IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SMART APPROACHES TO MARIJUANA
220 Maryland Ave NE, Washington, DC 20002,

CANNABIS INDUSTRY VICTIMS EDUCATING LITIGATORS
203 Main St, Suite 250, Flemington, NJ 08822,

NORTH CAROLINIANS AGAINST LEGALIZING MARIJUANA
1854 Hendersonville Rd, Suite 205, Asheville, NC 28803,

CANNABIS IMPACT PREVENTION COALITION, LLC
418 Broadway, Suite N, Albany, NY 12207,

CANNABIS INDUSTRY VICTIMS SEEKING JUSTICE
418 Broadway, Suite N, Albany, NY 12207,

DRUG FREE AMERICA FOUNDATION
333 3rd Ave N, Suite 200, St. Petersburg, FL 33701,

SAVE OUR SOCIETY FROM DRUGS
333 3rd Ave N, Suite 200, St. Petersburg, FL 33701,

DRUG WATCH INTERNATIONAL
6981 Tepper Dr, Clifton, VA 20124,

HILLSBOROUGH COUNTY ANTI-DRUG ALLIANCE
521 Lantern Circle, Temple Terrace, FL 33617,

Case No. _____

ILLINOIS FAMILY INSTITUTE
PO Box 876, Tinley Park, IL 60477,

and

DAVID EVANS
10 Elmwood Lane, Asheville, NC 28803,

Plaintiffs,

v.

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

THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

MEHMET OZ, M.D., in his official capacity as Administrator of the Centers for Medicare & Medicaid Services,

and

THE CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants.

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

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I. INTRODUCTION

1. On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") created a program to distribute hemp-derived products containing the Schedule I substance delta-9 tetrahydrocannabinol ("THC") to Medicare beneficiaries. CMS called this program the Substance Access Beneficiary Engagement Incentive ("BEI"). The BEI imposes binding rules on participating health care providers. These rules include how doctors and patients officially sign up and which doctors are eligible to distribute these products, create detailed implementation plans that must first be approved by CMS, set THC limits and other product specifications, and require quarterly reporting by providers. The BEI does not involve the Food and Drug Administration ("FDA")'s medicine approval process.

2. CMS published no Notice of Proposed Rulemaking for the BEI, solicited no public comments, offered no reasonable explanation for its action, bypassed the Federal Register, gave eleven days' notice before the BEI's implementation, and contradicted *sub silentio* its own April 2025 final rule that declared cannabis products ineligible for supplemental Medicare coverage for chronically ill patients. 90 Fed. Reg. 15,792, 15,867 (Apr. 15, 2025).

3. The BEI violates the Administrative Procedure Act ("APA") in three ways.

4. *First*, the BEI's obligations are the hallmarks of a legislative rule requiring notice-and-comment rulemaking under the APA. CMS's failure to solicit notice and comment violated 5 U.S.C. §§ 553 and 706(2)(D). CMS cannot evade notice-and-comment by embedding a substantive rule in a participation agreement.

5. *Second*, CMS reversed its prior rule without explanation, ignored well-documented health risks to elderly Americans (including a two-fold increase in cardiovascular death risk, an increase in the risk of developing or exacerbating mental health disorders, and pervasive contamination of CBD products), disregarded the absence of any FDA regulatory framework, and launched a program that violated the 0.4mg-per-container ceiling set by the 2026 Agriculture Appropriations Act by permitting the distribution of products with up to 3 mg of THC per serving. As such, the BEI is facially arbitrary, capricious, and not in accordance with law, in violation of 5 U.S.C. § 706(2).

6. *Third*, the BEI exceeds CMS's statutory authority in violation of the major questions doctrine. Section 1115A of the Social Security Act, under which the BEI is promulgated, allows CMS to test payment and delivery models for Medicare services. It does not allow CMS to sanction the possession and use of illegal and dangerous Schedule I substances by Medicare patients without clear congressional authorization.

7. CMS's action represents an unprecedented and unlawful assertion of binding decision-making authority that will profoundly affect the health of elderly Americans. CMS took this action without the guardrails imposed by the administrative process, without any reasoned explanation, in conflict with the agency's own recent APA-compliant determination, and without statutory authority. Plaintiffs bring this action under the APA, 5 U.S.C. § 701–706, to vacate the BEI, declare it unlawful, and permanently enjoin its implementation.

II. PARTIES

A. Plaintiffs

8. Smart Approaches to Marijuana, Inc. ("SAM") is a corporation headquartered at 220 Maryland Ave NE, Washington, D.C. 20002 and incorporated in Virginia. SAM's mission includes education and advocacy regarding the public health and safety impacts of marijuana and cannabis policy. SAM operates concrete programmatic activities, including public health education campaigns directed at healthcare providers and patients, direct information services regarding cannabis-related health risks, and research and policy analysis programs. SAM is a participant in the ongoing Drug Enforcement Administration marijuana rescheduling proceedings as an interested party in opposition to the Notice of Proposed Rulemaking. *See* Exhibit A. The BEI directly impairs SAM's 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. The BEI provides marijuana products via a medical source, meaning that SAM's expenditure of resources opposing rescheduling of marijuana in administrative proceedings has been rendered essentially moot. SAM's injury is not abstract policy disagreement but concrete impairment of specific programmatic activities with a consequent drain on organizational resources. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). In addition, SAM's donor, volunteer, and consultant David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and

in the alteration of his healthcare relationship due to the BEI. SAM also has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

9. Cannabis Industry Victims Educating Litigators ("CIVEL") is an organization based in New Jersey. CIVEL's mission includes educating legal professionals and the public about the harms caused by the cannabis industry. CIVEL operates concrete programmatic activities including legal education seminars, victim assistance programs, and community outreach. CIVEL is a participant in the ongoing administrative process opposing the rescheduling of cannabis. The BEI has directly impaired CIVEL's core programmatic activities by requiring diversion of resources from its victim assistance and legal education programs. In addition, CIVEL's Senior Counsel and Executive Director David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, CIVEL has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

10. North Carolinians Against Legalizing Marijuana ("NCALM") is an organization based in Asheville, North Carolina, and is registered with the North Carolina Secretary of State for lobbying purposes. NCALM's mission includes opposing

the legalization of medical hemp-derived and marijuana products in North Carolina and advocating that only medicines produced and distributed with standard best-practice pharmaceutical protocols and approved by the FDA should be available to patients. NCALM operates concrete programmatic activities including legislative advocacy, public education campaigns, and policy analysis regarding the risks of marijuana. The BEI has directly affected and interfered with NCALM's core programmatic activities beyond its issue-advocacy or mission, because the BEI authorizes the distribution of cannabis- and hemp-derived products that have not been approved by the FDA—the very outcome NCALM's programs are designed to prevent. NCALM's Executive Director David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, NCALM has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

11. Cannabis Impact Prevention Coalition, LLC ("CIPC") is a corporation organized under the laws of the State of New York. CIPC's mission is to prevent the negative social, health, public safety, and environmental impacts of marijuana. CIPC operates concrete programmatic activities including public education, community outreach, and policy advocacy directed at reducing the harms caused by marijuana use. The BEI has directly affected and interfered with CIPC's core programmatic activities

beyond its issue-advocacy or mission. CIPC's Executive Director David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, CIPC has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

12. Cannabis Industry Victims Seeking Justice ("CIVSJ") is a corporation organized under the laws of the State of New York. CIVSJ's mission is to make the marijuana industry legally accountable to its victims and to provide advocacy services to the many victims of the cannabis industry. CIVSJ operates concrete programmatic activities including victim advocacy, legal accountability initiatives, and public education regarding the harms caused by the cannabis industry. The BEI has directly affected and interfered with CIVSJ's core programmatic activities beyond its issue-advocacy or mission. CIVSJ's Executive Director David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, CIVSJ has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

13. Drug Free America Foundation ("DFAF") is a nonprofit organization based in Florida. DFAF is a drug prevention and policy organization committed to developing strategies and educational programs that prevent drug use and promote sustained recovery. The BEI has directly affected and interfered with DFAF's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs, including drug prevention education programs, student assistance initiatives, community outreach, workplace drug prevention programs, and related operational activities. DFAF's consultant and volunteer David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, DFAF has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

14. Save Our Society from Drugs ("SOS") is a nonprofit organization based in Florida. Its mission includes establishing, promoting, and enabling sound drug laws and policies that will reduce illegal drug use, drug addiction and drug-related illness and death. The BEI has directly affected and interfered with SOS's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs, including drug prevention education programs, public awareness campaigns, community intervention initiatives, support and resources for professionals working in fields impacted by drug use and abuse, and related operational activities.

SOS's consultant and volunteer David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, SOS has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

15. Drug Watch International ("DWI") is a nonprofit organization based in Virginia. Its mission includes promoting "healthy drug-free cultures" globally, advocating for the prohibition of and abstinence from all drugs including alcohol and tobacco, and opposing the legalization of drugs prohibited by national and international laws. The BEI has directly affected and interfered with DWI's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs. Since the BEI was announced, DWI's board and members have spent considerable time on collecting and disseminating information about cannabis- and hemp-derived products and the BEI to its stakeholders and constituents, thus diverting members from the mission of Drug Watch International, Inc., which seeks to prevent the abuse of all drugs, not just cannabis, through education, prevention, and treatment. DWI's member David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI. Additionally, DWI has an informational interest in the administrative record

that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

16. Hillsborough County Anti-Drug Alliance ("HCADA") is a nonprofit organization based in Florida. Its mission includes engaging in community-based alcohol, tobacco, and substance abuse education and prevention activities, as well as participation in the development of related planning strategies statewide. The BEI has directly affected and interfered with its core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its other programs and activities, including legislative advocacy, education, community outreach, and volunteering. Additionally, HCADA has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

17. Illinois Family Institute ("IFI") is a nonprofit organization based in Illinois. Its mission includes advancing public policy initiatives consistent with Judeo-Christian teachings and traditions, including opposition to access to illegal drugs, educating citizens so that they can better influence their local communities and the state. IFI has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

18. David Evans is a Medicare beneficiary aligned with an ACO REACH participant provider who has been injured by the denial of his right to participate in notice-and-comment rulemaking, and in the alteration of his healthcare relationship due to the BEI.

B. Defendants

19. Defendant Robert F. Kennedy, Jr. is the Secretary of Health and Human Services. He is sued in his official capacity. Secretary Kennedy oversees the Department of Health and Human Services, which houses CMS, and bears ultimate responsibility for the adoption and implementation of the BEI.

20. Defendant United States Department of Health and Human Services ("HHS") is an executive department of the United States government responsible for administering federal healthcare programs, including the Medicare program.

21. Defendant Mehmet Oz, M.D. is the Administrator of the Centers for Medicare & Medicaid Services. He is sued in his official capacity. Administrator Oz publicly announced in December 2025, at the signing ceremony for Executive Order No. 14370, that "millions of Americans on Medicare" would become eligible to receive cannabis products "as early as April of next year—and at no charge if their doctors recommend them." Administrator Oz has played a central role in the development and public promotion of the BEI.

22. Defendant Centers for Medicare & Medicaid Services ("CMS") is a federal agency within HHS. CMS administers the Medicare program and operates the Center for

Medicare & Medicaid Innovation ("Innovation Center"), which developed and published the BEI.

III. JURISDICTION AND VENUE

23. Plaintiffs bring this action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. The APA provides a right of review under 5 U.S.C. § 702 for persons adversely affected or aggrieved by agency action and under 5 U.S.C. § 704 for final agency action for which there is no other adequate remedy in a court.

24. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, 5 U.S.C. §§ 701-706 (APA) and 28 U.S.C. § 2201 (Declaratory Judgment Act). The relief requested is authorized by 28 U.S.C. § 2201 (declaratory judgment), 28 U.S.C. § 2202 (injunctive relief), and 5 U.S.C. §§ 701-706 (APA).

25. This Court has jurisdiction pursuant to 28 U.S.C. § 1331, which grants the district courts "original jurisdiction of all civil actions arising under the . . . laws . . . of the United States."

26. Venue is appropriate in this Court pursuant to 28 U.S.C. § 1391(e)(1) because the defendants are officers and agencies of the United States and this action is brought where the agency defendants maintain their principal offices. Venue is also appropriate under 5 U.S.C. § 703.

27. An actual, justiciable controversy exists between the parties within the meaning of 28 U.S.C. § 2201.

28. The federal Government has waived sovereign immunity in this action pursuant to 5 U.S.C. § 702.

29. Plaintiffs have exhausted all administrative remedies, the agency action is final and ripe for review, and all Plaintiffs have standing because they are injured in fact because of the defendants' actions or omissions and this court has the power to redress those injuries.

A. Final Agency Action

30. The BEI constitutes final agency action because it (1) "mark[s] the consummation of the agency's decision-making process" and is "not . . . of a merely tentative or interlocutory nature" and (2) is "one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (cleaned up); *see also United States Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 597 (2016). It was published to CMS's website on March 20, 2026, with an effective date of April 1, 2026. It imposes binding requirements regarding participant election, submission of an implementation plan, eligibility determinations, and quarterly reporting to CMS. These requirements complete CMS's decision-making and produce concrete legal consequences for participating organizations and Medicare beneficiaries aligned with them. *See Bennett*, 520 U.S. at 178 (action is final where it has "direct and appreciable legal consequences").

B. The Section 1115A Review Bar Does Not Apply

31. Section 1115A of the Social Security Act, 42 U.S.C. § 1315a(d)(2), bars judicial review of "the selection of models for testing," "the selection of organizations, sites, or participants," and "the elements, parameters, scope, and duration" of Innovation Center models.

32. Plaintiffs do not challenge any of these enumerated decisions. Plaintiffs challenge the procedures CMS used to adopt and publish the BEI by bypassing APA rulemaking and exceeding its statutory authority. *See Regeneron Pharmaceuticals, Inc. v. United States HHS*, 510 F. Supp. 3d 29, 42 (S.D.N.Y. 2020) (holding that Section 1115A "does not bar review of the propriety of the procedures used" to establish models); *see also Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986) (recognizing a "strong presumption that Congress intends judicial review of administrative action").

C. Medicare Channeling Does Not Apply

33. Plaintiffs do not seek benefits determinations, reimbursement calculations, or participant-specific Medicare payment review. No adequate administrative remedy exists for this pre-enforcement APA challenge to CMS's procedural deficiencies in adopting the BEI. *See Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1, 19 (2000) (channeling requirements do not apply where they would result in "complete preclusion of judicial review").

IV. STANDING

A. Individual and Associational Standing

34. David Evans is a 78-year-old Medicare beneficiary with individual standing to sue.

35. Mr. Evans is a donor, consultant, and volunteer for SAM.

36. Mr. Evans is Executive Director and Senior Counsel of CIVEL.

37. Mr. Evans is Executive Director of NCALM, CIPC, and CIVSJ.

38. Mr. Evans is a consultant and volunteer of DFAF.

39. Mr. Evans is a consultant and volunteer of SOS.

40. Mr. Evans is a member of DWI.

41. Mr. Evans is a Medicare beneficiary who is aligned with Hopscotch Primary Care, PLLC. This provider has joined ACO REACH as part of Physicians Healthcare Collaborative ACO, and faces imminent implementation of the BEI beginning April 1, 2026.

42. Mr. Evans was deprived of his right to participate in notice-and-comment rulemaking as an interested party. Mr. Evans is opposed to expanded access to cannabis- and hemp-derived products, and does not want them provided by his Medicare provider, due to their serious health risks. Mr. Evans also has extensive evidence of the harms caused by these products. Because there was no opportunity for public comment on the BEI, Mr. Evans could not submit this evidence to CMS.

43. The following Plaintiffs have associational standing: SAM; CIVEL; NCALM; CIPC; CIVSJ; DFAF; SOS; and DWI (collectively, the "Associational Plaintiffs").

44. At least one identified member of each Plaintiff, namely Mr. David Evans, has standing to sue in his own right.

45. The interests each Associational Plaintiff seeks to protect—including public health, product safety, and lawful agency procedure—are germane to their purposes.

46. Finally, neither the claims asserted nor the declaratory and injunctive relief requested requires the participation of individual members.

B. Procedural Standing

47. All Plaintiffs assert the denial of their right to participate in notice and comment rulemaking under 5 U.S.C. § 553. They have suffered a "reasonably increased

risk of injury" to their particularized interests due to CMS's decision to create and institute the BEI without the required procedure. *Cap. Area Immigrants' Rts. Coal. v. Trump*, 471 F. Supp. 3d 25, 38 (D.D.C. 2020); *see also Mendoza v. Perez*, 754 F.3d 1002, 1010 (D.C. Cir. 2014).

48. Plaintiffs' concrete interests include: (1) the health and safety of their individual members who are Medicare beneficiaries exposed to the BEI, including Mr. Evans, (2) the informational interest in the administrative record that would have been developed through notice and comment rulemaking, and (3) the participatory interest in shaping the regulatory outcome through the procedures Congress established.

49. Plaintiffs SAM and CIVEL are also involved in ongoing administrative proceedings opposing the DEA's efforts to expand access to cannabis through rescheduling under the Controlled Substances Act. *See* Exhibit A (order granting SAM and CIVEL standing in DEA administrative proceeding). They are injured by their inability to comment on the BEI, which seeks to expand access to cannabis for certain Americans.

C. Organizational Standing

50. All Plaintiffs except for David Evans and Illinois Family Institute (collectively, the "Organizational Plaintiffs") have organizational standing to sue.

51. Organizational Plaintiffs' primary interest is in preventing the expansion of access to cannabis products and proper use of the FDA medicine approval process. They have standing to challenge CMS's action in creating and instituting the BEI on their own behalf due to concrete and demonstrable injury to these respective interests.

52. Moreover, CMS's action has impaired specific, concrete programmatic activities undertaken by Organizational Plaintiffs, including direct patient education services, clinician training programs, community health intervention programs, and victim assistance operations, by requiring diversion of resources from these programs to counteract the public health and societal effects of the BEI. This constitutes an injury to each Organizational Plaintiff's respective organizational interests. *See People for the Ethical Treatment of Animals v. United States Department of Agriculture*, 797 F.3d 1087, 1094 (D.C. Cir. 2015).

53. Organizational Plaintiffs have standing to challenge the BEI because counteracting it requires diversion of resources from their efforts to prevent rescheduling of cannabis through the administrative process.

V. LEGAL STANDARD

54. Under 5 U.S.C. § 706(2), a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or] without observance of procedure required by law . . . ."

55. The court must examine whether the agency has "examined the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983). Agency action

must be "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

56. Under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), courts must "exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the [APA] requires." *Id.* at 413. Courts "need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous." *Id.*

VI. FACTUAL ALLEGATIONS

A. The CMS Innovation Center

57. Section 1115A of the Social Security Act, 42 U.S.C. § 1315a, established the Center for Medicare & Medicaid Innovation ("Innovation Center") within CMS. The Innovation Center's statutory purpose is to test "innovative payment and service delivery models" to reduce program expenditures "while preserving or enhancing the quality of care" for "individuals who are enrolled under such titles and . . . for defined populations with deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. § 1315a(a)(1).

58. The specific models at issue are ACO REACH (a model for accountable care organizations), the Enhancing Oncology Model or EOM (a model for oncology care), and the LEAD Model (an upcoming model for community-level addiction and overdose treatment). These are payment and delivery models.

59. The ACO Reach brings together doctors, hospitals and other healthcare providers into a single team called an Accountable Care Organization (ACO). *See Innovation Models: ACO REACH*, Ctrs. for Medicare & Medicaid Servs.,

https://www.cms.gov/priorities/innovation/innovation-models/aco-reach. These teams coordinate patient care, making sure patients get the right tests, follow-up, and preventative services to reduce duplication or unnecessary procedures. *Id.* If the ACO keeps costs below a benchmark while meeting quality standards, the team shares in the savings thereby encouraging providers to work together efficiently to focus on preventive care, chronic disease management, and patient outcomes rather than simply the number of services delivered. *Id.* Currently, there are approximately 74 ACOs made up of approximately 126,000 providers and organizations providing care to approximately 1.7 million Medicare beneficiaries. *Id.*

60. The EOM focuses on Medicare patients with certain cancers and tests a new way of paying oncology practices. *See Innovation Models: EOM*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/priorities/innovation/innovation-models/eom. Participating clinics are given bundled payments or target budgets for patients' entire course of cancer treatment, rather than being paid separately for every test or procedure. *Id.* The incentive is that if the clinic keeps costs within the target and meets quality and outcome goals, it can earn shared savings bonuses. *Id.* Based on the most recent publicly available information, the total number of Medicare participants is unknown. *Id.* However, 28 physician group practices and one commercial payer are participating, accounting for approximately 2,000 practitioners across more than 350 care sites. *Id.*

61. The BEI also applies to another payment model, LEAD, which does not begin until January 1, 2027. *See LEAD (Long-Term Enhanced ACO Design) Model*, Ctrs. for

Medicare & Medicaid Servs., https://www.cms.gov/priorities/innovation/innovation-models/lead.

62. Section 1115A was designed to test payment and delivery models, not to create access to specific consumer products.

B. CMS's Position on Cannabis Products

63. In April 2025, CMS issued a final rule, effective June 3, 2025, that states 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) (codifying "cannabis products" as non-allowable special supplemental benefits for the chronically ill ("SSBCI")).

64. To date, CMS has not rescinded this rule.

65. Yet, the BEI allows access to cannabis products for Medicare Advantage beneficiaries. This contradictory position was issued without any reasoned explanation.

C. Executive Order No. 14370

66. On December 18, 2025, President Donald J. Trump signed Executive Order No. 14370, titled "Increasing Medical Marijuana and Cannabidiol Research."

67. At the signing ceremony, CMS Administrator Oz publicly stated that "millions of Americans on Medicare" would become eligible to receive cannabis and hemp-derived products "as early as April of next year—and at no charge if their doctors recommend them." This announcement predated any agency action by three months and signaled a predetermined outcome.

D. The Substance Access BEI

68. On March 20, 2026, CMS published the BEI on its website.

69. The BEI is an optional feature embedded in participation agreements for ACO REACH and EOM (effective April 1, 2026) and the LEAD Model (effective January 1, 2027).

70. For participants in ACO REACH and EOM who elect the BEI, it is a binding, generally applicable framework that imposes legal obligations on participants and their aligned beneficiaries.

71. The BEI imposes the following mandatory program mechanics, which include: (a) participant election; (b) submission of a CMS-required implementation plan; (c) CMS approval of the implementation plan, with CMS retaining authority to reject or suspend participation; (d) physician determination of beneficiary eligibility, including that the beneficiary is over 18 years of age and does not have a disqualifying condition[1]; (e) shared decision-making with beneficiaries; (f) cannabis and hemp-derived products provided are limited to 0.3% delta-9 THC per dry weight of the product and in products that are ingested orally, no more than 3 mg per serving of total tetrahydrocannabinols; (g) a $500 annual cap per beneficiary; and (h) quarterly reporting obligations.

