of the Court's Standing Order, ECF No. 6, the Secretary respectfully requests relief from the foregoing local rule in a separate motion contemporaneously with filing this dispositive motion. *See, e.g.*, *Varghese v. Blinken*, Civ. A. No. 21-2597 (CRC), 2022 WL 3016741, at *2 n.3 (D.D.C. July 29, 2022) (finding compliance with Local Civil Rule 7(n)(1) unnecessary where the "administrative record would not help resolve the government's motion [to dismiss]").

Plaintiffs are unregulated parties in every sense. CMS has not required them to do or refrain from doing anything. They do not participate in ACO REACH or EOM. They do not administer the Substance Access BEI. They seek to challenge CMS's regulation of others. None of their standing theories withstands scrutiny.[2]

A. The Organizational Plaintiffs Lack Standing.

The organizational Plaintiffs claim that the Substance Access BEI has "directly impaired" their "core programmatic activities" by "requiring" them to "divert staff and resources" to "monitor, analyze, and provide direct informational services" regarding the BEI. Compl. (ECF No. 8) ¶ 8. This is the same theory the Supreme Court unanimously rejected in *AHM*.

In *AHM*, the plaintiff medical associations argued that FDA had "'impaired' their 'ability to provide services and achieve their organizational missions'" and had "'forced' the associations to 'expend considerable time, energy, and resources' drafting citizen petitions to FDA, as well as engaging in public advocacy and public education." 602 U.S. at 369-370. The Court held that "an organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action." *Id.* at 370. The Court further held that an "organization may not establish standing simply based on the intensity of the litigant's interest or because of strong opposition to the government's conduct." *Id*. at 394 (quotation omitted).

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[2] Plaintiffs have indicated an intent to add MMJ International Holdings and its subsidiaries as plaintiffs. Defendants note that this will not cure the standing deficiencies addressed herein. MMJ does not compete in the same market, its claimed injuries depend on a speculative chain of contingencies, and it does not appear to hold the regulatory authorizations its standing theories presuppose. The legal framework set forth in this opposition applies with equal force to MMJ. Defendants can address MMJ's specific deficiencies with more particularity in a supplemental filing, including under seal to the extent necessary.

Years earlier, the D.C. Circuit has applied the same principle in a cannabis case. In *Gettman v. DEA*, 290 F.3d 430 (D.C. Cir. 2002), the court dismissed a petition to reschedule marijuana for lack of standing where the petitioners—a cannabis policy advocate and High Times magazine—could show nothing more than a generalized interest in marijuana policy and speculation about downstream economic effects. The court held that "'[A] mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself[.]" *Id.* at 434 (quoting *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972)). The petitioner's "desire to achieve vague objectives with relation to marijuana" did not "cross the Article III threshold." *Id.*

The organizational Plaintiffs' theory here is indistinguishable. If a longstanding interest in cannabis reform did not confer standing in *Gettman*, a longstanding interest in cannabis opposition does not confer standing here. For example, the mission of Smart Approaches to Marijuana, Inc. (SAM) "includes education and advocacy regarding the public health and safety impacts of marijuana and cannabis policy." Compl. (ECF No. 8) ¶ 8. The mission of Cannabis Industry Victims Educating Litigators (CIVEL) "includes educating legal professionals and the public about the harms caused by the cannabis industry." *Id.* ¶ 9. Every organizational Plaintiff exists to oppose cannabis access. The BEI did not divert these organizations from some unrelated core activity. It gave them exactly the kind of government action they exist to oppose. Their expenditure of resources to oppose it is the execution of their organizational missions, not a diversion from them. That is precisely the distinction the Supreme Court drew in *AHM* when it held that *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), does not support "the expansive theory that standing exists when an organization diverts its resources in response to a defendant's actions." 602 U.S. at 370.

SAM's own filings confirm the point. SAM attaches as Exhibit A (ECF No. 4-1) to Plaintiffs' motion its participation in the ongoing DEA marijuana rescheduling proceedings and alleges in the Complaint that the BEI has "rendered essentially moot" its expenditure of resources opposing rescheduling because the BEI "provides marijuana products via a medical source." Compl. (ECF No. 8) ¶ 8. This argument fails twice. For starters, the BEI does not provide marijuana products but concerns hemp products. Hemp is not marijuana. Equally important, even accepting SAM's mischaracterization, its argument is that a separate government action under separate statutory authority has made SAM's advocacy in a different proceeding less effective. That is not Article III injury. It is a complaint that law and policy landscape has shifted in a direction SAM dislikes. The Supreme Court rejected precisely this theory in *AHM*: an organization's frustration that its advocacy efforts have been undermined by government action does not constitute standing.

Havens involved a housing counseling organization whose "core business activities" were "directly affected and interfered with" by the defendant's discriminatory conduct—specifically, the defendant gave the organization's employees false information about apartment availability, impairing the organization's ability to provide counseling and referral services. *AHM*, 602 U.S. at 395. Nothing analogous is present here. CMS's action does not interfere with any Plaintiff's ability to conduct its existing programs. Plaintiffs remain free to educate the public, train physicians, assist victims, and advocate for restrictions on cannabis access. The Substance Access BEI does not impede those activities in any way. Plaintiffs simply object to CMS's policy and have chosen to spend resources opposing it. Under *AHM* and *Gettman*, that is not enough.[3]

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[3] Plaintiffs do not and could not assert associational standing on behalf of their members. *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977) (associational standing

The D.C. Circuit's most recent application of these principles confirms that *AHM* did not displace Circuit precedent but reinforced it. In *Center for Biological Diversity v. DOI*, 144 F.4th 296 (D.C. Cir. 2025), environmental organizations challenged over 4,000 Bureau of Land Management drilling permits, claiming organizational standing on the theory that BLM's failure to publicize information about the permits' climate impacts forced them to divert resources to their own informational and advocacy efforts. The court held that the organizations' alleged injuries were "limited to issue advocacy" and did not show "'a concrete and demonstrable injury to the organization's activities'" within the meaning of *Havens*. *Id.* at 314-315.

Critically, the court read *AHM* as clarifying rather than overruling D.C. Circuit organizational standing doctrine, noting that *AHM* "cautioned against extending [*Havens*] beyond circumstances in which the challenged action directly affected and interfered with a plaintiff's core business activities." *Id.* at 315 (quot. omitted). The court thus reaffirmed the distinction this Circuit has drawn for over three decades: an organization has standing when the defendant's conduct operationally impairs the organization's ability to deliver services to the people it serves; it does not have standing merely because it has chosen to spend money opposing a government policy it disfavors. *See also Fair Emp't Council of Greater Wash., Inc. v. BMC Mktg. Corp.*, 28 F.3d 1268, 1276–77 (D.C. Cir. 1994) (holding that an organization's "own budgetary choices" to investigate and oppose a defendant's conduct are "self-inflicted" and do not constitute injury in fact fairly traceable to the defendant).

