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.	Case No. 1:26-cv-1081 (TNM)

MEMORANDUM OPINION

In a founding era exchange about agricultural affairs, Gouverneur Morris commented to Thomas Jefferson that hemp "is of Necessity to the Commerce and Marine in other Words to the Wealth and Protection of the Country." Enclosure: Notes respecting Tobacco (March 16, 1791), in 19 Papers of Thomas Jefferson 576–578 (Boyd ed. 1974). Though the cannabidiol product known as "hemp" no longer forms part of the backbone of American commerce, its role in American medicine has grown large enough to prompt regulatory action.

This case concerns recent developments on that front. In April 2026, the Center for Medicare and Medicaid Innovation ("CMMI") implemented a new, optional pathway for qualifying Medicare providers to furnish qualifying beneficiaries with hemp. That decision drove many challengers—spanning from patients and providers to several organizations to pharmaceutical companies—to this Court. They seek a preliminary injunction to put the new pathway on hold. In support, Plaintiffs mount a series of claims under the Administrative Procedure Act ("APA") and the Constitution, arguing that the pathway conflicts with federal law and that CMMI failed to follow required procedures in creating it.

But the Court need not address those question to resolve this dispute. Plaintiffs, though numerous, have not established standing to bring this case. Each claims an injury too abstract or too remote to open the courtroom doors. The Court will thus grant Defendants' motion to dismiss and deny Plaintiffs' motion for a preliminary injunction as moot.

I.

For more than a decade, the federal government has been in the business of testing new ways to serve Medicare beneficiaries. It began that effort in 2010 when Congress, through § 1115A of the Social Security Act, established CMMI within the Centers for Medicare & Medicaid Services ("CMS"). *See* 42 U.S.C. § 1315a. As § 1115A instructs, CMMI tests "innovative payment and service delivery models" that aim to "reduce program expenditures . . . while preserving or enhancing the quality of care" for Medicare and Medicaid beneficiaries. *See id.*

In creating CMMI, Congress delegated authority to the Secretary of Health and Human Services ("HHS") to design and implement these payment models. *See id.* The Secretary may select models, determine their elements and parameters, set their scope and duration, and choose their participants. *Id.* § 1315a(b). CMMI has tested numerous payment models since its creation. Fishman Decl. ¶ 5, ECF No. 30-2. Many models or components of them—like those at issue—are voluntary. *Id.* Eligible healthcare providers can choose to opt into them by signing a participation agreement with CMS. *Id.*; Am. Compl. ¶ 81, ECF No. 25. These participation agreements define model requirements including quality benchmarks, spending targets, reporting obligations, beneficiary engagement incentives, payment methodologies, and other conditions. Fishman Decl. ¶ 5; *see* Am. Compl. ¶ 83. Over its sixteen-year existence, CMMI has never

conducted a notice-and-comment rulemaking for a voluntary model component. Fishman Decl. ¶ 5; *see* Hr'g Tr. at 13:23–14:25.

In March 2026, CMS announced a new voluntary model component to participants in three existing CMMI models. This component, called the Substance Access Beneficiary Engagement Incentive ("BEI") allows providers who opt in to consult with eligible patients about the possible use of certain hemp products to address their health needs. Am. Compl. ¶ 83; Fishman Decl. ¶ 8. If appropriate, those healthcare providers may furnish beneficiaries with up to $500 of hemp products annually. Am. Compl. ¶ 83.

A law unrelated to CMMI model mechanics lets the agency treat hemp this way. Hemp, after all, is a marijuana derivative. And marijuana is a Schedule I substance that is generally illegal under federal law. 21 U.S.C. § 812(c)(10).[1] But the Agriculture Improvement Act of 2018 ("2018 Farm Bill") drew 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). At the same time, it amended the Controlled Substances Act to exclude hemp from the definition of "marihuana." *See* Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 12619, 132 Stat. 4490, 5018. Put together, these features mean that hemp is not a

[1] Recent initiatives have carved out exceptions to marijuana's Schedule I status. *See* Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana From Schedule I to Schedule III, 81 Fed. Reg. 22714 (April 28, 2026) (to be codified at 21 C.F.R. pts. 1300, 1301, 1308, and 1312) (placing certain FDA-approved products containing marijuana in Schedule III). While marijuana otherwise remains a Schedule I substance, initiatives to more broadly reschedule it are under way. *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 91 Fed. Reg. 22777 (April 28, 2026).

Schedule I controlled substance and is not illegal under federal law. *See DeLorean 88 LLC v. District of Columbia*, 806 F. Supp. 3d 49, 54–55 (D.D.C. 2025).

This statutory and regulatory background sets the scene for this dispute. Plaintiffs include one patient, one physician, eleven organizations, and a pharmaceutical company and its subsidiaries. Am. Compl. ¶¶ 6-21. All oppose the BEI for many reasons. The Court briefly describes each Plaintiff below.

Individual Plaintiffs. The first individual Plaintiff is David Evans, a 78-year-old Medicare beneficiary who receives care from Hopscotch Primary Care, which participates in a CMMI model eligible for the BEI (though it has not opted into the BEI). Evans Decl. ¶¶ 4, 6, ECF No. 28-6. Evans is "opposed to expanded access to cannabis and hemp-derived products" and does "not want such products provided by or through [his] Medicare provider." *Id.* ¶ 7.

Next is physician Dr. Kenneth Finn, who practices pain medicine in Arizona. Finn Decl. ¶ 3 ECF No. 28-7. While he does not claim to participate in any CMMI model that could opt into the BEI, he fears he will be asked to participate in the BEI, and he expects the BEI to result in increased emergency room visits and more malpractice liability. *Id.* ¶¶ 17–19.

Organizational Plaintiffs. Turning to the eleven organizational Plaintiffs, each stands on similar footing. None participates in the BEI or has members that do. *See generally* Am. Compl. ¶¶ 6–16. Rather, each claims the BEI impeded their programming. Because these Plaintiffs' operations differ, a description of each is in order.

Many organizational Plaintiffs work in the drug-education and safety realm. Smart Approaches for Marijuana ("SAM"), for instance, does "education and advocacy regarding the public health and safety impact of marijuana and cannabis policy." Niforatos Dec. ¶ 5, ECF No.

28-1. To support its mission, SAM runs "public health education campaigns" and "research and policy analysis programs." *Id.* ¶ 6.