72. CMS claims that Medicare does not pay for the cannabis products or hemp-derived THC products approved under the BEI directly, and that they are funded at the

[1] Beneficiaries are not eligible for the BEI if they are not aligned to a participating organization, meets the model's frailty exclusion, is pregnant or breastfeeding, or if a physician does not determine the product is appropriate. *See Substance Access Beneficiary Engagement Incentive*, Centers for Medicare & Medicaid Services (accessed Mar. 27, 2026), https://www.cms.gov/priorities/innovation/substance-access-beneficiary-engagement-incentive. Public-facing CMS documents do not reveal the actual list of "disqualifying conditions" for the BEI.

expense of participants. However, the limited information available about the BEI makes this unclear.

E. Absence of Notice and Comment

73. CMS issued no notice of proposed rulemaking and solicited no public comments before announcing and instituting the BEI.

74. CMS provided no formal administrative record before announcing and instituting the BEI.

75. CMS provided no reasonable or reasoned explanation for the BEI or for its departure from its April 2025 final rule, 90 Fed. Reg. 15,792, 15,867.

76. The BEI was not published in the Federal Register, but was announced on March 20, 2026 with a near-immediate effective date of April 1, 2026.

77. Public statements by hemp-industry stakeholders and later reporting suggest that selected stakeholders may have had advance notice of the BEI before CMS publicly announced the BEI.

78. On December 18, 2025, Charlotte's Web announced that it was prepared to participate as a CBD provider in a potential Innovation Center pilot. *Charlotte's Web Serves as a Premier CBD Partner for Landmark Medicare and Medicaid Pilot Program*, Charlotte's Web (Dec. 18, 2025), https://investors.charlottesweb.com/press-releases/press-release-details/2025/Charlottes-Web-Serves-as-a-Premier-CBD-Partner-for-Landmark-Medicare-and-Medicaid-Pilot-Program/default.aspx.

79. Charlotte's Web co-founder Jared Stanley confirmed on February 13, 2026 that the program was "internally finalized" by CMS weeks prior, without public

announcement or opportunity to comment, and referred to a "briefing" when discussing the pilot program's anticipated scope. Kyle Jaeger, *Federal Agency Finalized Rule for CBD Medicare Coverage Pilot Program Weeks Ago, Key Hemp Stakeholder Says*, Marijuana Moment (Feb. 13, 2026), https://www.marijuanamoment.net/federal-agency-finalized-rule-for-cbd-medicare-coverage-pilot-program-weeks-ago-key-hemp-stakeholder-says/.

80. Upon information and belief, Charlotte's Web, a major hemp company, collaborated with CMS in shaping and finalizing the BEI.

81. At no point was the public afforded any opportunity to participate in the development of the BEI.

F. Conflict with the 2026 Agriculture Appropriations Act

82. The 2026 Agriculture Appropriations Act, signed by the President, sets a total THC limit of 0.4 mg per container for hemp-derived products, effective November 2026.

83. CMS's BEI permits 3 mg of total THC per serving, which is more than seven times the statutory limit.

84. CMS's only response to this conflict has been that it "will adjust its definition in accordance with the law." *See Substance Access Beneficiary Engagement Incentive*, Centers for Medicare & Medicaid Services (accessed Mar. 27, 2026), https://www.cms.gov/priorities/innovation/substance-access-beneficiary-engagement-incentive.

85. CMS has provided no details on when or how this adjustment will occur nor why it promulgated a program in explicit conflict with clearly established law.

86. Accordingly, CMS launched a program it already knows to be inconsistent with enacted federal law.

G. Conflict with Established and Documented Health Risks of Cannabis and Hemp-Derived THC Products for Medicare Populations

87. The BEI allows elderly Americans to access cannabis products, which contain substances that provably cause harm to their health.

88. A 2025 narrative review published in the Journal of the American Medical Association ("JAMA") of 124 recent randomized controlled trials and meta-analysis found that the evidence that cannabis "treats" disorders such as pain, anxiety, post-traumatic stress disorder ("PTSD"), insomnia, and most other hyped uses is weak or non-existent. M. Hsu et al., Therapeutic Use of Cannabis and Cannabinoids: A Review, JAMA (Nov. 26, 2025).

89. The position of the American Psychiatric Association ("APA") as of December of 2025 is that "[t]here is insufficient evidence that cannabis is an effective treatment for any psychiatric disorder." AM. PSYCHIATRIC ASS'N, *Position Statement in Opposition to Cannabis as Medicine for Psychiatric Disorders* (approved by Board of Trustees Dec. 2025 and Assembly Nov. 2025).

90. The scientific evidence documenting cardiovascular, neurological, and other health risks from cannabis and hemp-derived THC products is substantial and directly relevant to the Medicare population, which consists predominantly of adults over 65 (the population most vulnerable to these harms).

91. Heart disease is the leading cause of death among Americans over 65.

92. A June 2025 meta-analysis published in *Heart* (BMJ), encompassing 24 studies and approximately 200 million participants, found that cannabis use was associated with a two-fold risk of cardiovascular death, a 29% higher risk of acute coronary syndrome, and a 20% higher risk of stroke. Wilhelm Storck et al., *Cardiovascular Risk Associated with the Use of Cannabis and Cannabinoids: A Systematic Review and Meta-Analysis*, 111 Heart 1047 (2025).

93. A 2024 study published in the *Journal of the American Heart Association*, analyzing data from approximately 434,000 U.S. adults, found that daily cannabis users had a 25% higher risk of heart attack and a 42% higher risk of stroke compared to non-users, with risk increasing in a dose-response fashion with more frequent use. Abra M. Jeffers et al., *Association of Cannabis Use with Cardiovascular Outcomes Among US Adults*, 13 J. Am. Heart Ass'n e030178 (2024).

94. A May 2025 study published in *JAMA Cardiology* by researchers at the University of California, San Francisco, found that chronic cannabis use—whether smoked or consumed as THC-containing edibles—was associated with vascular endothelial dysfunction comparable to that observed in tobacco smokers. Vascular function in chronic cannabis users was reduced by approximately 50% compared to non-users. *See* Leila Mohammadi et al., *Association of Endothelial Dysfunction with Chronic Marijuana Smoking and THC-Edible Use*, JAMA Cardiology (May 28, 2025).

95. Memory and cognitive impairment are already prevalent concerns among older adults. THC products appear to worsen these outcomes.

96. A 2025 study found that individuals who presented to the emergency room due to cannabis use were at a 1.5-fold to 3.9-fold increased risk of dementia diagnosis within five years, relative to individuals with all-cause acute care visits and the general population. Daniel T. Myran *et al.*, *Risk of Dementia in Individuals With Emergency Department Visits or Hospitalizations Due to Cannabis*, 82 JAMA Neurology 570–79 (June 2025).

97. A 2021 study found that long-term marijuana users scored significantly lower on measures of executive function, processing speed, and general cognition than non-users, and that more frequent and more recent use was negatively associated with working memory. Katie Stypulkowski & Rachel E Thayer, *Long-Term Recreational Cannabis Use Is Associated With Lower Executive Function and Processing Speed In A Pilot Sample of Older Adults*, J. Geriatric Psychiatry Neurology (Sept. 2021).

98. A 2020 study found that fewer than 250 older adults have been included in cannabis studies to date, meaning that there is a substantial body of potential harm to that population that remains unknown to science. Brooke Porter *et al.*, *Cannabidiol (CBD) Use by Older Adults for Acute and Chronic Pain*, 47 J. Gerontological Nursing 7, 6–15 (July 2021).

99. CMS did not address this research gap before launching a program directed at older adults.

100. Commercially available CBD products are pervasively contaminated and mislabeled. M.O. Bonn-Miller et al., *Labeling Accuracy of Cannabidiol Extracts Sold Online*, 318 JAMA 17 at 1708–09 (2017).

101. A peer-reviewed 2022 study published in *Science of the Total Environment*, analyzing 516 CBD products sold in the United States, found that only 42% of products fell within ±10% of the CBD content claimed on the manufacturer's label. Among 121 edible CBD products tested, lead was detected in 42%, mercury in 37%, arsenic in 28%, and cadmium in 8%. Four edible products exceeded the California Proposition 65 threshold for daily lead consumption in two servings. Hannah Gardener et al., *Heavy Metal and Phthalate Contamination and Labeling Integrity in a Large Sample of US Commercially Available Cannabidiol (CBD) Products*, 851 Sci. Total Env't 158110 (2022).

102. These contamination and accuracy risks are especially acute for older adults, who must carefully manage their medical intake and who are particularly vulnerable to pathogen and toxin exposures. Stacy Cooper Bailey et al., *Longitudinal Investigation of Older Adults' Ability to Self-Manage Complex Drug Regimens*, 68 J. Am. Geriatrics Soc'y 569 (2020); John F. Risher et al., *The Elderly as a Sensitive Population in Environmental Exposures: Making the Case*, 7 Int'l J. Envtl. Res. Pub. Health 228 (2010).

103. A 2025 study found that even small doses of CBD can cause significant elevations in liver enzymes (specifically alanine aminotransferase and aspartate aminotransferase), indicative of possible liver injury, which can lead to fatigue and jaundice—issues of special concern for older adults seeking to avoid unnecessary hospitalizations. Jeffry Florian, *et al.*, *Cannabidiol and Liver Enzyme Level Elevations in Healthy Adults: A Randomized Clinical Trial*, 185 JAMA Internal Medicine 9, 1070–78 (July 2025).

104. A 2021 review found that a wide variety of drugs in common use by older people, from blood pressure medications to antifungals, belong to a class called CYP3A4 inhibitors that can interact with CBD and increase the bioavailability of its active chemicals, leading to possible adverse effects. Brooke Porter *et al.*, *Cannabidiol (CBD) Use by Older Adults for Acute and Chronic Pain*, 47 J. Gerontological Nursing 7, 6–15 (July 2021).

105. The same review noted that older adults can suffer from a condition in which protein binding is inhibited, which can also lead to elevated bioavailability and unintentionally higher dosing. *Id.*

106. It also noted that patient safety is a concern with CBD use, and that poison phone calls for CBD have increased from 3 in 2014 to 2,218 in 2020. *Id.*

107. CMS created and instituted the BEI despite the extensive scientific evidence demonstrating that cannabis products, hemp-derived THC products, and CBD will harm elderly Americans.

108. To date, CMS has not conducted or published any analysis of whether the products permitted under the BEI are lawful under federal law, safe for the Medicare populations at issue, or consistent with the agency's obligations under existing statutory frameworks.

109. CMS has not addressed the cardiovascular risks documented in peer-reviewed meta-analyses, the vascular dysfunction findings involving THC edibles, the pervasive contamination and mislabeling of commercially available CBD products, the drug-interaction risks for older adults on common medications, or the near-total absence of clinical research on cannabis use in populations over 65.

H. Federal Legal Status of Cannabis Products and Hemp-Derived THC Products

110. Cannabis, including delta-9 THC, remains a Schedule I controlled substance under the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801–901.

111. Hemp-derived THC products are derived by distilling delta-9 THC and other cannabinoids from hemp plants into a concentrated substance and mixing it into consumable products. As such, hemp-derived THC products contain illegal Schedule I compounds, sometimes (due to mislabeling and poor regulation) in amounts higher than the 0.3% permitted for hemp-derived products under Federal law. The hemp-derived product industry exploits this regulatory loophole for profit, to the tune of $5.5 billion. Beau R. Whitney, *An Economic Impact Analysis of the Hemp Cannabinoid Industry in Texas* (Mar. 2025), https://texashempbusinesscouncil.com/wp-content/uploads/2025/07/2024-An-Economic-Impact-Analysis-of-the-Hemp-Cannabinoid-Industry-in-Texas-Whitney-Economics-03-25-Public-Facing-1.pdf.