The organizational Plaintiffs here are indistinguishable from the unsuccessful plaintiffs in *Center for Biological Diversity*. Their claimed injuries are not that the BEI has interfered with their

requires at least one member has standing to sue in his own right). No individual member of these organizations has standing for the same reasons Mr. Evans does not.

ability to educate physicians, counsel patients, or deliver any service to any person. Their claimed injuries are that the BEI exists and they choose to spend money opposing it. That is issue advocacy, not operational impairment. And under Circuit law and *AHM*, it is not enough.

B. David Evans Lacks Standing.

Mr. Evans is a 78-year-old Medicare beneficiary who receives care from Hopscotch Primary Care, an ACO REACH participant. His claimed injury is that if his provider elects the BEI and offers him hemp products, he "would lose all faith in them and would be forced to seek out a different medical provider." TRO Mem. (ECF No. 10) at 19.

Starting with the obvious: Mr. Evans opposes hemp products and will not use them. He says so himself. Evans Decl. (ECF No. 4-2) ¶ 7. The Substance Access BEI is voluntary for beneficiaries. No one will force Mr. Evans to consume a hemp product. No one will force his provider to offer him one. His alleged injury is thus not that the BEI will cause him any physical, monetary, or regulatory harm. His alleged injury is that he might be offered a product he will decline. That is not an Article III injury. It is an offense to his sensibilities.

"[D]istress at or disagreement with the activities of others is not a basis under Article III for a plaintiff to bring a federal lawsuit challenging the legality of a government regulation allowing those activities." *AHM*, 602 U.S. at 390 n.3 (cite omitted). Mr. Evans is not distressed by something that has happened to him. He is distressed by the possibility that a program he opposes might exist in the vicinity of his medical care. That is a moral and ideological objection—sincere, perhaps—but not cognizable under Article III. *Id.* at 381 (the standing requirement "screens out plaintiffs who might have only a general legal, moral, ideological, or policy objection to a particular government action").

Even setting aside the nature of the claimed injury, the causal chain is wholly speculative. To connect the Substance Access BEI to any injury to Mr. Evans, Plaintiffs must establish that:

(1) Hopscotch Primary Care voluntarily elects the BEI; (2) Hopscotch submits an implementation plan and CMS approves it; (3) Hopscotch offers hemp products to Mr. Evans specifically; and (4) Mr. Evans suffers some concrete harm from that offer beyond being offended by it. No link in this chain is alleged to have occurred. No link is alleged to be imminent. Each depends on "unfettered choices made by independent actors not before the courts." *Clapper*, 568 U.S. at 414 n.5.

Mr. Evans's standing theory reduces to this: CMS created a voluntary program, and a provider he visits might someday elect it, and that provider might someday offer him a product, and he might be upset. This hypothetical in *AHM* is apt: If an emergency room doctor lacks standing to challenge increased speed limits because he might treat more car accident victims, 602 U.S. at 391, then a Medicare beneficiary surely lacks standing to challenge a voluntary model component because he might someday be offered a product he can freely refuse.

C. Plaintiffs' Procedural Standing Theory Does Not Save Their Claims.

Plaintiffs also assert procedural standing, arguing that CMS denied them the right to participate in notice-and-comment rulemaking under 5 U.S.C. § 553. This is Plaintiffs' only colorable standing theory. Still, it fails.

Even under the relaxed requirements for procedural standing, a plaintiff must show that the challenged action threatens a concrete, "particularized interest"—not merely a generalized ideological concern. *Summers*, 555 U.S. at 496–97. The relaxed standard relieves a procedural-rights plaintiff of the obligation to show that the agency might have reached a different result had it followed correct procedure. It does *not* relieve the plaintiff of the obligation to show that the plaintiff has a concrete stake in the outcome at all. *See id.* at 496 ("[D]eprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing." (emphasis original)). A procedural injury is

cognizable only when the procedure in question is "designed to protect some threatened concrete interest" of the plaintiff. *Lujan*, 504 U.S. at 573 n.8.

What concrete interests do Plaintiffs have? As they describe it, their interest is in opposing the expansion of access to hemp products and protecting the public from cannabis-related harms. But *AHM* held that opposition to a product being made available to others is a "moral, ideological, and policy objection" that "do[es] not establish a justiciable case or controversy in federal court." 602 U.S. at 396. Plaintiffs cannot transform that same insufficient interest into a sufficient one by repackaging it as a procedural gripe. Their interest in commenting on this policy is indistinguishable from their interest in opposing it.

The D.C. Circuit's decision in *American Institute of Certified Public Accountants v. IRS*, 804 F.3d 1193 (D.C. Cir. 2015) (*AICPA*), is instructive. There, a professional association challenged an IRS program for failure to conduct notice-and-comment rulemaking before implementing it. The court held that the right to participate in notice-and-comment rulemaking is not a generalized entitlement available to anyone who objects to a government action. Rather, it is a procedural mechanism that protects the concrete interests of parties with a stake in the regulatory outcome. *Id.* at 1198.

Plaintiffs here cannot satisfy that requirement. Their interest in commenting on the Substance Access BEI is indistinguishable from their interest in opposing it. They wish to participate in notice-and-comment proceedings for the purpose of urging CMS not to implement a policy they find objectionable—not because the BEI threatens any concrete interest of theirs that the rulemaking process is designed to protect. Under *AICPA* and *Summers*, the procedural right to comment does not exist in the abstract. It exists to safeguard concrete interests. Where, as here,

the only interest at stake is ideological opposition to the substance of the policy, the procedural claim adds nothing that *AHM* has not already held insufficient.

Mr. Evans is the plaintiff closest to having a concrete interest. He alleges that he receives care from an ACO REACH participant. But as discussed, his alleged injury is that he might someday be offered a product he can freely decline. He faces no regulatory obligation. He faces no economic injury. He faces no physical harm. His interest reduces to the desire not to be in the vicinity of a program he finds objectionable. That is not a concrete interest the notice-and-comment process is designed to protect.

Finally, as discussed below, there is another reason Plaintiffs' procedural theory fails. Even if the BEI were a rule, Section 553(a)(2) exempts matters relating to benefits from notice-and-comment requirements. Put simply, if Section 553 does not apply, there is no procedural right to invoke, and procedural standing collapses.

II. Section 1115A Precludes Judicial Review.

Even if Plaintiffs could establish Article III standing, their claims are statutorily barred. Congress dictated that "[t]here shall be no administrative or judicial review of" specified actions under Section 1115A, including "the selection of models for testing or expansion under this section," "the selection of organizations, sites, or participants to test those models selected," and "the elements, parameters, scope, and duration of such models." 42 U.S.C. § 1315a(d)(2).