Cannabis Industry Victims Educating Litigators ("CIVEL") has a similar purpose. Am. Compl. ¶ 7. It educates "legal professionals and the public about the harms caused by the cannabis industry." *Id.* CIVEL does so through "legal education seminars, victim assistance programs, and community outreach." *Id.*

Americans Against Legalizing Marijuana ("AALM") is likewise "dedicated to providing information on the harms of marijuana to individuals and our country," *id.* ¶ 8, and it likewise runs "education programs" and "public awareness campaigns," and supports doctors and lawyers in these fields, *id.*

North Carolinians Against Legalizing Marijuana ("NCALM") opposes the "legalization of medical hemp-derived" products. *Id.* ¶ 9. Its activity includes "legislative advocacy, public education campaigns, and policy analysis regarding the risks of marijuana." *Id.*

Cannabis Industry Victims Seeking Justice ("CIVSJ") seeks to hold "the marijuana industry legally accountable to its victims and to provide advocacy services to the many victims of the cannabis industry." *Id.* ¶ 11. It runs "victim advocacy" programs, "legal accountability initiatives, and public education" programs to do so. *Id.*

Cannabis Impact Prevention Coalition, LLC ("CIPC") strives to "prevent the negative social, health, public safety, and environmental impacts of marijuana." Am. Compl. ¶ 10. CIPC also operates "public education, community outreach, and policy advocacy" programs to further its mission. *Id.*

Drug Free America Foundation ("DFAF") is a "drug prevention and policy organization" that seeks to "prevent drug use and promote sustained recovery." Ronshausen Decl. ¶ 5, ECF

No. 28-2. It serves its aims through "education programs, student assistance initiatives, community outreach," and similar activities. *Id.* ¶ 6.

Save Our Society From Drugs ("SOS") is a nonprofit that promotes "sound drug laws and policies that will reduce illegal drug use, drug addiction and drug-related illness and death." *Id.* ¶ 7. It does so through "education programs, public awareness campaigns, community intervention initiatives . . . and related operational activities." *Id.* ¶ 8.

Drug Watch Internation ("DWI") is similar. It promotes "healthy drug-free cultures" and advocates "for the prohibition of and abstinence from all drugs," and "oppose[s] the legalization of drugs prohibited by national and international laws." Coleman Decl. ¶ 4, ECF No. 28-3. DWI researches and analyzes "international drug policy" and consults government agencies. *Id.* ¶ 5.

Some organizations do more than oppose cannabis legalization laws. Hillsborough County Anti-Drug Alliance ("HCADA"), for instance, supports law enforcement, the courts, prevention agencies, and substance abuse treatment providers through substance abuse education activities. Snelling Decl. ¶ 4, ECF No. 28-4. Those activities span from addressing alcohol issues on college campuses to work on "smoking effects on pets." *Id.* ¶ 5. Cannabis awareness fall within that realm. *Id.*

Illinois Family Institute ("IFI") also has a broad reach. This nonprofit aims to advance public policy initiatives consistent with "Judeo-Christian teachings and traditions." Valente Decl. ¶ 4, ECF No. 28-5. In line with that goal, IFI educates "Christians and the general public on matters of moral concern," such as "opposition to further access to drugs, including cannabis- and hemp-derived products." *Id.*

This legion of organizations opposes the BEI for similar reasons. Each claims the BEI required them to divert resources from their regular programming. Am. Compl. ¶¶ 6–16. Some say they had to use those resources to research and oppose the BEI. *See id.* Some say those resources went to educating the public about the BEI. *See id.* Some do not specify where the resources went. Am. Compl. ¶¶ 8, 10–11, 13. Whatever the variation, the theme is the same: the BEI allegedly stood in the way of these organizations' usual work.

Pharmaceutical Company Plaintiff. Last is pharmaceutical company MMJ International Holdings, Inc. and its subsidiaries (collectively, "MMJ"). MMJ develops cannabinoid therapeutics through FDA's "botanical drug development framework." Boise Decl., ¶ 4, ECF No. 28-8. Over the past eight or so years, MMJ has invested over $10 million into this work. *Id.* ¶ 43. That capital and labor has gone toward a variety of efforts, including "regulatory strategy, clinical development planning, chemistry, manufacturing . . . and Investigational New Drug ("IND") submissions for cannabinoid-based treatments targeting Huntington's disease and multiple sclerosis." *Id.* ¶ 4.

Many moving parts make up MMJ's work. One subsidiary, for instance, sought registration with the U.S. Drug Enforcement Administration to bulk manufacture marijuana's active ingredient for use in FDA-authorized clinical trials. *Id.* ¶ 6. That application remains pending, and no clinical trials have started. *Id.* ¶¶ 6, 13. Another subsidiary, meanwhile, obtained a "Schedule I analytical laboratory registration" from the DEA to support MMJ's cannabis research. *Id.* ¶¶ 8, 12. MMJ has also "initiated formal regulatory engagement" with FDA by submitting "Investigational New Drug" requests to support its Huntington's disease program and multiple sclerosis program. *Id.* ¶ 20. Since then, FDA granted has MMJ "Orphan

Drug Designation" for its treatment targeting Huntington's disease. *Id.* ¶ 21. That designation recognizes that MMJ's treatment targets a rare disease or condition. *See* 21 C.F.R. § 316.23.

MMJ's efforts have yet to see fruition. MMJ has evaluated seven prototype formulations of its product and scaled one of them for production. Boise Decl. ¶ 23. In February 2025, however, FDA issued a "Full Clinical Hold letter," halting MMJ's multiple sclerosis efforts. *Id.* ¶¶ 20, 25. Though none of its products are ready for public use, *see generally id.*, MMJ challenges the BEI for allowing the "distribution of hemp-derived cannabinoid products outside the FDA drug approval framework" while MMJ remains "subject to full pharmaceutical regulatory requirements." *Id.* ¶ 36.

* * *

Together, Plaintiffs turned to this Court to challenge the BEI a few days before it was set to go into effect. They sue HHS, CMS, HHS Secretary Robert F. Kennedy, Jr., and CMS Administrator Mehmet Oz (collectively, "the Secretary"). Plaintiffs bring a variety of claims under the Administrative Procedure Act ("APA") and the Constitution. To sum up their grievances, Plaintiffs claim that, in implementing the BEI, the Secretary: (1) violated the APA's notice-and-comment requirements; (2) acted arbitrarily and capriciously by failing to consider relevant evidence and by changing courses from his prior positions; (3) exceeded CMS's statutory authority; (4) conflicted with the 2026 Agriculture Appropriations Act; (5) denied MMJ its Fifth Amendment equal protection guarantee[2]; and (6) denied all Plaintiffs procedural and substantive due process in violation of the Fifth Amendment. Am. Compl. ¶¶ 159, 162, 163, 178, 183, 191, 193.

[2] Though part of the Fourteenth Amendment, the Equal Protection Clause applies to the District of Columbia through the Due Process Clause of the Fifth Amendment. *Bolling v. Sharpe*, 347 U.S. 497, 499 (1954).