112. The FDA has not approved hemp-derived THC products for medical use. Epidiolex, a CBD product that may be used to treat rare seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, has been approved by the FDA, but has not been tested for safety for people over the age of 55. *See EPIDIOLEX New Drug Application Letter*, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/210365orig1s000ltr.pdf.

113. The FDA has stated that no federal regulatory framework for CBD or hemp-derived cannabis products exists.

114. The FDA has identified specific safety risks associated with CBD and hemp-derived THC products, including liver injury, drug interactions, and harm to vulnerable populations, and has stated that it has "not found adequate information showing how much CBD can be consumed, and for how long, before causing harm."

115. These FDA warnings are consistent with the peer-reviewed evidence of cardiovascular, neurological, contamination, drug-interaction, and other health risks detailed above.

VII. PLAINTIFFS' CLAIMS FOR RELIEF

First Claim for Relief
THE BEI VIOLATED THE APA'S NOTICE-AND-COMMENT REQUIREMENTS
(Violation of 5 U.S.C. §§ 552(a)(1), 553, 706(2)(D))

116. The plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 115 as though fully set forth herein.

117. The BEI constitutes a "legislative rule" in that it imposes legally binding obligations on participating organizations, creates a new benefit structure, establishes detailed eligibility criteria, requires CMS approval processes, and has "the force and effect of law." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302–303 (1979)). A legislative rule is one that "effects a substantive regulatory change to the statutory or regulatory regime." *Mendoza v. Perez*, 754 F.3d 1002, 1006 (D.C. Cir. 2014) (quotation omitted).

118. Agencies cannot "avoid notice and comment simply by mislabeling their substantive pronouncements." *See Azar v. Allina Health Services*, 587 U.S. 566, 575 (2019) (courts look to "the *contents* of the agency's action, not the agency's self-serving *label*,

when deciding whether statutory notice-and-comment demands apply" (emphasis in original)).

119. "[A]ny contract provisions that are legislative [in character] are subject to § 553's notice and comment requirements." *American Hospital Ass'n v. Bowen*, 834 F.2d 1037, 1054 (D.C. Cir. 1987). CMS "may not hide behind its authority to contract in order to evade the APA." *Id.* (quoting district court).

120. No exception to the APA's notice-and-comment requirement applies. The BEI is not an interpretive rule because it does not merely clarify an existing statute or regulation. Rather, the BEI creates entirely new programmatic requirements. *See Tennessee v. Dep't of Educ.*, 104 F.4th 577, 608 (6th Cir. 2024) (legislative rules have "the force and effect of law" and are "subject to notice and comment"). The BEI is not a general statement of policy because it has binding effect through mandatory implementation mechanics on participating providers. And it is not a rule of agency organization, procedure, or practice because it directly affects the rights and obligations of participating organizations and Medicare beneficiaries.

121. Section 1115A does not expressly exempt CMS from APA rulemaking requirements. Under 5 U.S.C. § 559, a subsequent statute supersedes the APA's rulemaking provisions only if it "does so expressly." An exemption is express only when Congress "has established procedures so clearly different from those required by the APA that it must have intended to displace the norm." *Asiana Airlines v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998). Section 1115A contains no such express exemption.

122. CMS adopted and published a generally applicable policy with legal effect without the Federal Register publication required for substantive rules under the APA and the Federal Register Act, 44 U.S.C. § 1505. The failure to publish in the Federal Register independently violates 5 U.S.C. § 552(a)(1). *See Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000) (an agency "can inform those affected simply by posting its new guidance or memoranda or policy statement on its web site," but this does not satisfy statutory publication requirements for substantive rules).

123. The precedent from CMS's own prior use of Section 1115A authority is instructive. When CMS issued an Interim Final Rule implementing Most Favored Nation ("MFN") drug pricing using Section 1115A authority without notice-and-comment, multiple federal courts enjoined the rule for failing to satisfy the good-cause exception. *See Regeneron Pharms.*, 510 F. Supp. 3d at 29. The same principle applies here: CMS cannot use Section 1115A to avoid the APA's core procedural protections simply by embedding a policy change in a participation agreement rather than a formal rule.

124. The BEI was adopted and published without observance of procedure required by law, in violation of 5 U.S.C. § 706(2)(D).

Second Claim for Relief
THE BEI IS ARBITRARY AND CAPRICIOUS
(Violation of 5 U.S.C. § 706(2)(A))

125. The plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 124 as though fully set forth herein.

126. The BEI is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

127. First, CMS's decision to allow access to cannabis- and hemp-derived products to Medicare recipients, without analysis or explanation, differs from its approach in a final rule issued only one year ago that cannabis- and hemp-derived products were ineligible for Medicare coverage. CMS has also provided no explanation for its sudden decision to allow access to substances it previously affirmed, in its published April 2025 rule, were illegal under federal law. When an agency changes course, it must provide "a reasoned explanation for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009)). An "unexplained inconsistency" renders a changed policy arbitrary and capricious. *Children's Hospital Ass'n of Texas v. Azar*, 933 F.3d 764, 773 (D.C. Cir. 2019). CMS quietly inserted the BEI into participation agreements without any explanation for why the prior position is no longer appropriate and has not, to date, provided any analysis for its action.

128. Second, CMS entirely failed to consider important hazards that arise from this policy reversal. The agency did not address:

a. the federal legal status of the products under the CSA;

b. the substantial and growing peer-reviewed evidence of adverse health outcomes or risks associated with the use of cannabis- and hemp-derived THC products by an aging and vulnerable population, namely the risk of cardiovascular harm, liver injury, dangerous drug interactions with

medications commonly used by older adults, cognitive harms risk, and pervasive contamination and mislabeling;

c. the absence of an FDA regulatory framework for CBD;

d. the near-total absence of clinical research on cannabis use in populations over 65; or

e. the conflict with the FY2026 Agriculture Appropriations Act's THC limits.

Each of these failures independently renders the BEI arbitrary and capricious. *See State Farm*, 463 U.S. at 43 (agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem").

129. Third, CMS's THC limit of 3 mg per serving directly conflicts with the 2026 Agriculture Appropriations Act's limit of 0.4 mg per container, effective November 2026. CMS's admission that it "will adjust its definition in accordance with the law" is itself an acknowledgment that the current program conflicts with enacted and unambiguous federal law. A deliberate decision to launch a program that the agency already knows will be inconsistent with federal law is arbitrary agency action.

130. Fourth, CMS has not demonstrated that the BEI satisfies the statutory prerequisites of Section 1115A, which limits testing to models for "defined populations with deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. § 1315a(a)(1). The BEI is available to any aligned beneficiary over age 18 without a disqualifying condition. Far from targeting a defined population or reasonably limiting eligibility based on statutory criteria, the model's scope effectively encompasses nearly all Medicare beneficiaries, regardless of clinical outcomes or

incurred expenditures, so long as they are aligned with an ACO REACH, EOM, or LEAD participating provider.

131. Accordingly, the BEI is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(A).

Third Claim for Relief
THE BEI EXCEEDS CMS'S STATUTORY AUTHORITY AND VIOLATES THE MAJOR QUESTIONS DOCTRINE
(Violation of 5 U.S.C. § 706(2)(C))

132. The plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 131 as though fully set forth herein.

133. Under *West Virginia v. EPA*, 597 U.S. 697 (2022), in "extraordinary cases" where an agency asserts authority of vast economic and political significance, "the agency . . . must point to 'clear congressional authorization' for the power it claims." *Id.* at 723 (quoting *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014)). The major questions doctrine applies when the agency's action is "unheralded" and represents a "transformative expansion" of its authority under vague statutory language, and the regulation is of "vast economic and political significance." *Nebraska v. Su*, 121 F.4th 1, 14 (9th Cir. 2024).

134. CMS has acted in excess of its statutory authority under Section 1115A by creating—for the first time in history—federally sanctioned access to cannabis products and hemp-derived THC products through Innovation Center program amendments, without APA rulemaking, without clear congressional authorization, and in violation of federal law.

135. No Innovation Center precedent exists for distributing specific consumer products to beneficiaries. Innovation Center models are used to test payment methods, not to increase access to unapproved drugs.

136. Congress never authorized CMS to use the Innovation Center to facilitate access to products containing substances listed as Schedule I under the CSA.

137. The political and policy significance of the program, as evidenced by Administrator Oz's public statements and the Executive Order that preceded it, is considerable.

138. The BEI's potential reach across multiple models covering substantial Medicare populations, the unprecedented nature of CMS facilitating access to any specific consumer product, and the absence of any prior Innovation Center precedent for distributing specific products to beneficiaries all confirm that this is an extraordinary assertion of authority requiring clear congressional authorization. *See Missouri v. Biden*, 112 F.4th 531, 537 (8th Cir. 2024) (applying the major questions doctrine where the government asserted "an unheralded power to regulate a significant portion of the American economy" under a long-extant statute (quoting *Util Air Regul. Grp.*, 573 U.S. at 324)).

139. Under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), the court must exercise independent judgment and not merely defer to CMS's assertion that its action falls within Section 1115A authority.

140. The BEI exceeds CMS's statutory jurisdiction, authority, or limitations, in violation of 5 U.S.C. § 706(2)(C).

Fourth Claim for Relief
THE BEI IS NOT IN ACCORDANCE WITH LAW
(Violation of 5 U.S.C. § 706(2)(A))

141. The plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 140 as though fully set forth herein.

142. The BEI is "not in accordance with law" because it conflicts with controlling federal statutes.

143. The BEI's THC limits conflict with the 2026 Agriculture Appropriations Act, which sets a total THC limit of 0.4 mg per container for hemp-derived products, effective November 2026.

144. The BEI conflicts with the Controlled Substances Act. It facilitates access to products that contain substances illegal under the CSA, including cannabis, delta-9 THC, and other cannabinoids.

145. The FDA has only approved Epidiolex, a CBD medication, but has not approved any other hemp-derived THC products for medical use and has identified specific safety risks including liver injury, drug interactions, and other harms.

146. CMS did not conduct or publish any compliance analysis for the BEI before creating and authorizing it.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and grant the following relief:

a. A declaration that the BEI was adopted and published in violation of the APA's notice-and-comment requirements, 5 U.S.C. § 553, and the Federal Register publication requirements of 5 U.S.C. § 552(a)(1);

b. A declaration that the BEI is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A);

c. A declaration that the BEI exceeds CMS's statutory authority under Section 1115A and is in excess of statutory jurisdiction, authority, or limitations under 5 U.S.C. § 706(2)(C);

d. An order vacating and setting aside the BEI;

e. A permanent injunction prohibiting Defendants from implementing, applying, or enforcing the BEI;

f. An award of costs and attorneys' fees as permitted by law; and

g. Such other and further relief as the Court deems just and proper.