The Substance Access BEI falls squarely within the precluded categories. The BEI is an element of existing Innovation Center models. CMS did not create a new model. It added a beneficiary engagement incentive—a component—to ACO REACH, EOM, and (prospectively) LEAD. The participation agreements governing those models define their elements. CMS's decision to include a beneficiary engagement incentive involving eligible hemp products is a

decision about what elements those models contain and what parameters govern their operation. Section 1115A(d)(2) places those decisions beyond judicial review.

Plaintiffs attempt to evade the preclusion bar by recharacterizing their challenge as one to CMS's "procedures" rather than to model elements. They contend that they do not challenge what CMS did but how it did it—that is, without notice-and-comment rulemaking. This framing is more clever than persuasive. The substance of Plaintiffs' complaint is that CMS should not have added this element to these models, or at minimum that CMS should have used different procedures before doing so. But the decision to add a particular element to a model—including the process by which that element is added—is part and parcel of the "elements, parameters, scope, and duration" of the model. Congress did not preclude challenges to model elements while leaving open a backdoor challenge to the procedures by which those elements are adopted. The preclusion bar would be meaningless if any challenger could circumvent it simply by recasting a substantive objection as a procedural one.

This statutory structure confirms this reading. Section 1115A contains no requirement that CMS conduct notice-and-comment rulemaking before implementing model elements. It does not cross-reference the rulemaking requirements of 5 U.S.C. § 553. It does not require Federal Register publication of model components. Instead, it grants the Secretary broad discretion to "test" models, 42 U.S.C. § 1315a(b)(1), specifies factors the Secretary must consider in selecting models, *id.* § 1315a(b)(2), and requires periodic reports to Congress on model performance, *id.* § 1315a(b)(4).

The absence of any procedural rulemaking requirement in Section 1115A is not an oversight. It is a design choice. Congress built the CMMI for speed and flexibility. It shielded model-design decisions from judicial review to ensure that courts would not second-guess the agency's testing choices. Plaintiffs ask this Court to graft onto Section 1115A a procedural

requirement Congress omitted and then to adjudicate a claim that Congress precluded. The Court should decline.

Plaintiffs rely on *Regeneron Pharmaceuticals, Inc. v. HHS*, 510 F. Supp. 3d 29 (S.D.N.Y. 2020), which concluded that Section 1115A "does not bar review of the propriety of the procedures used" to establish models. *Id.* at 42. But *Regeneron* is distinguishable in a key respect. In *Regeneron*, CMS used its CMMI authority to impose a mandatory "Most Favored Nation" pricing model on drug manufacturers. The manufacturers had to accept reduced reimbursement rates or exit Medicare entirely. The district court held that a procedural challenge to a *mandatory* model, brought by parties subject to such a model, was not precluded.

The BEI is the opposite in every relevant respect. It is optional for model participants. Providers who do not wish to offer hemp products do not need to elect the BEI. Beneficiaries who do not wish to use hemp products may decline them. The Plaintiffs in this case are not model participants at all—they are unregulated third parties with no connection to any Innovation Center model. The mandatory dynamic that animated *Regeneron* is entirely absent.

The same is true of other Most Favored Nation model cases. *See, e.g.*, *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020). Those cases involved the same mandatory model that required participation by regulated entities. District courts outside this Circuit held that Congress did not intend Section 1115A's preclusion bar to shield mandatory programs—imposed on regulated parties with the force of law—from all judicial review. Whatever the merits of that holding, it has no application here because the Substance Access BEI is completely voluntary.

III. Plaintiffs Cannot Satisfy the *Winter* Factors.

To obtain a temporary restraining order or preliminary injunction, Plaintiffs must show "(1) that [they are] likely to succeed on the merits, (2) that [they are] likely to suffer irreparable

harm in the absence of preliminary relief, (3) that the balance of equities tips in [their] favor, and (4) that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Because the government is a party, the third and fourth factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). The same standard applies to a request for interim relief under 5 U.S.C. § 705. *See Coal. for Humane Immigrant Rights v. DHS*, 780 F. Supp. 3d 79, 87 (D.D.C. 2025) (McFadden, J.). Plaintiffs cannot satisfy any of these elements.

A. Plaintiffs Are Not Likely to Succeed on the Merits.

Plaintiffs advance four merits theories: (1) the Substance Access BEI is a legislative rule that required notice-and-comment rulemaking; (2) the BEI is arbitrary and capricious; (3) the BEI exceeds CMS's statutory authority under the major questions doctrine; and (4) the BEI conflicts with federal law. None has merit.

1. The Substance Access BEI is not a legislative rule requiring notice and comment.

The APA's notice-and-comment requirements apply to legislative rules—agency statements that carry "the force and effect of law." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015). Whether an agency action constitutes a legislative rule depends on the substance of what the agency did, not the label it applied. *See Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109–12 (D.C. Cir. 1993). The Substance Access BEI is not a legislative rule.

The BEI is an optional component of existing voluntary Innovation Center models. It is implemented through amendments to participation agreements—the same mechanism CMS has used to administer every voluntary model tested under Section 1115A since 2010. It applies only to organizations that voluntarily enter model participation agreements and that affirmatively elect the component. It imposes no obligations on any person or entity that does not choose to

participate. It is not published in the Code of Federal Regulations. It does not amend any existing regulation. It does not bind the public at large.

These features distinguish the BEI from a legislative rule in every material respect. A legislative rule affects "individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979). The BEI affects the rights and obligations of no one who does not voluntarily elect it. A legislative rule "has the force and effect of law." *Mortgage Bankers Ass'n*, 575 U.S. at 96. The BEI has force and effect only within the four corners of a participation agreement voluntarily entered by model participants—it has no effect in any broader sense.

CMS's sixteen-year practice confirms this conclusion. Since CMMI's creation, CMS has stood up dozens of models and added, modified, and removed model components through participation agreements. These components routinely include quality benchmarks, spending targets, reporting requirements, beneficiary engagement incentives, and payment methodologies—all of which impose binding conditions on participants who elect them. CMS has never conducted notice-and-comment rulemaking for any *voluntary* model component. No court has ever required it to do so. This consistent, longstanding practice reflects the statutory design: Congress created CMMI to test models with speed and flexibility and did not subject model implementation to Section 553's rulemaking requirements.

The BEI's economic structure confirms that it is a model component, not a regulation of general applicability. CMS does not pay for hemp products. The participating provider furnishes products at its own cost, bears the downside risk, and shares in any savings generated by reduced claims. This is an incentive mechanism embedded within a shared-savings payment model—the core of what CMMI models do. It is not a mandate. It is not an entitlement. It is a bet that a

particular intervention will reduce costs and improve care, with the provider putting its own money on the line. That is the definition of a model element, not a legislative rule.