Upon filing a Complaint, Plaintiffs moved for a temporary restraining order to stop the BEI's impending implementation. Emergency Mot. for TRO, Mot. for Prelim. Inj., Mot. to Stay, ECF No. 3. The Court denied that request. Order, March 31, 2026, ECF No. 14. After amending their initial Complaint, *see* Am. Compl., Plaintiffs sought a preliminary injunction and stay. Mot. for Prelim. Inj., Mot. to Stay ("Pls.' Mot."), ECF No. 27. The Secretary opposes and moves to dismiss the case on a variety of grounds. Mot. to Dismiss and Opp'n to Pls.' Mot. ("Defs.' Mot.), ECF No. 30. These motions are now ripe, and the Court held argument on them. *See* Minute Entry, May 1, 2026. It turns to them now.[3]

At the outset, the Court notes that it need not tackle the bulk of questions that Plaintiffs raise in their motions. That is because Plaintiffs' case suffers from a fatal flaw: the failure to establish Article III standing to bring their claims. The Court addresses only this jurisdictional hole and will dismiss the entire suit and deny Plaintiffs' motion for a preliminary injunction as moot.

II.

To survive a motion to dismiss under Rule 12(b)(1), the plaintiff bears the burden of proving that the Court has subject matter jurisdiction to hear his claims. *See Arpaio v. Obama*, 797 F.3d 11, 19 (D.C. Cir. 2015). Federal district courts possess limited jurisdiction, and it is "presumed that a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Thus, the plaintiff "bear[s] the burden of establishing jurisdiction by a preponderance of the evidence." *Yaghoubnezhad v. Stufft*, 734 F. Supp. 3d 87, 95 (D.D.C. 2024).

[3] Because an administrative record is unnecessary for the Court resolution of this case, it grants the Secretary's Motion for Relief from Local Civil Rule 7(n)(1), to which Plaintiffs do not object. Defs.' Mot. for Relief from LCvR 7(n)(1), ECF No. 32.

When evaluating a motion to dismiss under Rule 12(b)(1), the Court must "treat the Complaint's factual allegations as true . . . and must grant plaintiff the benefit of all inferences that can be derived from the facts alleged." *Sparrow v. United Air Lines, Inc.*, 216 F.3d 1111, 1113 (D.C. Cir. 2000) (cleaned up). But those factual allegations "will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim." *Schilling v. Speaker of U.S. House of Reps.*, 633 F. Supp. 3d 272, 275 (D.D.C. 2022), *aff'd sub nom. Schilling v. U.S. House of Reps.*, 102 F.4th 503 (D.C. Cir. 2024). And a court may consider documents outside the pleadings to evaluate whether it has jurisdiction. *See Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1253 (D.C. Cir. 2005). If the Court determines that it lacks jurisdiction, it must dismiss the claim or action. Fed. R. Civ. P. 12(b)(1), 12(h)(3).

One jurisdictional issue proves dispositive—whether Plaintiffs have standing to sue. *Warth v. Seldin*, 422 U.S. 490, 498 (1975). Federal courts "do not possess a roving commission to publicly opine on every legal question" and do not "exercise general legal oversight" of private parties or the other branches of the federal government. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423–24 (2021). Standing doctrine focuses courts on "matters of a Judiciary Nature," by ensuring that the proper plaintiff sued the proper defendant over an injury a court can remedy. *Id.* at 424 (cleaned up).

To establish this "irreducible constitutional minimum," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (cleaned up), a plaintiff must establish that he "has suffered or likely will suffer an injury in fact"; "that the injury likely was caused or will be caused by the defendant"; and "that the injury likely would be redressed by the requested judicial relief." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024). At the pleading stage, a plaintiff must "clearly allege . . . facts demonstrating each element." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338

(2016) (cleaned up). And he must do so for each defendant and for each form of relief sought. *See Davis v. FEC*, 554 U.S. 724, 734 (2008).

A recent case—*FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024)—directly relates to several of Plaintiffs' standing theories and thus deserves a word at the outset. In *Hippocratic Medicine*, a group of pro-life medical associations and several individual doctors sued the FDA to challenge its approval of an application for generic mifepristone, an abortifacient. *Id.* at 376. None prescribed, consumed, or manufactured mifepristone. *Id.* at 386. None sponsored a competing drug. *Id.* And none suffered an injury to property from FDA's actions. *Id.* Given the attenuation between themselves and mifepristone, plaintiffs mounted "several complicated" arguments to establish standing to challenge the drug. *Id.* None worked.

The Supreme Court first rejected the individual plaintiffs' claimed injury to their "conscience" because nothing about FDA's mifepristone approval required those doctors "to participate in an abortion or provide" related treatment "over their conscience objections." *Id.* at 386–87. It likewise discounted the individual plaintiffs' claim that treating patients with mifepristone complications would increase "risk of liability suits." *Id.* at 390. The causal link between FDA's regulatory actions and that possibility proved too little for standing. *Id.* The medical association plaintiffs fared no better. Even though mifepristone's approval "caused" them to spend considerable time and resources on studying mifepristone and engaging in "related public advocacy and education" to the "detriment of other spending priorities," they too lacked standing. As the Supreme Court put it, an organization "cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action." *Id.* at 394. At bottom, the *Hippocratic Medicine* plaintiffs had a sincere objection to FDA's

relaxed regulation of mifepristone, but no matter how they framed it, that objection could not establish a "justiciable case or controversy." *Id.* at 396.

III.

Given the variety of Plaintiffs, this case involves a few different flavors of standing analysis. The Court considers each group of Plaintiffs' standing in turn.

A.

Start with the individual Plaintiffs, David Evans and Dr. Kenneth Finn. Both falter at the first hurdle, injury-in-fact. A few showings are required for an Article III injury to "screen[] out plaintiffs who might have only a general legal, moral, ideological, or policy objection to a particular government action." *Hippocratic Med.*, 602 U.S. at 381. Two pose problems for the pair. First, a plaintiff must identify a "concrete" injury, meaning one that is "real and not abstract." *Id.* Second, a plaintiff must allege that his injury is "actual or imminent, not speculative," meaning that the injury "must have already occurred or be likely to occur soon." *Id.* Evans and Finn do neither.

Up first is Evans, who claims that the BEI will harm him in a few ways. He fears that if his Medicare provider opts in to the BEI, he will be offered hemp products for his health conditions. Evans Decl. ¶¶ 7, 12, ECF No. 28-6. Because Evans opposes expanded access to hemp products, that possibility could impair his "healthcare relationship." *Id.* More, Evans owns a nursing home and fears the nursing home "may be asked to participate in the BEI process" now that it is in place. *Id.* ¶ 11.