Date: March 30, 2026

Respectfully submitted,

/s/ Patrick Kenneally

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CERTIFICATE OF SERVICE

I hereby certify that, on March 30, 2026, I electronically filed the foregoing Complaint for Declaratory and Injunctive Relief, Corporate Disclosure Statement, and this Certificate of Service with the Clerk of Court for the United States District Court for the District of Columbia by using the CM/ECF system. In accordance with Fed. R. Civ. P. 4, I am causing to be served one true and correct copy of the filed documents via certified mail, along with a summons, on each of the following persons:

ROBERT F. KENNEDY, JR.
in his official capacity as Secretary of Health
and Human Services
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THE UNITED STATES DEPARTMENT OF
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MEHMET OZ, M.D.
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JEANINE FERRIS PIRRO
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PAMELA BONDI
in her official capacity as Attorney General
of the United States
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Washington, DC 20530

/s/ Patrick Kenneally
Patrick Kenneally

EXHIBIT A

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Schedules of Controlled Substances: Proposed Rescheduling of Marijuana**	**DEA Docket No. 1362** **Hearing Docket No. 24-44**

ORDER REGARDING STANDING, SCOPE, AND PREHEARING PROCEDURES

On Standing

The United States Department of Justice (DOJ) through the Drug Enforcement Administration (DEA or Agency) has initiated rulemaking proceedings to reschedule marijuana from Schedule I of the Controlled Substances Act (CSA) to Schedule III. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44597, 44597 (2024). In another order (General Notice of Hearing or GNoH) published in the Federal Register, the DEA Administrator (the Administrator) subsequently determined that hearing procedures are appropriate and fixed a December 2, 2024 hearing commencement date. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 70148, 70148-49. Subsequent correspondence by the Administrator listed twenty-five (25) designated participants (Designated Participants or DPs).[1] Concluding that more information about the DPs was a necessary prerequisite to competently conducting a fair hearing,[2] I tasked the Government and the DPs with furnishing additional information by November 12, 2024 in an order dated October 31, 2024 (Preliminary Order or Prelim. Ord.). Prelim. Ord. at 3. Most of the DPs timely complied with this directive,[3] including the instruction to supply information related to their respective

[1] The American Academy of Hospice and Palliative Medicine withdrew its request to participate in a document filed on November 8, 2024, as did the American College of Occupational and Environmental Medicine on November 12, 2024. Similarly, the National Sheriffs' Association has signaled its intent to submit a hearing waiver. These DPs are no longer parties to this proceeding and no standing recommendations have been made regarding them.

[2] 5 U.S.C. § 556(c)(5); 21 C.F.R. § 1316.52(c), (g), (h).

[3] The International Academy on the Science and Impact of Cannabis (IASIC) and Saint Michael's College (SMC) did not respond to the Preliminary Order. However, Ari Kirshenbaum, PhD is affiliated with SMC, and Kenneth Finn, M.D. is affiliated with IASIC. Neither of these DPs sought to either speak on behalf of these institutions or made any assertions relative to associational standing based on their respective affiliations. IASIC and SMC are no longer parties to this proceeding and this order contains no standing recommendations with respect to them.

arguments for standing under the Administrative Procedure Act (APA) and CSA and its implementing regulations.

The non-legislative transfer of controlled substances from one schedule to another by the DEA[4] is authorized only "after opportunity for a hearing pursuant to the rulemaking procedures" set forth in the Administrative Procedure Act. 21 U.S.C. § 811(a). Both the Agency's NPRM and the GNoH expressly invited "interested persons" seeking participation in this potential scheduling action to file applicable requests within specified deadlines. 89 Fed. Reg. at 44598; 89 Fed. Reg. at 70148-79; 21 U.S.C. § 811(a); 21 C.F.R. § 1308.44(a), (b).

The APA provides that "[s]o far as the orderly conduct of public business permits, an interested person may appear before an agency or [one of its ALJs][5] for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding. . . in connection with an agency function."[6] 5 U.S.C. § 555(b). When agencies are "charged with administering congressional statutes[, b]oth their power to act and how they are to act is authoritatively prescribed by Congress[.]" *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 297 (2013); *see American Trucking Associations, Inc. v. United States*, 627 F.2d 1313, 1320 (D.C. Cir. 1980) ("When an agency exercises authority expressly delegated to it by Congress it is at the zenith of its powers."). However, even when operating "at the zenith of its powers,"[7] the agency is constrained to act within the parameters of the APA, the CSA, and any related regulations, and must refrain from actions which are arbitrary, capricious, and demonstrate an abuse of its Congressionally-authorized discretion. *American Trucking*, 627 F.2d at 1316, 1320-21.

Prior to the commencement of a hearing on the rescheduling of a controlled substance, a threshold determination must be made regarding the proper cadre of hearing participants. Standing to appear in an APA agency proceeding can differ markedly from the rigid standing

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[4] The Attorney General's CSA authority has been delegated to the DEA Administrator by regulation. 28 C.F.R. § 0.100.

[5] 5 U.S.C. § 556(b)(3). The APA prescribes only three types of officials that may preside over an agency's evidentiary hearing: the agency head; one or more members of a body that comprises the agency; or an ALJ appointed in accordance with 5 U.S.C. § 3105. *Id.* at § 556(b). In the Department of Justice, the DEA is organizationally structured to exclusively utilize the third option. The same is true of the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) and the Bureau of Prisons (BOP). Neither the Attorney General nor the DEA Administrator preside over hearings, and neither agency has been equipped by Congress with a body such as the National Labor Relations Board, the Securities and Exchange Commission, or the National Transportation Safety Board to adjudicate factually contested cases.

[6] It is beyond argument that the scheduling, rescheduling, and descheduling of controlled substances is an agency function assigned to the DEA and specifically authorized by Congress. 21 U.S.C. § 811(a).

[7] *American Trucking*, 627 F.2d at 1320.

requirements incumbent on those seeking relief in the federal courts. *Fund Democracy, LLC v. SEC*, 278 F.3d 21, 27 (D.C. Cir. 2002) ("Because agencies are not constrained by Article III, they may permit persons to intervene in the agency proceedings who would not have standing to seek judicial review."). To ensure proper separation of powers from the political branches, Article III, section 2 of the Constitution cabins the jurisdiction of the federal courts to cases and controversies. As such, those appearing before the courts must possess the requisite elements of Article III standing, *to wit*, a demonstration of a particularized injury that is: (1) actual or imminent; (2) caused by, or fairly traceable to an act that the litigant challenges in the litigation; and (3) redressable by the court. *FDA v. Alliance for Hippocratic Medicine*¸ 602 U.S. 367, 380-81 (2024); *Gettman v. DEA*, 290 F.3d 430, 432-33 (D.C. Cir. 2002). While this Article III standing threshold is present for a party seeking to challenge an action in the courts (even a person challenging an agency action under the APA),[8] it is not perforce coextensive with the relaxed level of standing required to appear in an agency administrative proceeding. *Gettman*, 290 F.3d at 433-34. The constraints of Article III standing rest "on considerations about the proper—and properly limited—role of the courts in a democratic society," *Envirocare of Utah, Inc. v. NRC*, 194 F.3d 72, 75 (D.C. Cir. 1999) (quoting *Warth v. Seldin*, 422 U.S. 490, 498 (1975)), whereas federal administrative agencies are not likewise restricted. *See, e.g.*, *New World Radio, Inc. v. FCC*¸ 294 F.3d 164, 172 (D.C. Cir. 2002); *Envirocare*¸ 194 F.3d at 74.

A lower standing threshold is often sensible in view of the potential public policy implications of many agency actions, and the application of this less rigorous procedural bar has been recognized, reviewed, and affirmed by the courts. *See, e.g., Gettman*, 290 F.3d at 433-34; *Animal Legal Defense Fund, Inc. v. Vilsack*, 237 F.Supp.3d 15, 21-22 (D.D.C. 2017). Further, as discussed, *supra*, because agencies are not limited in this way by Article III, they may, in their discretion, permit persons to intervene in their proceedings who would not otherwise have standing to seek judicial review of the agency action ultimately taken. *See, e.g.*, *Fund Democracy*, 278 F.3d at 27. However, this is not to say that everyone must be inexorably welcomed to appear before every agency on every issue that touches widely on society or tugs at the heartstrings. The APA limits the ability to appear before an agency to "interested persons," which Congress further qualified by the phrase "[s]o far as the orderly conduct of public business permits . . . ." 5 U.S.C. § 555(b). Regrettably, the legislative histories of the APA and the CSA

[8] 5 U.S.C. § 702.

are of negligible assistance when narrowing the definition of who properly rests within the parameters of an "interested person" as it pertains to an administrative scheduling hearing before the DEA.

To be sure, agency adjudications (including DEA adjudications) can and do have their own standing requirements that are baked into the process by the APA, their enabling statutes, and their implementing regulations. It follows then, that leave to appear before an agency in its APA adjudications, that is, discernment of who is an "interested person" takes on a different form based on the fixed navigation points, including (and especially) the agency's regulations.

"[T]he starting point for an APA standing determination for a litigant before an administrative agency is not Article III, but is the statute that confers standing before that agency." *Ritchie v. Simpson*, 170 F.3d 1092, 1095 (Fed. Cir. 1999). The courts will generally examine an agency's enabling statute and implementing regulations to discern the intended, reasonable breadth of those with APA standing. *See, e.g., Ritchie*, 170 F.3d at 1095 (The court interpreted the standing language in the Lanham Act more broadly than did the agency.); *Koniag, Inc. v. Andrus*, 580 F.2d 601, 607-88 (D.C. Cir. 1978) (The court held that Alaska Statehood Act's attendant regulations indicated a broader class of interested parties than had been interpreted by the Secretary of the Interior.). Thus, the proper inquiry is centered around an interpretation of the statute(s) the agency administers. This analysis involves an examination of existing agency precedent, the legislative history of the statute(s), and/or subsequent regulations which the agencies have sought to carve out the proper scope of the relevant statute(s). *Ritchie*, 170 F.3d at 1095.

Turing to the present case, the Supreme Court has characterized the primary objectives of the CSA as aiming "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances" by protecting against the diversion of drugs from legitimate channels. *Gonzales v. Raich*, 545 U.S. 1, 12-13 (2005). Further, the ultimate goal of protecting the public is served by the CSA's creation of "a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances in any of the Act's five schedules." *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). In promulgating controls against diversion through the passage of the CSA, Congress manifested its intent to protect the public from the siphoning of dangerous and fungible controlled substances from the "closed regulatory" system. *Id.*

In delimiting the correct scope of public participation in agency proceedings, the courts have acknowledged that agencies possess broad discretion to limit the participation of interested individuals and organizations. *Nichols v. Board of Trustees of the Asbestos Workers Local 24 Pension Plan*, 835 F.2d 881, 897-99 (D.C. Cir. 1987); *Vilsack*, 237 F.Supp.3d at 21-22. Those who qualify as "interested persons" are entitled to participate in the hearing process[9] so long as their involvement does not compromise the "orderly conduct of public business." 21 C.F.R. § 1316.52; 5 U.S.C. § 555(b). This right to participate in the hearing process is not "blindly absolute" and considerations regarding the logistics of the hearing must be factored into the conferral of standing.[10] *Easton Utilities,* 424 F.2d at 852. However, in an agency's exercise of that discretion to limit participation, the courts will not countenance participation denial policies that are unreasonably overbroad or otherwise arbitrary, or merely based on assertions that interventions are generally burdensome or dilatory.[11] *Nichols*, 835 F.2d at 897.

Regrettably, the CSA, its legislative history, and its attendant regulations offer little in terms of guidance on the issue of who is an "interested party" in the context of controlled substance scheduling proceedings. The CSA regulations define the term "interested person" as "mean[ing] any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [the scheduling provisions set forth in] 21 U.S.C. § 811." 21 C.F.R. § 1300.01(b); *see, e.g., Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. 26701, 26703 (2013). It is noteworthy that, "[t]he phrase 'person adversely affected or aggrieved' is a term of art used in many statutes to designate those who have standing to challenge or appeal an agency decision, within the agency or before the courts." *Dir., Office of Workers' Comp. Programs, Dep't of Labor v. Newport News Shipbuilding & Dry Dock*

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[9] The APA intervention right as set forth in 5 U.S.C. § 555(b) "is universally understood to establish" participation rights for interested persons in "on-going agency proceeding[s]." *Block v. SEC*, 50 F.3d 1078, 1085 (D.C. Cir. 1995).