Plaintiffs contend the BEI is a legislative rule because it imposes "binding obligations" on participating organizations—implementation plans, product specifications, dosing limits, reporting requirements. TRO Mem. at 13, ECF No. 10. That argument proves too much. Every participation agreement imposes binding obligations on participants. That is what a participation agreement does. If binding conditions in a voluntary participation agreement were sufficient to trigger Section 553, then every model component CMS has ever implemented—every quality benchmark, every spending target, every reporting requirement—would require notice-and-comment rulemaking. That has never been the law, and Plaintiffs cite no authority for such a sweeping proposition.

Plaintiffs' cannot rely on Most Favored Nation model cases. Those cases involved a mandatory model that required Medicare-participating drug manufacturers to accept reduced reimbursement rates. *See, e.g.*, *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020). The district courts held that a mandatory model—imposed through the force of law—was a legislative rule requiring notice and comment. The logic of those cases turned on the absence of voluntariness: manufacturers could not avoid the model's requirements without exiting Medicare entirely. The Substance Access BEI presents the opposite case. Model participants choose whether to enter ACO REACH or EOM. Having entered, they choose whether to elect the BEI. Having elected, they must submit an implementation plan for CMS approval. Participation is voluntary at every stage. The coercive features that made the Most Favored Nation model a legislative rule in the view of certain district courts are entirely absent.

Plaintiffs also invoke *American Hospital Ass'n v. Bowen*, 834 F.2d 1037 (D.C. Cir. 1987) (*AHA v. Bowen*), for the proposition that "contract provisions that are legislative [in character] are subject to § 553's notice and comment requirements." *Id.* at 1054. But *AHA v. Bowen* involved a *mandatory* Medicare condition of participation—the requirement that hospitals have an agreement with a peer review organization acting under contract with the Secretary—to participate in Medicare at all. The court held that the government could not use its contracts with peer review organizations to evade Section 553 when the substance of the requirements was mandatory and applied to all Medicare-participating hospitals. The Substance Access BEI is not a condition of participation in Medicare. It is not a condition of participation in ACO REACH or EOM. It is an optional add-on that model participants may elect or decline. *AHA v. Bowen* does not stand for the proposition that optional components of voluntary programs require notice-and-comment rulemaking.

2. Even if the BEI were a rule, the APA exempts it from notice-and-comment requirements.

Even assuming the BEI could be characterized as a rule, it would not be subject to Section 553's notice-and-comment procedures. Section 553(a)(2) exempts from rulemaking procedures any matter "relating to . . . benefits." 5 U.S.C. § 553(a)(2); *see also* Policy on Adhering to the Text of the Administrative Procedure Act, 90 Fed. Reg. 11,029, 11,029 (Mar. 3, 2025) (rescinding agency policy waiving benefits exception). The BEI is implemented through participation agreements between CMS and model participants related to Medicare benefits. Section 553(a)(2) exempts it from notice and comment by its plain text.

The D.C. Circuit has squarely held that the benefits exception applies to Medicare. In *Humana of South Carolina, Inc. v. Califano*, 590 F.2d 1070 (D.C. Cir. 1978), a hospital challenged a Medicare reimbursement regulation on the ground that HHS had failed to conduct notice-and-

comment rulemaking before adopting it. The hospital argued that providers were more like regulated entities than benefits recipients and therefore deserved the procedural protections of Section 553. The court rejected that argument. It held that even "construed narrowly, Section 553(a)(2) cuts a wide swath through the safeguards generally imposed on agency action," and that the exemption "prevails when 'grants,' 'benefits' or other named subjects are 'clearly and directly' implicated." *Id.* at 1082. The court applied the exemption to Medicare notwithstanding the public interest in participation and the impact of the rule on affected parties—holding that "in all cases in which the excepted subject matter is 'clearly and directly' involved, the congressional aim was to afford agencies procedural latitude regardless of the interest of affected parties and the public generally in contributing to formulation of the exempted rule." *Id.*

Humana has never been overruled or distinguished by the D.C. Circuit. It remains binding law in this Court. The BEI—a *voluntary* component of Medicare payment models—clearly and directly involves Medicare benefits. Under *Humana*, Section 553(a)(2) applies.

The exemption's original meaning confirms this reading. The Attorney General's Manual on the Administrative Procedure Act (1947)—the "most authoritative interpretation" of the APA, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 218 (1988) (Scalia, J., concurring)—explains that the § 553(a)(2) exemption covers government "proprietary" as opposed to "regulatory" functions. The Manual identifies "benefits" as referring to "such programs as veterans' pensions and old-age insurance payments." Attorney General's Manual on the Administrative Procedure Act 27 (1947). Medicare is an old-age insurance program. A voluntary component of a Medicare payment model is, if anything, a clearer case than the examples the Manual provides, because it lacks the mandatory character of the programs the Manual describes.

Little case law beyond *Humana* interprets "benefits" under § 553(a)(2) in the Medicare context. The reason is historical, not doctrinal. In 1971, HHS adopted a policy known as the Richardson Waiver that voluntarily committed to follow notice-and-comment procedures even for matters the APA exempts, including those relating to benefits and contracts. 36 Fed. Reg. 2,532 (Feb. 5, 1971). *See also Stewart v. Smith*, 673 F.2d 485, 497 n.39 (D.C. Cir. 1982) (noting that many agencies voluntarily adopted notice and comment rulemaking procedures). Because HHS waived the exemption as a matter of policy for over fifty years, few occasions arose to litigate its scope. That policy was rescinded on March 3, 2025. See Policy on Adhering to the Text of the Administrative Procedure Act, 90 Fed. Reg. 11,029 (Mar. 3, 2025). The absence of case law reflects the exemption's dormancy, not its inapplicability.

Plaintiffs invoke *Azar v. Allina Health Services*, 587 U.S. 566 (2019) (*Allina*), which held that Section 1871(a)(2) of the Social Security Act independently requires notice-and-comment rulemaking for "substantive legal standards" governing Medicare. But *Allina* interpreted a different statute. Section 1871(a)(2) applies to rules that "establish[] or change[] a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter." 42 U.S.C. § 1395hh(a)(2). The BEI does not satisfy that standard. It does not change the scope of Medicare benefits—CMS does not pay for hemp products, no Medicare claim is submitted, and no entitlement is created. Nor does it change the payment for services—providers furnish products at their own cost within a shared-savings framework. And any conditions it establishes bind only participants who voluntarily elect it through a participation agreement, not the Medicare program at large. The BEI relates to Medicare benefits for purposes of Section 553(a)(2)'s exemption but

does not establish a substantive legal standard governing benefits "under this subchapter" for purposes of Section 1871(a)(2).