None of these claimed injuries is concrete or imminent. Evans's healthcare provider has not opted into the BEI, and Evans has not alleged that it "imminently" will. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 411 (2013); *see generally* Evans Decl. Even if his provider did, the

possibility that Evans's provider would recommend hemp products remains just that: possible, not "certainly impending." *Clapper*, 568 U.S. at 401.

In any case, if Evans's worst-case-scenario—his doctor recommends hemp to him—came true, Evans would lack a concrete harm. Mere "distress at or disagreement with" his doctor's hemp recommendation would not cut it. *See Hippocratic Med.*, 602 U.S. at 390 n.3. Neither does Evans's fear that, if his provider enrolls in the BEI, and if his provider recommends hemp, Evans's "healthcare relationship" may decline. Evans Decl. ¶ 12. "[C]onjectural" and "hypothetical" claims like these do not establish standing. *Lujan*, 504 U.S. 555 at 560 (cleaned up). And to the extent Evans worries that his provider's recommendation would overcome Evans's will and prompt him to consume hemp despite his objections to it, that prospect is especially farfetched. Evans serves as a director or consultant for no less than seven anti-marijuana organizations (also Plaintiffs here), and he has even published books on the topic. Evans Decl. ¶¶ 3, 8. Given his thoughtful, vociferous opposition, Evans's involuntary use of hemp surpasses the realm of hypothetical possibilities.

The same is true about Evans's claims linked to his nursing home. It remains unclear whether his nursing home qualifies for the BEI, let alone whether it will ever "be asked" to participate in the BEI process. Evans Decl. ¶ 11; *TransUnion LLC*, 594 U.S. at 436–37 (rejecting the "risk of future harm" that may never "materialize" as sufficient grounds for standing). Should that day ever come, Evans may decline to participate. Again, the mere request to participate in a program with which Evans "disagree[s]" in not a cognizable harm. *Hippocratic Med.*, 602 U.S. at 390 n.3. This theory falls short.

Similar problems plague Dr. Finn's standing. He complains that the BEI "requires participating physicians" to consider whether patients will benefit from hemp products, yet it

leaves those physicians without clinical guidelines to inform their hemp determinations. Finn Decl. ¶ 13. Absent regulatory guidelines, Finn says he cannot, consistent with his "professional obligations," recommend hemp products in accordance with the BEI, so he anticipates that he will lose patients who want them. *Id.* ¶ 16. He adds that the BEI's creation of new pathways to hemp may result in an "increase in emergency room" visits and may prompt more "malpractice" suits by patients who overuse hemp products. *Id.* ¶¶ 17, 19.

Finn's alleged harms are a few layers too speculative to establish standing. He has not opted into the BEI and need not opt-in going forward. Nothing thus "requires" him to consider whether hemp suits his patients, and there is no sign that reality will change any time soon. *Id.* ¶ 13. Finn also fears patient loss from his unwillingness to offer hemp products, but he has not lost any patients, so the harm remains "hypothetical." *Lujan*, 504 U.S. 555 at 560 (cleaned up). Indeed, Finn has not even had a patient request a BEI-related product. *See generally* Finn Decl.

Coming from a different angle, Finn also expects more emergency room visits, but none has occurred, and he alleges no facts establishing imminent likelihood of such events. *Id.* ¶ 17. In any case, such an increase would not afford him standing. *See Hippocratic Med.*, 602 U.S. at 391 (rejecting the notion that an "emergency room doctor" would have standing to challenge a speed limit increase that may mean "he may have to treat more car accident victims").

Similarly, he hypothesizes malpractice suits from hemp "overuse." *Id.* ¶ 17. This allegation is as speculative as the rest and a notch more confusing. Recall that Finn insists that, if he opted into the BEI, he would not recommend hemp products absent regulatory dosing guidelines. *Id.* ¶ 16. If Finn plans to refuse to offer his patients hemp, why would those patients sue him for overprescribing it? Finn cannot claim injury from hypothetical harms that have not

yet resulted (and may never result) from a voluntary program that he has not joined (and likely never would).

B.

A variety of organizations make up the next batch of Plaintiffs. Groups of this sort can establish standing in two ways. First, they can assert "associational standing" on behalf of their members. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). "[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.*[4]

Second, they can invoke "organizational standing" to sue on their own behalf. *See PETA v. U.S. Dep't of Agric.*, 797 F.3d 1087, 1093 (D.C. Cir. 2015). Under this avenue, Plaintiffs must plausibly allege they suffered an "actual or threatened injury in fact" to their own interests that is "fairly traceable to the alleged illegal action and likely to be redressed by a favorable court decision." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015).

Either way, the Constitution demands "an injury that is actual, imminent, or certainly impending." *Viasat, Inc. v. FCC*, 47 F.4th 769, 778 (D.C. Cir. 2022). At the motion-to-dismiss stage, Plaintiffs must "clearly . . . allege . . . facts demonstrating" that injury. *Spokeo*, 578 U.S. at 338.

[4] As this Court has observed before, scholars and jurists have questioned the doctrinal soundness of associational standing. *See, e.g.*, *Coal. for Humane Immigrant Rts. v. DHS*, 780 F. Supp. 3d 79, 91 n.3 (D.D.C. 2025); *Cape Cod Charter Boat Ass'n v. Burgum*, 810 F. Supp. 3d 1, 11 n.3 (D.D.C. 2025). Precedent nevertheless requires the Court to consider the doctrine here.

No Plaintiff has established standing under either avenue. Start with Plaintiffs who claim associational standing. Am. Compl. ¶ 62 (listing nine Plaintiffs who "have associational standing"). Attempting to meet the doctrine's demands, each organizational Plaintiff claiming associational standing points to a member they allege would have standing to sue in his own right. *See id.* ¶ 63. To whom do they point? David Evans. *Id.* ("At least one identified member of each of Plaintiff, namely Mr. David Evans, has standing to sue in his own right."). Because Evans lacks an injury-in-fact, and thus standing, *see* Supra Part III.A, the organizations cannot rely on his purported injuries either.[5]

Turning to organizational standing, Plaintiffs still fall short. No Plaintiff has adequately alleged an injury. *Food & Water Watch, Inc.*, 808 F.3d at 919.

Consider what it takes for an organization to surmount the injury-in-fact hurdle. Because mere "frustration of an organization's objectives is the type of abstract concern that does not impart standing," an organization must show "more" than that for an injury. *Id.* (cleaned up). What suffices? Claims that a defendant's conduct "perceptibly impaired the organization's ability to provide services" *and* prompted the organization to use "its resources to counteract that harm." *Turlock Irrigation Dist. v. FERC*, 786 F.3d 18, 24 (D.C. Cir. 2015) (cleaned up); *PETA*, 797 F.3d at 1094.