[10] Specifically, the "time of appearance, the status of the proceedings, [and] the administrative avenues established by other statutes and agency rules for participation" should be afforded consideration when fashioning rules of procedure and participation standards in agency proceedings. *Easton Utilities Commission v. Atomic Energy Commission,* 424 F.2d 847, 852 (D.C. Cir. 1970). Further, if the parties participating in an agency proceeding adequately represent the public interest and the interests of the petitioners, limiting the number of parties otherwise entitled to participate may be appropriate to avoid duplicative presentations. *See, e.g., City of San Antonio v. Civil Aeronautics Board*, 374 F.2d 326, 332-333 (D.C. Cir. 1967).

[11] A reviewing court's confidence in an agency's decision to limit public participation may be further bolstered by an agency's efforts to adhere to its own rules and procedures as set forth in their governing statutes and implementing regulations. *See, e.g.*, *Easton Utilities*, 424 F.2d at 851 ("We find nothing whatsoever in the record which in any way challenges the reasonableness, the necessity for, or the propriety of this Commission rule. We are confronted only with the Commission's utilization of this rule under the factual situation of this case.").

Company, 514 U.S. 122, 126 (1995) ("person adversely affected or aggrieved" interpreted as sufficient to fulfill Article III standing requirements under the APA). By cabining its own scope of the term "interested persons" to include only "person[s] adversely affected or aggrieved by any rule or proposed rule" it is reasonable to conclude that the Agency regulation drafters intended a narrow, somewhat heightened interpretation of those permitted to appear in scheduling actions. 21 C.F.R. § 1300.01(b). There can be little doubt that the stewards of the Agency, at the time the regulation was promulgated, elected to seek input from a potential rules detractors/critics/opponents; in short, those who could demonstrate that they would be "adversely affected or aggrieved"[12] should the proposed rule become law. Stated differently, the Agency was not keen on producing an echo chamber of supportive comments to reinforce its intended result, but focused on hearing from those who feared the consequences of the proposed rule. A restricted standing interpretation is further buttressed by the highly technical nature of the facts to be adduced and analysis employed at a scheduling hearing. 21 U.S.C. § 811(b)-(f). Further, the NPRM, citing 21 C.F.R. § 1308.42, dictates that "the purpose of a hearing would be to receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III of the list of controlled substances." 89 Fed. Reg. at 44599 (cleaned up).

Beyond the stark definition of "interested party"[13] employed in its regulations, the DEA has not promulgated additional regulations regarding the parameters that could assist in delineating the boundaries of who may appear at its internal proceedings. It is axiomatic that an ALJ may not entertain a challenge to its agency's regulations,[14] and the DEA has certainly not been bashful about reminding its judges that "[o]nce the [A]gency has ruled on a given matter … it is not open to reargument by the [ALJ]." *Clair L. Pettinger, M.D.*, 78 Fed. Reg. 61592, 61600 n.13 (2013). Among its published precedential decisions, the Agency has insisted that those seeking APA standing as an "interested person" must, in the hearing request, sufficiently articulate a persuasive basis for their standing. *See, e.g., Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. at 26703 (The Agency denied a hearing request filed by a commenter "[b]ecause the commenter failed to provide sufficient information

[12] 21 C.F.R. § 1300.01(b).
[13] *Id.*
[14] *CropLife America v. EPA*, 329 F.3d 876, 882 (D.C. Cir. 2003); *Iran Air v. Kugelman*, 996 F.2d 1253, 1260 (D.C. Cir. 1993) ("It is commonly recognized that ALJs are entirely subject to the agency on matters of law.") (internal quotation marks omitted); *Oestereich v. Selective Service System Local Bd. No. 11,* 393 U.S. 233, 242 (1968) (Harlan, J., concurring).

to demonstrate that he meets the definition of "interested person" as set forth in the regulations ….").

Relaxed is not synonymous with nonexistent, and an *interesting* person (someone the ALJ—or the Administrator—may subjectively believe possesses the potential for objectively meaningful and insightful input) is likewise not synonymous with an "interested person" (a person entitled to request and participate in an APA hearing before DEA involving the scheduling of controlled substances). The potentially relaxed requirements of APA standing notwithstanding, the Agency has a right to exercise some level of control over those who appear in its proceedings,[15] and a concomitant right to expect its ALJs to adhere to its regulations and its precedents.[16] Contrariwise, that the regulations authorize a narrow segment of the population to *request* and participate in a scheduling hearing (in the case of the CSA regulations, a very narrow segment) does not perforce preclude the Agency (or this tribunal) from hearing and considering viewpoints from those unable to shoulder the burden of establishing standing. Stated differently, the Agency may be at liberty to conclude that its proposed action could benefit somewhat by listening to at least some of those who might support is proposed rule (*i.e.*, the echo chamber). Logically, however, the applicable CSA regulations were clearly drafted in a manner that the views of those participants who demonstrate APA standing (within the bounds of reasonable discretion) should be afforded a stronger voice or more weight in the ultimate decision. A contrary conclusion would arguably eviscerate the purpose for the regulation's standing standards.

With those parameters in mind, a review of available precedent, in the courts and inside the Agency, reveals some considerations that can inform an equitable determination here on the issue of APA standing in scheduling matters before the DEA.[17] Several of the Agency's

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[15] *City of San Antonio*, 374 F.2d at 329 ("No principle [of] administrative law is more firmly established than that of agency control of its own calendar.").

[16] *Pettinger*, 78 Fed. Reg. at 61600 n.13.

[17] Agencies, including the DEA, are empowered to issue "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" without engaging in the formal notice and comment or hearing procedures set elsewhere in the APA. 5 U.S.C. § 553. It is worth noting, that when presented with the opportunity to adjust its stance on the definition of "interested persons," the Agency has declined to do so and has demonstrated some level of consistency (albeit sparse in analysis) in fashioning its own view of who is "adversely affected or aggrieved." *See Consolidation, Elimination, and Clarification of Various Regulations* , 62 Fed. Reg. 13938, 13942 (1997); *Consolidation, Elimination, and Clarification of Various Regulations*, 61 Fed. Reg. 8503, 8508 (1996). In its response to a commenter who sought to amend the definition of "interested person" in proceedings involving the importation of controlled substances, DEA concluded that the definition of "interested person" was "sufficiently

previous scheduling endeavors pursuant to 21 U.S.C. § 811 failed to garner hearing requests,[18] however, there are some analytical navigation points, including measures some other federal agencies have taken (with varying levels of success on review in the courts) to assist in shaping the appropriate contours of APA standing in scheduling actions at DEA. To that end, the issue of whether the DPs have alleged sufficient APA standing to participate in this rescheduling hearing should be assessed by balancing the following four considerations (the Standing Considerations or SCs): (1) whether the requestor possesses a substantial interest in the proceedings (*to wit*, would be adversely affected or aggrieved if the proposed rule were promulgated) and/or otherwise satisfies the requirements of Article III standing; (2) whether the request complies with clear, reasonable procedural agency directives; (3) whether the request exceeds the scope of the NPRM; and (4) whether, in the discretion of the Agency, the participation of a particular requestor would meaningfully assist the decisionmaking and/or whether the interests of multiple requestors are amenable to consolidation or exclusion to accommodate orderly proceedings.

> ***APA Standing Consideration One**: Whether the DP/Requestor Possesses a Substantial Interest in the Outcome of the Proceedings (to wit, would be adversely affected or aggrieved if the proposed rule were promulgated) and/or Otherwise Satisfies the Requirements of Article III Standing*. Beyond a doubt, by the plain language of the CSA and its implementing regulations, this is the most powerful and issue-dispositive factor. *Ritchie*, 170 F.3d at 1095; *Koniag*, 580 F.2d at 608 Where a requestor demonstrates a substantial interest in the outcome of an administrative proceeding (*to wit*, aggrievement or adverse affect from promulgation of the NPRM), that requestor should ordinarily have a right to participate. *See BPI v. Atomic Energy Commission*, 502 F.2d 424, 427 (D.C. Cir. 1974). Likewise, a demonstration that a requestor would be entitled, when the adjudication is final, to judicial review of an agency action (*i.e.*, the requestor has proffered enough to satisfy the requirements of Article III standing) will ordinarily

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precise to fulfill [its] intended purpose." *Consolidation, Elimination, and Clarification of Various Regulations*, 62 Fed. Reg. at 13938.

[18] *See, e.g., Schedules of Controlled Substances: Removal of Naloxegal from Control*, 80 Fed. Reg. 3468, 3469 (2015); *Schedules of Controlled Substances: Placement of Brivaracetam into Schedule V*, 82 Fed. Reg. 13067, 13067 (2017); *Schedules of Controlled Substances: Placement of Solriamfetol in Schedule IV*, 85 Fed. Reg. 643, 643 (2020).

qualify that person as an "interested person" who normally should be permitted to be heard in an administrative proceeding. *Nichols*, 835 F.2d at 896; *Vilsack*, 237 F.Supp.3d at 21; *but see Envirocare*, 194 F.3d at 75.[19] *Envirocare* notwithstanding, granting APA standing to a requestor who, in its request and attendant filings, has averred sufficient facts to demonstrate that it would have Article III standing to challenge a DEA scheduling action on appeal in federal court is the analytically superior option. Further, the legislative history of the Controlled Substances Act illuminates that requestors that possess sufficient interest in engaging with the dual goals of the Act (to protect the public's health and ensure the closed regulatory system of controlled substances) will likely have a strong case for establishing their participation rights.[20] In view of the DEA's narrow definition of "interested person" under its regulations,[21] this aspect of Standing Consideration One, must generally be afforded controlling weight. That is to say, the Agency's insistence that some demonstration that the person seeking a ticket to appear in its proceedings articulate a demonstration that the interested person will be "adversely affected or aggrieved by any … proposed rule," constitutes a condition precedent for APA standing is not unreasonable. Others who are interested, but do not qualify as "interested persons" under the regulations, may not necessarily be foreclosed from a voice in the process, and had the opportunity to file written comments. 5 U.S.C. § 553(c); 21 C.F.R. § 1308.44(g); 89 Fed. Reg. at 44598. That said, a rational, supported application of the APA qualifier language that interested persons may appear "[s]o far as the orderly conduct of public business permits" can trump standing in APA proceedings. 5 U.S.C. § 555(b); *Vilsack*, 237 F.Supp.3d at 22.

***APA Standing Consideration Two**: Whether the Request Complies with Clear, Reasonable Procedural Agency Directives*. While the Consideration One requirements

[19] The *Envirocare* court relied liberally on *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 84-42 (1984), which has been subsequently reversed by *Loper Bright Enterprises v. Raimondo*, 144 S.Ct. 2244, 2273 (2024).

[20] The text and legislative history of the CSA appears bereft of any indication that it was promulgated to protect the employment interests of a registrant. *See, e.g., Bonds v. Tandy*, 457 F.3d 409, 415-16 (5th Cir. 2006) ("a pharmacist's interest in employment is not arguably within the zone of interests protected by the statute. Accordingly, [the pharmacist] is not a 'person aggrieved' under [the CSA]"). *See also*, *Alliance for Hippocratic Medicine*, 602 U.S. at 385-87 (finding that doctors lacked Article III standing when attempting to challenge the regulation of a drug they did not prescribe or use themselves).