Nor could it. Section 1871 applies to rules adopted under Title XVIII of the Social Security Act. The BEI was adopted under Section 1115A, codified in Title XI of the Social Security Act, which is a separate statutory scheme with its own preclusion provision, its own grant of authority, and no cross-reference to Section 1871's rulemaking requirements. Congress did not incorporate Section 1871 into Section 1115A. It required only that the Secretary report to Congress on model performance. 42 U.S.C. § 1315a(b)(4). Applying Section 1871's rulemaking requirements to CMMI model components would nullify Section 1115A(d)(2)'s preclusion bar, because every model element could then be challenged in court for failure to comply with notice-and-comment procedures—the very result Congress precluded.

3. The BEI is not arbitrary and capricious.

Plaintiffs' centerpiece merits argument is that the BEI represents an unexplained reversal of CMS's April 2025 final rule, which stated that "medical marijuana or derivatives, such as cannabis oil, cannot be covered by [Medicare Advantage] organizations as they are illegal substances under Federal law." 90 Fed. Reg. 15,792, 15,867 (Apr. 15, 2025). This argument depends on a mischaracterization of the April 2025 rule that this Court should reject.

The April 2025 rule addresses marijuana. It says so. Its reasoning turns on a specific legal predicate: that the substances in question "are illegal substances under Federal law." *Id.* As to marijuana, that predicate is correct: it remains a Schedule I controlled substance under the CSA. 21 U.S.C. § 812 sched. I(c)(10). But it is inapplicable to hemp. The 2018 Farm Bill expressly removed hemp—defined as cannabis with a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis—from the CSA's definition of marijuana. 7 U.S.C. § 1639*o*(1); *see*

also 2018 Farm Bill § 12619, 132 Stat. at 5018. Hemp is not a controlled substance. Hemp is not illegal under federal law. The April 2025 rule, by its own terms, does not address hemp.

The Substance Access BEI addresses hemp. Eligible products must contain no more than 0.3% delta-9 THC by weight—the 2018 Farm Bill's definitional threshold. Products above that threshold are marijuana and are not eligible. Plaintiffs assert that "hemp and marijuana are both forms of cannabis." Compl. (incorporating TRO Mem.). That is a botanically accurate statement. But Congress drew a bright line in the 2018 Farm Bill between hemp and marijuana. That line has legal consequences. One of those consequences is that a rule addressing "illegal substances under Federal law" does not apply to a substance that Congress removed from the schedules.

There is therefore no inconsistency between the April 2025 rule and the BEI. The April 2025 rule remains in effect. Medicare Advantage organizations (insurance companies offering health plans as an alternative to original Medicare) still cannot offer marijuana products as supplemental benefits. The BEI does not purport to change that. It creates a voluntary testing pathway for a legally distinct category of products—hemp—under a separate statutory authority. An agency does not act inconsistently when it treats legally distinct substances differently. It acts rationally. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016), requires a reasoned explanation when an agency "departs from a prior policy." CMS has not departed from its prior policy. Its prior policy addressed marijuana. The BEI addresses hemp. Hemp is not marijuana. There is nothing to explain.

Plaintiffs further contend that CMS failed to consider important aspects of the problem, including the health risks of hemp-derived products, the absence of FDA approval, and contamination concerns. *See Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). But the BEI is not a regulation of general applicability promulgated without

analysis. It is a limited, voluntary pilot program with multiple built-in safeguards: product eligibility requirements, THC limits, physician determination of beneficiary eligibility, disqualifying conditions (which CMS retains authority to specify), shared decision-making, a $500 annual cap, CMS approval of implementation plans, CMS authority to reject or suspend participation, and quarterly reporting. Plaintiffs may prefer different safeguards or no program at all. But the arbitrary-and-capricious standard does not require an agency to adopt the policy its critics prefer. It requires "reasoned decisionmaking." *State Farm*, 463 U.S. at 52. CMS's inclusion of multiple layers of safeguards in a voluntary, limited-scope testing program satisfies that standard.

4. The major questions doctrine does not apply.

The major questions doctrine applies when an agency claims authority to resolve a question of "vast economic and political significance" without clear congressional authorization. *West Virginia v. EPA*, 597 U.S. 697, 723 (2022). The doctrine is reserved for "extraordinary cases" in which the "history and the breadth of the authority that the agency has asserted" and the "economic and political significance of that assertion" provide "a reason to hesitate before concluding that Congress meant to confer such authority." *Id*. at 721 (quotation omitted).

A voluntary BEI capped at $500 per beneficiary attached to a CMMI model is not such a case. It does not mandate anything. It does not restructure an industry. It does not assert authority over a significant portion of the American economy. It is, by design, a limited pilot program—exactly the kind of incremental testing that Section 1115A authorizes.

Plaintiffs invoke the political attention the BEI has received as evidence of its significance. But the major questions doctrine does not turn on whether a policy is controversial. It turns on whether the agency has claimed authority of a scope and significance that Congress could not

plausibly have intended to delegate. *See West Virginia*, 597 U.S. at 725. Congress gave CMMI authority to test models. The BEI tests a model component.

5. The Substance Access BEI does not conflict with federal law.

Plaintiffs allege that the BEI conflicts with federal statutes. TRO Mem. at 17-18. None of these arguments has merit.

The 2018 Farm Bill removed hemp—defined as cannabis with a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis—from the CSA's definition of marijuana. 7 U.S.C. § 1639*o*(1). Products meeting that definition are not Schedule I controlled substances. The BEI limits eligible cannabis products to those containing no more than 0.3% delta-9 THC by weight. Hemp is not marijuana. Plaintiffs' assertion that the BEI is "making Schedule I substances available" is a slogan, not a legal statement.

The Appropriations Act argument is no more serious. As Plaintiffs acknowledge (TRO Mem. at 7), the provision they cite does not take effect until November 2026—seven months after the BEI's April 1 effective date. There is no present conflict with a statute not yet in force.

B. Plaintiffs Will Not Suffer Irreparable Harm.

Irreparable harm must be "likely," not merely possible, and must be "actual and imminent, not conjectural or hypothetical." *Winter*, 555 U.S. at 22. Plaintiffs' claimed harms are speculative at every step.

The organizational Plaintiffs claim the BEI forces them to divert resources. But the Supreme Court held in *AHM* that spending money to oppose a government policy is not a cognizable injury for standing purposes. 602 U.S. at 393–94. What fails as standing cannot succeed as irreparable harm. Courts are loathsome to find irreparable harm based on financial injury; and it is well settled that economic loss does not, in and of itself, constitute irreparable harm." *John Doe Co. v. CFPB*, 849 F.3d 1129, 1134 (D.C. Cir. 2017) (citation modified). "The first hurdle

Plaintiffs face is that the harms they identify are economic in nature and therefore not generally irreparable." *Air Transp. Ass'n of Am. v. Exp.-Import Bank of the United States*, 840 F. Supp. 2d 327, 335 (D.D.C. 2012).