To be clear, resource diversion "in response to a defendant's actions" alone does not suffice to show that the defendant's actions "perceptibly impaired" organizational activity.

[5] Plaintiffs note that one Plaintiff (CIVEL) who claims associational standing was "granted associational standing" by an administrative law judge ("ALJ") in a separate matter. Am. Compl. ¶ 7. That decision is irrelevant to the Article III standing inquiry. As the ALJ explained in CIVEL's proceeding, "agencies are not limited in this way by Article III" and thus may allow individuals to sue "who would not otherwise have standing to seek judicial review of the agency action ultimately taken." Am. Compl., Ex. B. at 3.

Hippocratic Med., 602 U.S. at 395 (cleaned up); *Nat'l Taxpayers Union, Inc. v. United States*, 68 F.3d 1428, 1434 (D.C. Cir. 1995). Rather, an organization must show that the defendant's actions subject it "to operational costs beyond those normally expended" to fulfill its core aims. *Hippocratic Med.*, 602 U.S. at 395. In other words, the organization must show that the defendant's conduct has forced it to "expend resources in a manner that keeps [it] from pursuing its true purpose[s]," *Nat'l Taxpayers Union, Inc.*, 68 F.3d at 1434, or has "directly affected and interfered with" the organization's "core . . . activities," *Hippocratic Med.*, 602 U.S. at 395.

So, for example, the D.C. Circuit found an injury in *PETA v. Department of Agriculture*, 797 F.3d 1087 (D.C. Cir. 2015). There, the animal-welfare organization PETA challenged the government's refusal to enforce certain animal welfare regulations of birds. *Id.* at 1091. The government's non-enforcement meant that it stopped publishing reports PETA had "routinely" used to educate the public on the treatment of birds. *Id.* at 1096. More, the non-enforcement prevented PETA from filing formal complaints with the agency to seek redress for avian mistreatment. *Id.* at 1095. Because these changes "shifted to the plaintiff organization the burden to investigate and respond to complaints about birds subjected to inhumane treatment, and/or to obtain appropriate and necessary relief for these animals," the Circuit concluded that plaintiffs identified a concrete harm. *See Ctr. for Biological Diversity v. Dep't of Interior*, 144 F.4th 296, 315 (D.C. Cir. 2025) (cleaned up); *PETA*, 797 F.3d at 1091. In that scenario, the challenged action posed a "concrete obstacle[]" to the organization's work. *See PETA*, 797 F.3d at 1092 (cleaned up).

In contrast, the Circuit rejected an environmental organization's claimed injury from the government's failure to produce opinions useful to its mission in *Center for Biological Diversity v. Department of Interior*, 144 F.4th 296 (D.C. Cir. 2025). There, an organization challenged the

Bureau of Land Management's ("BLM") decision to grant drilling permits on grounds that it failed to comply with laws requiring BLM to consult with certain marine life agencies and write a "biological opinion" assessing the permit's impact on various species. *Id.* at 300–01. This failure, the argument went, deprived the organization of information about the permits' impact on threatened species "that would have otherwise been disclosed in the final biological opinion." *Id.* at 315. Without it, the organization instead had to "expend resources pursuing Freedom of Information Act requests" for the same material. *Id.* The D.C. Circuit rejected this theory. It was not enough for injury that the organization would have to "work harder" to gather information helpful to its mission. *Id.* Unlike *PETA*, this organization failed to "identify programmatic expenditures" it had to make to "fill [a] gap" left open by the agency. *Id.*

The same result ensued in *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905 (D.C. Cir. 2015). There, a food-safety advocacy organization claimed injury from the government's loosening of restrictions on poultry inspection processes. *Id.* at 910–11, 919. Even though the organization alleged that the new regulation meant it would have to "spend resources educating its members and the public" about the change, nothing suggested its "organizational activities [had] been perceptibly impaired in any way." *Id.* at 921. Despite those expenses, the D.C. Circuit still held that the organization "alleged no more than an abstract injury to its interests." *Id.* at 920.

This case is more like the latter two than the first. No organizational Plaintiff shows enough for an injury-in-fact. All claim that they diverted resources in response to the BEI's implementation, but none established that such resource diversion "interfered" with its core activities or prevented it from "pursuing its true purpose." *Nat'l Taxpayers Union, Inc.*, 68 F.3d at 1434. Consider SAM. It alleges that the "BEI directly impairs [its] core programmatic

activities by requiring SAM to redirect staff and resources from its ongoing patient and provider education programs to monitor, analyze, and provide direct informational services to its members and stakeholders regarding the BEI's implications for vulnerable seniors, as well as engage in this litigation." Am. Compl. ¶ 6; Niforatos Decl. ¶ 9 (same).

SAM's claimed injury has a few problems. First, none of its post-BEI actions harms SAM's mission. To the contrary, monitoring, analyzing, and spreading word about the BEI "are a *fulfillment* of" SAM's 'mission.'" *Coal. for Humane Immigrant Rts. v. DHS*, 780 F. Supp. 3d 79, 90 (D.D.C. 2025). SAM itself describes its "programmatic activities" as including "research and policy analysis" and "public health education campaigns." Am. Compl. ¶ 6. "[M]onitoring" and "analyz[ing]" the BEI, and "provid[ing] direct informational services" about the BEI, as SAM claims it now must do, fall comfortably under those research and education umbrellas. *Id.*

Second, shifts in SAM's internal operations do not equate to constitutional injury. SAM suggests that even if researching and opposing the BEI falls in line with part of its mission, its other activity, like "ongoing patient and provider education programs" took a hit in staff and resources for SAM to focus on the BEI. Niforatos Decl. ¶ 9. But "organizations have not suffered a concrete injury just because shifts in government policy demand shifts in internal operations." *Coal. for Humane Immigrant Rts.*, 780 F. Supp. 3d at 91; *accord Env't Working Grp. v. FDA*, 301 F. Supp. 3d 165, 172 (D.D.C. 2018). "If that were the case, an organization could claim injury-in-fact nearly any time there was a change in the law relevant to its mission." *Coal. for Humane Immigrant Rts.*, 780 F. Supp. 3d at 91. Standing doctrine thus demands more. SAM needed to show that the BEI required "operational costs beyond those normally expended." *Nat'l Taxpayers Union*, 68 F.3d at 1434. As cannabis-safety organization, sinking costs to

respond to hemp regulatory activity fall within the "normally expended" realm even if internal resources shift in the process. *See id.*

Third, SAM's engagement "in this litigation" does not create an injury. *Id.* The D.C. Circuit has made "clear that an organization's use of resources for litigation . . . is not sufficient to give rise to an Article III injury." *Food & Water Watch*, 808 F.3d at 919. Like investing into BEI-research over other programming, investing in litigation over other programming will not put SAM on stronger footing.