[21] 21 C.F.R. § 1300.01(b).

are of paramount importance, there are also factors that can potentially further narrow participation, and satisfaction of Consideration One is by no means a *carte blanche* to entry into the proceedings. The courts have upheld an agency's requestor denials based on the failure of the requestor to abide the agency's reasonable procedural requirements. *BPI*, 502 F.2d at 427-29 (Participation denial upheld where requestor failed to fulfill agency requirement to specify the basis for the requested participation.); *Easton Utilities*, 424 F.2d at 850 (Participation denial upheld where requestor submitted petition beyond regulatory deadlines and after hearings had been conducted.). In *Easton Utilities* the court held:

> We do not believe that the affirmative grant of a right to appear is blindly absolute, without regard to time of appearance, the status of the proceedings, the administrative avenues established by other statutes and agency rules for participation, or most importantly, as 'the orderly conduct of public business permits.'

424 F.2d at 852. As discussed, *supra*, the DEA currently has no regulations specifically directed towards hearing requestor requirements beyond the bare "interested person" limitation and definition in the CSA and its implementing regulations. Accordingly, resort must be had to the relatively sparse collection of (analytically barren) final orders addressing participation requests, the APA and its interpretive precedent, and the terms of the NPRM. Hearing requests have been rejected by DEA in the face of an individual's failure to comply with procedural directives. *See Placement of Controlled Substances: Placement of Cathinone and 2,5-Dimethoxy-4-ethylamphetamine Into Schedule I*, 58 Fed. Reg. 4316, 4316 (1993) (denying a request for hearing because it was not filed in accordance with the directives as established by the regulation); *Schedules of Controlled Substances: Placement of ()cis-4-methylaminorex into Schedule I*¸ 54 Fed. Reg. 14799, 14799 (1989) (same). The Agency has held that a requestor must supply some specific information regarding his/her/its theory of standing under the "interested person" standard. *See Schedules of Controlled Substances: Placement of Lacosamide into Schedule V*, 74 Fed. Reg. 23789, 23789 (2009). Similarly, the Agency has interpreted its regulations as requiring that "any person requesting a hearing *must state with particularity* his interest in the proceeding." *Id.* (internal quotations omitted) (emphasis supplied). Inasmuch as the Agency has historically demanded a narrow, individualized,

statement of a requestor's adverse outcome or aggrievance to merit participation in the scheduling hearing process, the failure to provide one militates against participation.

The NPRM in this case has similarly required that hearing requests in this rescheduling action must: "(1) state with particularity the interest of the person in the proceeding; (2) state with particularity the objections or issues concerning which the person desires to be heard; and (3) state briefly the position of the person regarding the objections or issues." 89 Fed. Reg. at 44598. In this regard, it is not the place of the ALJ to conduct extra-record research or engage in broad conjecture about the potential benefits of each requestor. These hearing request requirements are not optional, and the evaluation can only be made on the four corners of the Designated Participants' responses to the Preliminary Order (Preliminary Order Responses or PORs).

***APA Standing Consideration Three**: Whether the Request Exceeds the Scope of the NPRM*. Consideration Three presents an additional limitation. As discussed, *supra*, the Agency is authorized to act within the parameters set forth by Congress. In *Olsen v. DEA*, 776 F.2d 267, 267 (11th Cir. 1985), the court upheld a participation denial by members of the Ethiopian Zion Coptic Church (the Church) in pursuit the Church's efforts to acquire a religious exemption for its members to use marijuana. The Church petitioned for rescheduling under 21 U.S.C. § 811, and the court held that an effort to seek a religious exemption fell outside the (scheduling) scope of § 811. *Id.* Thus, a requestor who seeks participation to acquire relief that is outside the scope of rescheduling (*e.g.*, descheduling, decriminalization, etc.) can properly be denied on that basis alone.

***APA Standing Consideration Four**: Whether, in the Discretion of the Agency, the Participation of a Particular Requestor Would Meaningfully Assist the Decisionmaking and/or Whether the Interests of Multiple Requestors are Amenable to Consolidation or Exclusion to Accommodate Orderly Proceedings*. The DEA Administrator has been charged by Congress in exercising discretion in assigning schedule placement for a plethora of potentially dangerous, addictive medications. 28 C.F.R. § 0.100; 21 U.S.C. § 811. It is imperative that she and her Agency possess the latitude to regulate participation

to include requestors who can render meaningful assistance to her determination, and to exclude those who are not objectively in a position to do so. *Cf., Nichols*, 835 F.2d at 897 (agencies should have discretion to exclude requestors who would fail to assist the agency's decisionmaking); *Cities of Statesville v. Atomic Energy Commission*, 441 F.2d 962, 977 (D.C. Cir. 1969) (agencies should have broad discretion to determine the sources reasonably required to supply the assistance it needs in vindicating the public interest). Thus, if there is a requestor who possesses information that the DEA Administrator deems keenly important to rendering a scheduling determination that is legally correct and consistent with public interest within the meaning of the CSA, she must be afforded a healthy level of discretion to grant participation. This Consideration by no means creates APA standing, but on a pragmatic level, the Administrator, through her Government counsel, are permitted to call witnesses at a contested hearing, and her inclination to hear from a wider spectrum of society is entitled to a level of deference.

Reasonable, pragmatic considerations on the part of the agency are also valid. Even parties with a solid, substantial interest in the proceedings (Consideration One) are not immune from logistical concerns. In upholding the authority of an agency to limit and consolidate an unwieldy number of requestors, the D.C. Circuit rendered the following holding:

> Practical problems of calendar administration confront an agency whenever related applications are pending at the same time. Consolidation, scope of the inquiry, and similar questions are housekeeping details addressed to the discretion of the agency and, due process or statutory considerations aside, are no concern of the courts.

City of San Antonio, 374 F.2d at 329. An agency may take reasonable steps to avoid obstructing or overburdening the proceedings, or to avoid unduly broadening the issues considered. *Nichols*, 835 F.2d at 897. Thus, the DEA is not required to accommodate a cast of thousands in conducting its scheduling hearings, and may, where appropriate, prescribe reasonable limits based on size and common interests of the requestors.[22] As

[22] The court went on to explain in *City of San Antonio* that while true "that a party with a substantial interest in the proceeding has a right to intervene . . . But a finding of substantial interest must be related to a particular proceeding. And a proceeding must be manageable if it is going to be conducted in such a manner as will be conducive to the proper dispatch of business and to the ends of justice." *Id.* at 332 (internal citation and punctuation omitted); *see also*, *Cities of Statesville*, 441 F.2d at 977 (*en banc*) (Even in the face of a substantial interest on the part of a requestor "an agency should be accorded broad discretion in establishing and applying rules for public participation,

discussed, *supra*, the APA qualifies the appearance rights of participants with the language "[s]o far as the orderly conduct of business permits,"[23] so long as the discretion is exercised rationally. *Vilsack*, 237 F.Supp.3d at 24. As a result, the consolidation of parties may be a necessary function of the administrative hearing process. When resolving procedural issues, such as consolidation, that are not specifically addressed by the relevant authorities (the APA, the CSA, and their implementing regulations), the Federal Rules of Civil Procedure provide useful guidance.[24] Rule 42(a) of the Federal Rules of Civil Procedure authorizes the consolidation of actions that "involve a common question of law or fact" by permitting the judge to "join for hearing . . . any or all matters at issue in the actions;" "consolidate the actions; or" "issue any other orders to avoid unnecessary cost or delay." The trial judge[25] is afforded "large discretion in the matter [of consolidation] which will not be interfered with except in a clear case of abuse …." *Davis v. Yellow Cab Co.*, 220 F.2d 790, 791 (5th Cir. 1955). There is no magic quantum of common facts (or law) and likewise no disparity as to which party's evidence should weigh in (or be omitted from) the analysis. Under the like considerations that support case consolidation, when requestors present overlapping or duplicative interests and proposed testimony, this may pose a powerful and persuasive reason to "avoid unnecessary cost or delay" through either limitation of viewpoints, or even consolidation of parties. Fed. R. Civ. P. 42(a). "Participation in agency [APA rulemaking] proceedings does not necessarily entail full-fledged party intervention. Rather, agencies have ample authority to shape the manner in which intervenors will participate." *Vilsack*, 237 F.Supp.3d at 24 (quotation marks and internal citation omitted).

As discussed, *supra*, this tribunal has not been furnished with copies of the responses filed by the DPs with the Administrator. Accordingly, the APA standing determinations set forth

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including how many are reasonably required to give the agency the assistance it needs in vindicating the public interest") (internal punctuation and quotation marks omitted).

[23] 5 U.S.C. § 555(b).

[24] *But see, Roy E. Berkowitz, M.D.*, 74 Fed. Reg. 36758, 36759 (2009) (noting that DEA administrative hearings are not bound by the Federal Rules of Civil Procedure); *Kamir Garces-Mejias, M.D.*, 72 Fed. Reg. 54931, 54932 (2007) (same).

[25] The Supreme Court, in reviewing the boundaries of immunity relative to an agency ALJ, has held that "[t]here can be little doubt that the role of the modern federal . . . administrative law judge within [the framework of the APA] is 'functionally comparable' to that of a [U.S. District Court] judge." *Butz v. Economou*, 438 U.S. 478, 513 (1978). While the scope of this functional equivalence is not without limitations, it is correctly applied to the issuance of procedural rulings within the context of an APA administrative hearing.

herein are rendered based exclusively on an evaluation of the Preliminary Order Responses provided by the Designated Participants. The respective determinations have been made light of the Four APA Standing Considerations (SCs One-Four) discussed above, and (in no particular order) will be herein evaluated *in seriatim*.

Cannabis Bioscience International Holdings (CBIH)

In its POR, CBIH describes itself as "a corporation devoted to research and development in healthcare, particularly in cannabinoid-based formulations aimed at advancing medical treatment options for serious diseases." CBIH POR at 1. This requestor elaborates that its "mission centers on leveraging the therapeutic potential of cannabis-derived compounds to enhance patient care and broaden the scientific understanding of cannabis in medical applications." *Id.*

As its basis for APA standing, CBIH represents that it anticipates that the placement of marijuana in Schedule III will "facilitate significant advancements in medical research, patient care, and regulatory clarity, directly impacting [CBIH's] ability to conduct cannabinoid-based research" and that the proposed rescheduling would be "integral to CBIH's mission to provide safe, accessible, and evidence-based cannabis-derived treatments, which would be otherwise constrained under the existing Schedule I classification." *Id.* at 2. Further, CBIH represents that rescheduling would advance its intellectual property goals, and specifically catalogues a list of recently-filed patent applications. *Id.*

The POR regarding this requestor does not specify how it would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule, but rather, explains that its research and pecuniary interests would be advanced by rescheduling. This is a requestor who aspires to pursue the purported benefits of marijuana for commercial use. Thus, this requestor has not demonstrated that it would be adversely affected or aggrieved by promulgation of the NPRM, and instead avers that it will not accrue the benefits it aspires to in the event marijuana is not rescheduled into Schedule III. Rescheduling presents a potential benefit to this requestor, but declining to do so will not adversely affect its interests beyond the status quo. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

Under SC Two (compliance with procedural directives), the RFH was apparently timely, and the POR is clear in its support of the proposed rescheduling, discusses the issues upon which it desires to be heard, and adequately outlines its position. On the whole, this requestor has complied with the relevant Preliminary Order and the procedural directives of the Agency in the NPRM. Thus, SC Two does not disfavor APA standing.

Similarly, inasmuch as the POR is laser focused on the rescheduling depicted in the NPRM and its potential impact on CBIH, SC Three (within the scope of the NPRM) militates in favor a grant of APA standing for this requestor.