Mr. Evans claims that the BEI will alter his relationship with his healthcare provider. But his provider has not elected the BEI. Even if the provider were to elect it, Mr. Evans would not be required to accept any product. His feared injury depends on a chain of contingencies—provider election, implementation plan approval, an offer of products to Mr. Evans personally, and Mr. Evans's subjective reaction to that offer—none of which has occurred or is alleged to be imminent. Speculation about what might happen if multiple independent actors make choices they have not yet made is not the kind of "certainly impending" injury that justifies emergency relief. *Clapper*, 568 U.S. at 410.

Plaintiffs further assert procedural harm—that CMS denied them the right to participate in notice-and-comment rulemaking. But a procedural injury cannot independently establish irreparable harm when the underlying procedural claim fails on the merits. As explained above, the Substance Access BEI is not a legislative rule subject to Section 553. There is no procedural right to vindicate, and therefore no procedural injury to remedy. And even if the procedural claim had merit, procedural injury alone does not automatically establish irreparable harm. Courts routinely deny preliminary relief where the procedural defect can be cured on remand without the need for emergency intervention. *See, e.g.*, *Nat'l Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 17 (D.D.C. 2017).

Finally, Plaintiffs invoke a "public health catastrophe." TRO Mem. (ECF No. 10) at 23. But hemp products are commercially available at a retail store, a pharmacy, or online—without a physician's involvement, without dosing limits, without product screening, and without any of the

safeguards the BEI provides. The BEI does not create access to hemp products. That access already exists, entirely outside the medical system. What the BEI does is allow participating providers to furnish up to $500 per year in eligible hemp products to consenting beneficiaries through a structured program that includes physician screening, product eligibility requirements, shared decision-making, disqualifying conditions, and quarterly reporting.

Plaintiffs' theory of irreparable harm is that seniors will be catastrophically harmed by receiving hemp products through a medical program that currently does not exist. That is not a theory of *harm*. It is a theory of *improvement*. Enjoining the BEI will not prevent a single Medicare beneficiary from purchasing hemp products. It only prevents them from doing so under medical supervision with safeguards CMS has built into the program.[4]

C. The Balance of Equities and Public Interest Favor Defendants.

The public interest weighs heavily against the requested relief. Congress created CMMI to test innovative payment and delivery models. Congress shielded model elements from judicial review. An injunction would override those legislative judgments. It would announce that advocacy organizations with mere opposition to a CMMI model can obtain emergency relief and halt model components they find objectionable. And it would establish a precedent requiring notice-and-comment rulemaking for optional model components—a requirement Congress deliberately omitted from Section 1115A and one that would undermine CMMI's core function.

The equities reinforce this conclusion. Model participants that wish to elect the Substance Access BEI—and the beneficiaries who might benefit from it—would be harmed by an injunction

[4] Plaintiffs have described hemp-derived products as a public health crisis precisely because of their widespread, unregulated commercial availability. *See, e.g.*, https://www.city-journal.org/article/hemp-thc-edibles-controlled-substances-act-loophole (op-ed from SAM CEO noting sale of hemp products at "convenience stores, gas stations, grocery stores, and other locations where families with children shop").

that prevents their voluntary participation in a program Congress authorized CMS to test. Those parties have concrete interests at stake. Meanwhile, Plaintiffs would suffer no cognizable injury from the denial of their motion. They face no regulatory obligation. They face no economic harm. They face no physical injury. They are not model participants. Their claimed injury is that a government program they oppose exists. That interest, however sincerely held, does not outweigh the interests of willing participants, CMMI's statutory mandate, and Congress's express judgment that model design decisions should not be subject to judicial review.

An injunction is an extraordinary remedy. It is not a tool for organizations with policy objections to halt government programs in which they do not participate. Plaintiffs ask this Court to enjoin a program that no provider has been forced to join, that no beneficiary has been forced to use, and that no Plaintiff has standing to challenge.

IV. If Preliminary Injunctive Relief Is Granted, A Bond Should Be Required.

To the extent the Court orders any injunctive relief, Defendant respectfully requests that any such relief be accompanied by a bond. "The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c). A bond is appropriate here given, among other things, the costs that would be associated with halting a program that already is underway.

CONCLUSION

Plaintiffs are advocacy organizations and one Medicare beneficiary who object to a government policy. Those objections may be sincere. But sincerity is not standing. Even if Plaintiffs could cross the Article III threshold, Congress barred their claims. And were the Court to reach the merits, Plaintiffs have shown no likelihood of success and no irreparable harm with respect to a voluntary program in which they do not participate. Finally, the balance of equities favors CMS, because an injunction would override Congress's judgment that model design decisions belong to CMMI, not the courts. Therefore, the Court should deny Plaintiffs' motion and dismiss the Complaint.

Dated: April 9, 2026

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al., Plaintiffs, v. ROBERT F. KENNEDY, JR., Secretary of Health and Human Services, et al., Defendants.	Civil Action No. 26-1081 (TNM)

[PROPOSED] ORDER

Upon consideration of Defendants' Memorandum of Points and Authorities (1) In Opposition to Plaintiffs' Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review and (2) In Support of Defendants' Cross Motion to Dismiss, and for good cause shown, it is hereby

ORDERED that Plaintiffs' Motion for a Preliminary Injunction is **DENIED**. It is further

ORDERED that Plaintiffs' Complaint is dismissed with prejudice.

SO ORDERED, this ___ day of _____________, 2026.

____
Trevor N. McFadden
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR.,
Secretary of Health and Human Services, et al.,

Defendants.

Civil Action No. 26-1081 (TNM)

DECLARATION OF ELIOT FISHMAN

I, ELIOT FISHMAN, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that my testimony below is true and correct:

1. I am the Director of the Policy and Programs Group at the Center for Medicare and Medicaid Innovation ("CMMI") within the Centers for Medicare & Medicaid Services ("CMS"), U.S. Department of Health and Human Services ("HHS"). I have served in this capacity since February 2023. In this role, I oversee multiple policy and technical support functions that cut across the various CMMI models.

2. The statements set forth in this declaration are based on my personal knowledge, information obtained in the course of performing my official duties, information provided to me by federal government employees acting within the scope of their employment, and my review of relevant government records maintained in the ordinary course of business.

3. I am providing this declaration in support of Defendants' Opposition to Plaintiffs' Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review.

4. CMMI was established by Congress in 2010 with the express purpose of testing innovative payment and service delivery models that could reduce program expenditures while preserving or enhancing the quality of care for Medicare and Medicaid beneficiaries. *See* Social Security Act § 1115A(a)(1), 42 U.S.C. § 1315a(a)(1).