Other organizational Plaintiffs take a similar approach. CIVEL starts by claiming that the BEI requires it to "divert" resources from "victim assistance and legal education programs to monitor, analyze, and respond to the BEI and its implications for vulnerable seniors." Am. Compl. ¶ 7. As was true for SAM, that is insufficient for standing.

CIVEL, though, adds that the BEI will "increase . . . hemp injuries" and thus bring "more litigation." *Id.* Because CIVEL's mission includes "educating legal professionals" about "cannabis industry" harms, an increase in litigation could bring on more costs. *Id.* Setting aside that CIVEL's theory requires multiple levels of speculation about injuries hemp *may* cause, and litigation those hypothetical injuries *may* generate, *see Lujan*, 504 U.S. 555 at 560, this addition leaves CIVEL on no less shaky grounds. Even if CIVEL dedicates more resources "to handle those cases," doing so *serves* its aim of supporting "legal professionals." Am. Compl. ¶ 7. More work does not amount to injury when CIVEL's purpose is that very work. *See Ctr. for Biological Diversity*, 144 F.4th at 315.

Other Plaintiffs fare similarly. DWI claims the BEI "interfered" with its anti-substance abuse programming by "requiring diversion of resources" from regular programming to instead "collect[] and disseminat[e] information" about cannabis, hemp, and the BEI to his constituents.

Coleman Decl. ¶¶ 7, 8. What DWI programs supposedly face neglect because of the BEI? "[D]rug policy research and analysis" and "public education campaigns" are at the top of the list. *Id.* ¶ 5. But if "collecting and disseminating information" about the BEI and hemp advances neither "drug policy research and analysis" nor a "public education campaign[]," one wonders what does. *Id.* ¶¶ 7, 8. If DWI's less related programming (such as providing "technical assistance to government agencies") was uniquely impaired, DWI has not explained how. *See id.* DWI has no injury-in-fact.

The list goes on, and the result is the same. *See* Ronshausen Decl. ¶¶ 10, 12 (claiming that because DFAF had to "oppose and counter the BEI," the BEI caused a "drain on organizational resources" from other programs); Snelling Decl. ¶ 8 (HCADA claiming that because its members "have spent considerable time on collecting and disseminating" information about hemp and the BEI to stakeholders, that the BEI diverted its resources); Valente Decl. ¶ 6 (IFI claiming that because it had to "oppose the BEI" instead of focus on its "public awareness campaigns and educational work," that the BEI harmed it).

Some Plaintiffs say even less. AALM, CIPC, CIVSJ, and SOS claim that the BEI has interfered with their anti-marijuana missions by "requiring diversion of resources" from their drug prevention programs. Am. Compl. ¶¶ 8 (AALM), 10 (CIPC), 11 (CIVSJ), 13 (SOS); Ronshausen Decl. ¶ 11 (SOS). But none of these Plaintiffs alleges where those resources went instead. They even omit the now-familiar allegation that they diverted resources to "monitor, analyze, and respond" to the BEI, *cf.* Am. Compl. ¶¶ 7 (CIVEL), 6 (SAM), and they provide no alternative explanation.[6]

[6] CIPC also alleges that a New York state court concluded it had standing in a similar case. Am. Compl. ¶ 10. That court's conclusion has no effect on this one's. "Standing to sue in any Article

NCALM charts its own path but arrives at the same destination. It alleges that the BEI directly interferes with its activities "beyond" its "issue-advocacy or mission" because the BEI "authorizes the distribution" of non-FDA approved hemp products, which is "the very outcome NCALM's" anti-drug "programs are designed to prevent." *Id.* ¶ 9. Fighting this supposed harm—a policy outcome antithetical to NCALM's policy goals—is not "beyond" NCALM's mission. It lies at the center of the mission. *See Food & Water Watch, Inc.*, 808 F.3d at 919. Implementing a program that NCALM opposes does injure it.

No authority Plaintiffs cite undermines this conclusion. They point to *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 469 F.3d 129 (D.C. Cir. 2006). But in that case, a patient advocacy organization challenged an FDA policy that directly denied its members' access to certain drugs. *Id.* at 132–33.

They also tout *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), the outermost boundary of the Court's organizational jurisprudence. *See Hippocratic Med.,* 602 U.S. 396 (describing *Havens* as "an unusual case," and noting "this Court has been careful not to extend the *Havens* holding beyond its context."). But in *Havens*, the defendant's false information directly impaired the organization's ability to accurately counsel the people it served. 455 U.S. at 374–75; *see also United States v. Texas*, 173 F.4th 659, 666 (5th Cir. 2026) (en banc) (rejecting a legal advocacy group's invocation of a *Havens* standing theory where it diverted resources in its work opposing a Texas law). Unlike those cases, Plaintiffs have not distinguished themselves as organizations "with a direct stake in the outcome of a litigation."

III court is, of course, a federal question which does not depend on the party's prior standing in state court." *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 804 (1985).

United States v. Students Challenging Regul. Agency Procs., 412 U.S. 669, 689 n.14 (1973). They thus lack standing.

C.

Next up is the pharmaceutical company MMJ, which pursues a different standing theory—competitor standing. As MMJ sees matters, the BEI "expands the competitive landscape by creating a federally supported pathway for non-FDA-approved cannabinoid products to reach Medicare beneficiaries—the very patient population" that MMJ's "therapies would target." Am. Compl. ¶ 41. More simply, because the BEI creates new ways for healthcare providers to get their patients hemp products, MMJ claims the BEI increases its competition.

Parties may indeed challenge an agency action that "allow[s] increased competition against" them. *PSSI Glob. Servs., LLC v. FCC*, 983 F.3d 1, 11 (D.C. Cir. 2020) (cleaned up). To prevail with this theory, the party claiming standing must be a "*direct* and *current* competitor whose bottom line may be adversely affected by the challenged government action." *New World Radio, Inc. v. FCC*, 294 F.3d 164, 170 (D.C. Cir. 2002). MMJ struggles with the first part of that requirement—establishing itself as a direct and current competitor—because it has no sense of when or even if it will begin competing with hemp-sellers for Medicare beneficiaries.