5. Since its creation, CMMI has fulfilled its mandate by testing dozens of models, such as ACO REACH, the Enhancing Oncology Model ("EOM"), and others. A voluntary CMMI model invites providers, payers, and accountable care organizations, to apply to participate. No accountable care organization, payer, or provider is required to participate in these models. These voluntary models and model components are implemented through participation agreements between CMS and model participants. CMS has added, modified, and removed voluntary models and model components since it was established in 2010. CMMI has never conducted notice-and-comment rulemaking for any voluntary model or model component.

6. On March 20, 2026, CMS announced the Substance Access Beneficiary Engagement Incentive ("Substance Access BEI"), an optional component available to voluntary participants in three existing CMMI models: ACO REACH, EOM, and (beginning January 1, 2027) the Long-term Enhanced ACO Design Model ("LEAD"). *See* CMS, Substance Access Beneficiary Engagement Incentive, https://www.cms.gov/priorities/innovation/substance-access-beneficiary-engagement-incentive (Mar. 20, 2026) ("March 2026 Announcement"). A beneficiary's participation is never required. Beneficiaries must elect to participate, and a physician must determine that use is appropriate and must document the required shared decision-making. A true and correct copy of the March 2026 Announcement is attached. CMS did not engage in notice-and-comment rulemaking before announcing the Substance Access BEI. Thus, the Substance Access BEI was

implemented in a manner similar to every voluntary model tested under Social Security Act § 1115A since 2010.

7. In my role as Director of the Policy and Programs Group at CMMI, I was involved in all major activities and decision-making regarding the policy and the implementation of the Substance Access BEI. In this role, I reviewed and edited drafts of all materials and made policy recommendations to CMS and HHS leadership.

8. The Substance Access BEI allows model participants that affirmatively elect it to consult with eligible beneficiaries about the possible use of eligible hemp products to improve symptom control and, if appropriate, to furnish such products up to $500 per year per eligible beneficiary. Medicare does not pay the participant for the products. If a provider's investment in beneficiary engagement reduces the beneficiary's total cost of care, the provider and CMS share in the resulting savings. If it does not, the provider absorbs the loss.

9. Model participants that elect the Substance Access BEI must submit an implementation plan for CMS approval and they must implement safeguards against abuse, including monitoring and oversight. CMS retains authority to reject or suspend participation.

10. None of the Plaintiffs in this case has submitted an implementation plan for CMS approval or has participated in any of the CMMI models that have the option of offering the Substance Access BEI.

11. Consistent with the voluntary nature of the component and the models involved, model participants are not required to elect Substance Access BEI. No model participant or provider is compelled to offer hemp products or to accept them.

12. To further inform model participants, providers, and the general public, the March 2026 Announcement includes answers to "Frequently Asked Questions" ("FAQs"). Among other

things, the FAQs explain that CMS's definition of "eligible hemp product" as used in the Substance Access BEI operates within the 2018 Farm Bill's hemp provisions, and neither overrides the Controlled Substances Act nor authorizes Schedule I substances (such as marijuana). The FAQs also emphasize that hemp products must comply with applicable state and local laws to be eligible, and model participants must meet certain quality and safety standards for the products, including third-party testing for potency, contaminants, and microbial hazards.

Executed on this 7th day of April, 2026.

Eliot Fishman

Eliot Fishman
Director, Policy and Programs Group
Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

Substance Access Beneficiary Engagement Incentive

The Substance Access BEI is an optional Beneficiary Engagement Incentive that allows participants in certain CMS Innovation Center models to consult with eligible beneficiaries about the possible use of eligible hemp products to improve symptom control. Participants implementing this BEI may elect to furnish such hemp products up to $500 a year, per eligible beneficiary, subject to model requirements and safeguards.

Note: Medicare does not pay the participant for the products, and beneficiaries should not be asked to submit a Medicare claim for the product.

Model participants will have the option to offer this BEI in three Innovation Center models:

- ACO REACH Model
- Enhancing Oncology Model (EOM)
- Long-term Enhance ACO Design (LEAD) Model

Participants may begin offering the Substance Access BEI for both ACO REACH Model and EOM starting April 1, 2026. The BEI will become available to eligible LEAD participants on January 1, 2027.

Participants must submit required quarterly reports to CMS and provide supplemental information upon request, consistent with participation documentation.

For more information on the Innovation Center models that include the Substance Access BEI, visit the ACO REACH, EOM, and LEAD model webpages.

Frequently Asked Questions

Which organizations are eligible for the Substance Access BEI?

Only participating organizations in ACO REACH, EOM and LEAD may offer the Substance Access BEI, and only if they:

- Elect the Substance Access BEI for the applicable performance period; AND
- Submit and maintain a CMS-required Implementation Plan describing, at minimum, the specific eligible hemp product(s) and dosing information, the amount/frequency of distribution, beneficiary eligibility criteria, safeguards/oversight, and other requirements outlined in participation agreements; AND
- Are approved by CMS (CMS may reject or suspend participation based on the Implementation Plan, compliance history, or other program integrity concerns).

Which beneficiaries are eligible for the Substance Access BEI?

Only beneficiaries currently aligned to participating organizations that have elected to offer the Substance ACCESS BEI in the REACH, EOM or LEAD models may receive the BEI. Additional beneficiary eligibility criteria are defined in each model's participation documentation and implementation plan, but generally includes:

- Being age 18 or older;
- Not meeting the model's frailty exclusion;
- Not having specified disqualifying conditions; and
- Not being pregnant or breastfeeding.

In addition, a physician must determine that use is appropriate and must document required shared decision-making (including medication review and follow-up planning). At a minimum, this includes a documented discussion of potential benefits and risks, the beneficiary's goals and preferences, and a review of current medications and potential interactions.

DISQUALIFYING CONDITIONS ARE SPECIFIED IN MODEL PARTICIPATION DOCUMENTATION AND ARE INTENDED TO REDUCE PATIENT SAFETY RISKS.

What is an "'eligible hemp product" for purposes of this BEI?

Eligible hemp products are limited to federally legal hemp-derived products containing no more than 0.3% delta-9 THC and expressly excludes inhalable products, any products containing more than 3 mg per serving of tetrohydrocannabinols (such as delta-8-tetrahyrdocannabinol, delta-10-tetrahyrdocannabinol, and tetrahydrocannabinolic acid) in an orally administered form, and any products containing cannabinoids not naturally produced or capable of being produced by or in the cannabis plant during its cultivation.

The definition operates within the 2018 Farm Bill's hemp provisions and does not override the Controlled Substances Act or authorize Schedule I substances. To be eligible, hemp products must also comply with applicable state and local laws.

If the legal limits on hemp-derived products changes, as with Section 781 of the FY2026 Agriculture Appropriations Act, CMS will adjust its definition in accordance with the law.

How are eligible hemp products procured and furnished?

Model participants are responsible for their own procurement and operational approach (including contracting, ordering, storage, inventory controls, and distribution workflows), consistent with model requirements and applicable law.

Eligible hemp products must be furnished and provided directly by a qualified physician affiliated with the participant organization, as specified by the model participation agreements.

Note: Model participants cannot instruct beneficiaries to purchase retail products and submit receipts for reimbursement under the BEI.

What are the key program integrity and contracting requirements?

Program integrity guardrails are described in model participation documentation and include:

- The BEI (and product availability) must not be marketed to induce beneficiaries to select or remain aligned to a participant organization; AND

- Participants may not enter into arrangements that provide remuneration to induce selection of a particular manufacturer or seller, and payments must be consistent with fair market value and not tied to the volume or value of referrals or other business; AND
- Participants must implement safeguards against abuse, including monitoring and oversight, and CMS may suspend or prohibit participation for integrity concerns.

What quality and safety standards apply to products?

Model participants are required to meet quality and safety standards requirements for products that at a minimum, must:

- Meet federal, state and local production, quality, and safety laws and other mandated standards; AND
- Come from a legally compliant source and high-quality farm, consistent with 2018 Farm Bill hemp requirements, AND
- Be tested by a third party for potency (including accurate cannabinoid measurement) and for contaminants and microbial hazards with negative results.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 26-1081 (TNM)

DEFENDANTS' CONSENT MOTION
FOR RELIEF FROM LOCAL CIVIL RULE 7(n)(1)

Defendants Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services ("HHS"), HHS, Dr. Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services ("CMS"), and CMS respectfully seek an order granting relief from Local Civil Rule 7(n)(1) for purposes of Defendants' Motion to Dismiss filed concurrently with this motion. Undersigned counsel has conferred with counsel for Plaintiffs, who consents to the relief requested but only for the present Motion to Dismiss (ECF No. 21). Good cause exists to grant the requested relief, in support of which Defendants state as follows:

1. In March 2026, CMS announced the Substance Access Beneficiary Engagement Incentive ("Substance Access BEI"), which is an optional component available to participants in certain voluntary Medicare models created by CMS under Social Security Act § 1115A, 42 U.S.C. § 1315a. The Substance Access BEI allows model participants that affirmatively elect it to consult with eligible beneficiaries about the possible use of eligible hemp products to improve symptom control and, if appropriate, to furnish such products up to $500 per year per eligible beneficiary.

2. Plaintiffs are anti-cannabis advocacy organizations and one Medicare beneficiary who "do not want" hemp products "provided by or through [his] Medicare provider." Evans Decl. ¶ 7, ECF No. 4-2. Plaintiffs challenge the Substance Access BEI on procedural and substantive grounds under the Administrative Procedure Act ("APA"). *See* Compl. for Injunctive & Declaratory Relief ¶¶ 116–46, ECF No. 1. For example, Plaintiffs allege that in announcing the Substance Access BEI, CMS violated the APA's procedural requirements for notice-and-comment rulemaking. *See id.* ¶¶ 116–24.

3. Contemporaneously with filing this motion, Defendants have moved to dismiss this case under Rule 12(b)(1) of the Federal Rules of Civil Procedure because (1) Plaintiffs lack Article III standing and (2) a statutory preclusion of judicial review bars Plaintiffs' legal claims.

4. Local Civil Rule 7(n)(1) states that "[i]n cases involving the judicial review of administrative agency action, *unless otherwise ordered by the Court*, the agency must file a certified list of the contents of the administrative record with the Court within 30 days following service of the answer to the complaint *or simultaneously with the filing of a dispositive motion, whichever occurs first*." (Emphasis added.) However, the "general practice in this Court" is that Local Civil Rule 7(n)(1) will be waived when the administrative record is unnecessary for the Court's decision on a dispositive motion. *Arab v. Blinken*, 600 F. Supp. 3d 59, 65 n.2 (D.D.C. 2022) (granting relief from the need to file a certified list of the contents of the administrative record as it was not necessary for the court's decision), *Liang v. United States Citizenship & Immigr. Servs.*, Civ A. No. 24-1690 (RJL), 2025 U.S. Dist. LEXIS 186238, at *8-9 (D.D.C. Sept. 22, 2025) (granting relief under Local Rule 7(n)(1) because the case was dismissed on jurisdictional grounds); *see also* Standing Order ¶ 13(B), ECF No. 6 ("If the Government is filing a motion to dismiss, and believes that the LCvR 7(n) requirement to 'file a certified list of the

contents of the administrative record . . . simultaneously' would not be helpful to the resolution of the case, the Government must file—simultaneously with the motion to dismiss—a motion asking the Court to excuse the agency from the requirements of LCvR 7(n).").

5. Such is the case here. In seeking dismissal, Defendants' memorandum of points and authorities relies on the allegations of Plaintiffs' Complaint, the declarations submitted by Plaintiffs in support of their motion for preliminary injunctive relief, a declaration submitted by a CMS official with knowledge of the Substance Access BEI and CMS rulemaking practices under Social Security Act § 1115A, and matters of public record published on the CMS website that are expressly referenced in Plaintiffs' Complaint. The Court may consider all of these materials in deciding a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1). *See Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992); *see also Langeman v. Garland*, 88 F.4th 289, 291–92 (D.C. Cir. 2023) (explaining "relevant public records are subject to judicial notice on a motion to dismiss when referred to in the complaint and integral to the plaintiff's claim") (cleaned up). Conversely, a complete administrative record—the exact contents of which would have to be resolved by CMS in the first instance and disputes over which might have to be litigated—is unnecessary to resolve Defendants' Motion to Dismiss and may delay these proceedings unnecessarily.

6. Pursuant to Local Civil Rule 7(m), undersigned counsel conferred with counsel for Plaintiffs, who stated that Plaintiffs consent to the relief requested but only for the present Motion to Dismiss (ECF No. 21).

WHEREFORE, Defendants request that the Court enter an order granting relief from Local Civil Rule 7(n)(1). A proposed order is attached.

Dated: April 9, 2026

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 26-1081 (TNM)

[PROPOSED] ORDER

UPON CONSIDERATION of Defendants' Consent Motion for Relief from Local Civil. Rule 7(n)(1), it is hereby

ORDERED that the motion is GRANTED; and it is

FURTHER ORDERED that, for purposes of Defendants' Motion to Dismiss, Defendants are relieved from complying with Local Civil Rule 7(n)(1).

SO ORDERED, this _______ day of ______________________, 2026.

____
Trevor N. McFadden
United States District Judge