As an illustration of what suffices for a "current" competitor, take *Associated Gas Distributors v. FERC*, 899 F.2d 1250, 1259 (D.C. Cir. 1990). There, a group of local gas distribution companies challenged a FERC decision that eliminated multiple restrictions on gas sales and gas transportation. *Id.* at 1256, 1258. The distributors established standing by arguing that the "newly authorized transactions" meant they "may lose business" to other distributors, who could enter the market more easily. *Id.* at 1258. The D.C. Circuit accepted that argument,

explaining that the "broadening" of gas sales and transportation "authorizations" opened the way for others "to invade the core markets" of these distributors. *Id.* (cleaned up). It rejected the notion that the distributors' "fear" of competition was too speculative for standing. *Id.* at 1258–59. Even though a "specific" transaction had not yet "hurt" the distributors "competitively," *id.* at 1259, they currently operated in the market, new distributors had already tried to enter their field, and FERC's decision removed further barriers for new competition, *id.* at 1258–59. All of this meant the gas distributors faced "clear and immediate" potential for competition. *Id.* That sufficed for standing.

Now for a plaintiff that did not meet the bar, consider *PSSI Global Services LLC v. FCC*, 983 F.3d 1 (D.C. Cir. 2020). There, three "small satellite operators" challenged an FCC order that promised certain payments to large satellite operators who transitioned their services to a new frequency band quickly. *Id.* at 5–6, 11. The small satellite operators claimed the FCC's payments to larger operators imposed competitive injuries on them. *Id.* at 11. Despite its ostensible economic logic, the D.C. Circuit rejected this theory. *Id.* The small satellite operators "d[id] not directly and currently compete" with the large satellite operators. *Id.* At that time, the small satellite operators provided services "almost exclusively" outside the United States and had taken only a "few steps to develop any United States markets." *Id.* While the Circuit recognized that it "may take time to develop new business" in the United States, it still rejected the claim because "competitor standing requires actual participation in the relevant market." *Id.*

The same was true in *New World Radio, Inc. v. FCC*, 294 F.3d 164 (D.C. Cir. 2002). In that case, New World Radio, a licensee of a Washington, D.C., radio station, claimed a "competitive injury" from the FCC's decision to renew Birach Broadcasting Corporation's broadcasting license for a Maryland city. *Id.* at 168–69, 171. Even though the two entities

operated in different geographic markets, New World argued that Birach's "past attempts to relocate" a radio station to the D.C. area suggested that it would do so again. *Id.* at 172. That possibility, New World continued, meant that the FCC's license renewal increased the chances of more competition for New World. *Id.* The D.C. Circuit disagreed. It explained that, despite Birach's "apparent desire to compete in the Washington, D.C. market, New World's 'chain of events' injury [was] too remote to confer standing." *Id.* Indeed, because Birach's market presence in Washington depended on the "independent actions of third parties," the court could not "simply acknowledge a chain of causation firmly rooted in the basic law of economics" and thus rejected New World's argument. *Id.* (cleaned up).

By those lights, MMJ is not a direct and current competitor with anyone selling hemp to Medicare beneficiaries. In short, MMJ has no product on the Medicare-beneficiary market and no sense of when it may. Recall where MMJ stands. MMJ researches and develops "cannabinoid-based treatments targeting Huntington's disease and multiple sclerosis." Boise Decl. ¶ 4. As part of that effort, MMJ has "submitted DEA applications to import and manufacture marijuana" to "eventually" conduct "FDA-approved clinical trials." *Id.* ¶ 13. The DEA has yet to issue a final determination on MMJ's manufacturing registration. *Id.* ¶ 19. MMJ has no sense of when that may occur. *See generally id.*

MMJ also engaged with FDA as part of its effort to get its cannabidiol drug to the clinical trial stage. In 2018, MMJ submitted Pre-Investigational New Drug meeting requests for its treatments. *Id.* ¶ 20. Two years later, FDA granted MMJ "Orphan Drug Designation" for its Huntington's disease treatment. *Id.* ¶ 21. That designation recognizes that MMJ's product targets rare diseases or conditions. *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 138 F. Supp. 3d 31, 34 (D.D.C. 2015). But that recognition is separate from and "does not alter the standard

regulatory requirements and process for obtaining marketing approval." *Id.* (cleaned up). Indeed, "a large majority of drugs with orphan designations do not have approval to be marketed in the United States at all." *Id.* (cleaned up).

MMJ has continued its efforts since then, but in February 2025, FDA issued a full clinical hold on MMJ's multiple sclerosis program. Boise Decl. ¶¶ 20, 25. That hold remains in place as of this lawsuit, and FDA-approval procedures may continue for years. Hr'g. Tr. at 39:25–40:03. Even Plaintiffs' counsel acknowledged at oral argument that a seven- or eight-year timeline for FDA approval would fall within "the normal course." *Id.* at 40:05.

This means that MMJ has not shown that it will offer its therapeutics to Medicare beneficiaries—and thus compete with those who do—anytime soon. It does not know, among other things: (1) when or if the DEA will approve its bulk manufacturing registration; (2) when FDA might lift its hold; (3) how long its clinical trials will run; (4) whether those trials will be successful; and (5) when (if ever) FDA will approve its products. *See generally* Boise Decl. That many steps away from entering the Medicare beneficiary market, MMJ's alleged competitive injury "is too remote to confer standing." *See New World*, 294 F.3d at 172. More, many of these links "depend[] on the independent actions" of FDA and DEA (neither of which plays any role in the BEI or is party to this lawsuit), calling for further speculation about MMJ's market entry prospects. *See id.* Because MMJ has not said—because it cannot say—when it may start competing in the Medicare beneficiary market, neither can this Court. MMJ lacks a competitive injury to mount its case.[7]

[7] Having concluded that MMJ is not a direct or current competitor, the Court need not address other questions competitor standing raises, such as whether there is sufficient market overlap between MMJ's marijuana product and the over-counter-hemp the BEI targets, *see Hemp Industries Ass'n v. DEA*, 36 F.4th 269, 270–71 (D.C. Cir. 2022), or whether the competition "adversely affect[s]" MMJ's "bottom line," *See New World*, 294 F.3d at 170.

Sherley v. Sebelius, 610 F.3d 69 (D.C. Cir. 2010), is not to the contrary. True, plaintiffs in that case had competitor standing without an approved product on the market. *Id.* at 71–72. But the parallels between them and MMJ end there. The *Sherley* plaintiffs were grant applicants, who sought federal funding for their research. *Id.* at 71. They challenged a rule that allowed more applicants to compete for the same pool of money. *Id.* Federal funding, not a product the plaintiffs or their competitors planned to sell, was thus the object of competition. MMJ is different. It does not gripe that the BEI vests others with funding or other federal benefits at its expense. It complains that the BEI could stiffen competition of cannabis-derived-product sales to Medicare beneficiaries even though MMJ has no sense of when it might make those sales. *Sherley* does not apply.

To the extent MMJ argues that weakening investment prospects alternatively establish an injury, that theory fails too. *See* Boise Decl. ¶ 37 (claiming the BEI "risks weakening incentives for investment" into its drug development program). MMJ makes no allegation that an investor pulled out, that revenue declined, or that partners walked. Its vague references to "investor confidence" without more, *Id.* ¶ 40, are too speculative to save MMJ's claims. *Lujan*, 504 U.S. 555 at 561. Even MMJ distanced itself from this standing theory at oral argument, explaining that investor uncertainty "goes to the merits more than standing." Hr'g Tr. 10:03–10:04. These allegations thus do not make up for what other allegations lacked. MMJ has not alleged standing.

IV.

All this leaves one more standing theory to go. Separate from individual, organizational, associational, and competitor standing, all Plaintiffs try another angle. They argue that procedural standing caselaw relieves them from the burden they would normally bear. Recall

that among Plaintiffs' bevy of claims, they fault CMS for denying them the right to participate in notice-and-comment rulemaking. Am. Compl. ¶ 52, 150–59. This claim triggers procedural standing's requirements. *See Nat'l Council for Adoption v. Blinken*, 4 F.4th 106, 113 (D.C. Cir. 2021).

When "plaintiffs allege injury resulting from violation of a *procedural* right afforded to them by statute and designed to protect their threatened concrete interest, the courts relax—while not wholly eliminating—the issues of imminence and redressability, but not the issues of injury in fact . . . ." *Ctr. for L. & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1157 (D.C. Cir. 2005); *see Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664–65 (D.C. Cir. 1996) (en banc). The relaxed standard still leaves Plaintiffs with two showings to make: (1) the Secretary violated a procedural right designed to protect their concrete interest; and (2) that violation resulted in "injury" to their "concrete, particularized interest." *Ctr. for L. & Educ.*, 396 F.3d at 1157. Plaintiffs fail on both fronts.

First, no Plaintiff has shown an injury to its concrete interests. To do so, Plaintiffs needed to show they "suffered personal and particularized injury" from the allegedly procedurally deficient BEI. *Int'l Bhd. of Teamsters v. Transp. Sec. Admin.*, 429 F.3d 1130, 1135 (D.C. Cir. 2005) (cleaned up). This Article III injury and the alleged procedural violation "are not one and the same." *Ctr. for L. & Educ.*, 396 F.3d at 1159. Indeed, the "mere inability to comment . . . in and of itself, does not establish an actual injury." *See Int'l Bhd. of Teamsters*, 429 F.3d at 1135 (cleaned up). Procedural standing instead demands a "concrete harm" like other standing theories. *Spokeo*, 578 U.S. at 341; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 497 ("Unlike redressability, however, the requirement of injury in fact is a hard floor of Article III jurisdiction that cannot be removed by statute."). Recall that Plaintiffs have not

met that bar. *See supra* Part III.A (explaining why individual Plaintiffs failed to show injury-in-fact); Part III.B (explaining why no organizational Plaintiffs established injury-in-fact); Part III.C (explaining why MMJ did not allege a competitive injury-in-fact). Repacking the same alleged harms under a new label will not change the outcome.

Even if Plaintiffs had an Article III injury, though, they collide with the next requirement. They have not identified a statute that affords the "procedural right" at hand. *Ctr. for L. & Educ.*, 396 F.3d at 1157. Plaintiffs point to the APA's requirement for agencies to conduct notice-and-comment rulemaking as the hook. 5 U.S.C. § 553; Pls.' Memo. at 25, ECF No. 28. The trouble for Plaintiffs is that a subsection of that very provision exempts from rulemaking procedures any matter "relating to . . . benefits." 5 U.S.C. § 553(a)(2). Even "construed narrowly," the D.C. Circuit has explained, this section "cuts a wide swath through the safeguards generally imposed on agency action," and it "prevails when grants, benefits or other named subjects are clearly and directly implicated." *See Humana of S.C., Inc. v. Califano*, 590 F.2d 1070, 1082 (D.C. Cir. 1978) (cleaned up). The BEI, as a voluntary component to a Medicare payment model, "implicate[s]" Medicare benefits. *Id.*; *see also Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019) ("While the APA requires many other agencies to offer public notice and a comment period before adopting new regulations, it does not apply to public benefit programs like Medicare."). Because the APA exempts the BEI from notice-and-comment rulemaking, it cannot provide grounds to challenge the failure to engage in that process.[8]

[8] The Court does not decide whether, the benefits-exemptions aside, CMS may implement the BEI without notice-and-comment under the theory that the BEI is not a legislative rule. This is a merits question that could prove a separate obstacle to the application of 5 U.S.C. § 553. *See Pac. Gas & Elec. Co. v. Fed. Power Comm'n*, 506 F.2d 33, 37 (D.C. Cir. 1974). For the same reason, the Court does not address whether Plaintiffs fall within a statute's zone of interests and thus have a cause of action. *See Herero People's Reparations Corp. v. Deutsche Bank, A.G.*, 370 F.3d 1192, 1194 (D.C. Cir. 2004) ("[T]he question whether a cause of action exists calls for

Plaintiffs respond first that *Humana* involved a different kind of agency action, a standard reimbursement regulation. Pls.' Opp'n at 12, ECF No. 34. But they never explain why a Medicare payment model component is less "related to" to Medicare benefits than a Medicare reimbursement programs. 5 U.S.C. § 553(a)(2). Plaintiffs separately assert that HHS's half-century practice of *voluntarily* conducting notice-and-comment rulemaking for benefits and contracts matters reflects the "importance of public participation in Medicare rulemaking." Pls.' Opp'n at 12. But HHS has rescinded that policy. *See* Policy on Adhering to the Text of the Administrative Procedure Act, 90 Fed. Reg. 11,029 (Mar. 3, 2025). Its past choice to do *more* than a statute demands does not increase what that statute actually demands. With no right to notice-and-comment rulemaking, Plaintiffs lack procedural standing.

V.

In sum, no matter the theory, Plaintiffs have failed to establish an Article III injury from the BEI's implementation. The use and regulation of hemp are important matters, and Plaintiffs understandably have strong views on these topics. But while they may not like the BEI, they have not been injured by it. The case will thus be dismissed for lack of subject matter jurisdiction. A separate Order will issue today.

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Dated: May 22, 2026

TREVOR N. McFADDEN, U.S.D.J.

a judgment on the merits, not jurisdiction."); *CSL Plasma Inc. v. U.S. Customs & Border Prot.*, 33 F.4th 584, 588 (D.C. Cir. 2022) ("Our cases have repeatedly recognized the non-jurisdictional nature of the zone of interests test since *Lexmark* was decided in 2014.").