Regarding SC Four (Meaningful Assistance/Consolidation Potential), a company dedicated to developing new, medically significant formulations of marijuana products with shared scientific and commercial objectives could potentially have expertise and access to relevant information that could potentially be helpful to the Agency in deciding whether to proceed with its proposed rescheduling rule. Beyond that, the Administrator has identified this requestor as a DP, which is entitled to significant deference. Inasmuch as CBIH shares a pecuniary/commercial concern with other requestors, it may by prudent to consider a consolidation of presentations with other DPs who also favor the proposed rescheduling.

Upon a thoughtful balance of the four SC Factors, CBIH has certainly not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its interests within the unambiguous, directive terms of the regulations. Upon consideration of the powerful Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Analyzing the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) militate in favor of CBIH's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision.

International Association of Chiefs of Police (IACP)

In its POR, the IACP describes itself as "the world's largest and most influential professional association for police leaders … committed to advancing safer communities through thoughtful, progressive police leadership." IACP POR at 1. This requestor claims to "speak[] out on behalf of law enforcement." *Id.*

IACP's POR opposes the NPRM because, in its view, the proposed rescheduling change would present "a significant shift in federal drug policy with significant implications for public safety, public health and the ability of police agencies to protect the public," presumably all of which would negatively impact on, *inter alia*: policing, firearms regulations, public and workplace safety, impaired driving, impairment standards, and firearms regulation. *Id.* at 2.

In this regard, IACP's assertion of standing under SC One (aggrievement, adverse impact or Article III standing) depends entirely upon its ability to demonstrate associational standing.

> An association only has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

Fund Democracy, 278 F.3d at 25 (citing *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)). Here, the interests cited by IACP, at least as articulated as adverse (that is, the potentially adverse impact rescheduling could have on the law enforcement efforts to enforce driving and other impairment-related and fit-for-duty laws regularly enforced by many of its members), could conceivably be adversely impacted by promulgation of the NPRM. Accordingly, SC One favors standing in this case.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential), the POR posits a wide reservoir of access to members with the potential to speak authoritatively on the listed issues of concern, a law enforcement perspective is quite valuable, and even beyond all that, that the Administrator approved IACP's status as a DP is entitled to significant deference. The law enforcement focus expressed by this requestor may well be best served by consideration of consolidation with other like-minded requestors.

Accordingly, inasmuch as all four of the SCs favor standing, this DP has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor may wish to give serious consideration to presentation consolidation with other enforcement-motivated requestors who are unsupportive of the proposed rescheduling.

Veterans Initiative 22 (VI-22)

In its POR, VI-22 defines itself as "a non-profit organization whose mission is veteran suicide prevention" and that its focus is helping veterans, their families and first responders "by providing resources, employment opportunities, and … advocating for safe access to affordable cannabis …." VI-22 POR at 2. The POR does not reference any specific or estimated number of veteran members or beneficiaries or how its services are designed to assist those veterans, but it does posit that the NPRM would facilitate cannabis research, improve veterans' access to marijuana as an alternative treatment option, and reduce legal barriers to veterans who seek to use marijuana as medicine. *Id.* at 5.

It is not necessary to reach the issue of associational standing. Irrespective of the size of its membership or the scope of its beneficiaries, VI-22's POR does not specify how it or its beneficiaries would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. It is VI-22's stated position that those it helps would markedly benefit by DEA's embracement of the NPRM and rescheduling of marijuana to Schedule III. Specifically, the POR argues that promulgation of the NPRM will encourage research into the substance's benefits, make it more accessible to veterans, and diminish some legal barriers that affect the organization's beneficiaries. Thus, this requestor has not demonstrated that it or those it assists would be adversely affected or aggrieved by promulgation of the NPRM. Rescheduling presents a potential benefit to this requestor and its veterans, and will not adversely affect any of its espoused causes related to marijuana. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) is stronger on its commitment to its positions than it is on access to a wide range of relevant experts, but that the Administrator approved VI-22's status as a DP is entitled to significant deference.

Upon a thoughtful balance of the four SC Factors, VI-22 has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its own interests or the interests of those on whose behalf it advocates. Placing appropriate regulatory emphasis on the powerful

Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Consideration of the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. The veteran-focused concerns of this requestor may lend itself well to consolidating its presentation with other veteran-focused DPs who also favor promulgation of the NPRM.

Kenneth Finn, M.D.

Dr. Finn's POR lists his extensive medical qualifications and his considerable experience writing, lecturing, and testifying on the issue of marijuana use. Finn POR at 1. Although affiliated with numerous organizations, including the International Academy on the Science and Impact of Cannabis,[26] the POR identifies his interest in the NPRM exclusively as a physician, and not on behalf of IASIC or any other organization, thereby precluding consideration of associational standing. According to the POR, this requestor has multiple relevant board certifications and practices pain medicine. *Id.* Dr. Finn alleges that as a physician, the promulgation of the NPRM would adversely affect him because the lack of satisfactory research into cannabis and the absence of any dosing guidelines or care standards from the Food and Drug Administration (FDA) would render him unable to competently prescribe or administer the substance as a drug for his patients. *Id.* at 1-3.

In *FDA v. Alliance for Hippocratic Medicine*, the Supreme Court held that a group of physicians challenging FDA regulations lacked standing to do so based on anticipated hurdles in patient treatment. 602 U.S. at 380-81. The Court specifically declined to create a "doctor standing" doctrine,[27] but was equally unambiguous in holding that the plaintiff-doctors "may present their concerns and objections to the President and FDA in the regulatory process …." *Id.* at 397. Which segues nicely to the subject of APA standing. As discussed, *supra*, the requirements of APA standing are not coextensive with standing under Article III, and are principally driven by the applicable agency regulations. *Ritchie*, 170 F.3d at 1095. Here, Dr.

[26] *Supra* note 3.
[27] *Id.* at 391-92.

Finn has raised issues related to his pain management practice where he claims that he will be adversely affected by the promulgation of the NPRM. Without reaching the issue as to whether any of his anticipated difficulties have merit, this type of allegation clearly sounds within the reach of the APA and CSA's standing requirements under the regulations, and militate in favor of standing under SC One (aggrievement, adverse impact or Article III standing).

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential), the POR essentially offers the potential testimony of Dr. Finn, whose credentials arguably represent a considerable array of subject matter experience and knowledge on subjects relevant to the NPRM determination. Furthermore, the Administrator approval of Dr. Finn's status as a DP is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, this DP has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. The medical practitioner-focused interests of this requestor may render it sensible for him to consider presentation consolidation with other, medical practitioner DPs who also disfavor the proposed rescheduling action.

Phillip Drum, PharmD

Dr. Drum's POR lists his extensive qualifications as a pharmacist and his considerable experience writing, lecturing, and testifying on the issue of marijuana use and impairment. Drum POR at 1-2. Dr. Drum alleges that as a pharmacist, the promulgation of the NPRM would adversely affect him because, at least in his view, the FDA did not perform the functions that pharmacists depend upon for the safe, effective, and professional exercise of pharmacy. *Id.* Specifically, the lack of the package inserts required to accompany all medications will, at least in his view, result in an inability to comply with the standards of his profession. *Id.* According to Dr. Drum's POR:

> As a [Schedule III] product, marijuana products need an approved package insert listing medical indication for use, scientific evidence of the benefits exceeding the risks, use in the approved indication, the appropriate dosage for various patient populations (age, pregnancy status, metabolic and clearance status, etc.), potential

> adverse effects along with the incidence of occurrence, standard concentrations of active ingredients (there are over 100+ cannabinoids in marijuana), storage requirements and clinically relevant drug interactions. Dispensing these products without such information pose[s] a safety risk and inability of a pharmacist to provide required patient education about the safe use of their medicine. None of this information for marijuana has been performed [sic] by the FDA, unlike the package insert currently available for the single [sic] cannabinoid products – dronabinol and cannabidiol.

Id. at 1-2. Thus, by Dr. Drum's reckoning, without research and action by FDA, he cannot do his job and serve his pharmacy patients within the standards of his profession.

As discussed, *supra*, inasmuch as in *Alliance for Hippocratic Medicine*, the Supreme Court declined to create standing for physicians, it is beyond doubt that a similar logic precludes Article III standing for Dr. Drum based exclusively on his status as a pharmacist. 602 U.S. at 396. As has been discussed extensively, elsewhere in this order, the requirements of APA standing are not coextensive with standing under Article III, and are principally driven by the applicable agency regulations. *Ritchie*, 170 F.3d at 1095. Here, Dr. Drum has raised issues related to pharmacy practice, and claims that he and his patients stand to be adversely affected by the promulgation of the NPRM. Without reaching the issue as to whether any of his anticipated difficulties have merit, this type of allegation clearly sounds within the reach of APA/CSA standing under the regulations, and militate in favor of standing under SC One (aggrievement, adverse impact or Article III standing).

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential), Dr. Drum's POR exclusively offers his own potential testimony, which arguably appears to reflect a considerable breadth of subject matter experience and knowledge on subjects relevant to the NPRM determination. Furthermore, the Administrator approval of Dr. Drum's status as DP's is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, this DP has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. The medical practitioner-focused interests of this requestor may render it

sensible to consider presentation consolidation with other, medical-practitioner DPs who also disfavor the NPRM.

Community Anti-Drug Coalitions of America (CADCA)

CADCA's POR states that it represents "over 7,000 substance use prevention coalitions that involve multiple sectors of a community including schools, law enforcement, youth, parents, healthcare, media, tribal communities and others who are involved in comprehensively addressing locally identified substance use issues, including marijuana." CADCA POR at 2. According to this DP, the mission of its members "is to keep communities safe, healthy and drug free by stopping, delaying and mitigating initiation into substance use …." *Id.* CADCA asserts that promulgation of NPRM would greatly increase funding sources of pro-marijuana entities, and thereby render it more difficult to achieve mission goals within its budget, thereby greatly reducing the support it will be able to render to its coalition members. *Id.* at 6.

SC One (aggrievement, adverse impact or Article III standing) consideration is dependent upon a determination that CADCA has associational standing. That is, that CADCA's "members would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181). Assuming (as proffered) that its substance abuse coalitions are uniformly dedicated to the local and national reduction of marijuana use, each one would be adversely affected by a regulatory action that would potentially disproportionately fund pro-marijuana advertising and advocacy efforts. Accordingly, CADCA has demonstrated sufficient associational standing to have that factor militate in favor of standing under SC One.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four, as described in the POR, CADCA's seven-thousand-member-coalition breadth would apparently make a potentially large number of experts with knowledge available to contribute to potentially add meaningful

input to the Agency's NPRM determination. Furthermore, that the Administrator approved CADCA's status as a DP is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, CADCA has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. The substance-abuse-prevention focus of this requestor may be best served by considering consolidation of its presentation with other abuse-prevention-motivated DPs who also are unsupportive of the proposed rescheduling.

Cannabis Industry Victims Educating Litigators (CIVEL)

In its POR, CIVEL describes itself as "a marijuana industry victims' advocacy organization" and alleges that its "victims of the marijuana industry … have been, are being, or will actually be harmed by [promulgation of the NPRM because it] will increase the use of marijuana, reduce the perception of its dangerousness and lower medical standards for deciding what is a medicine …."[28] CIVEL POR at 4. While not altogether clear from the POR, CIVEL is apparently engaged in the active representation of individuals who claim/have claimed harmful effects from marijuana, and equips trial attorneys and the public with legal citations and tactical approaches for engaging in anti-marijuana litigation. *Id.* at 3-4.

Reviewing its POR under SC One (aggrievement, adverse impact or Article III standing) CIVEL's APA standing is dependent on whether it has made a persuasive case for associational standing. That is, that CIVEL's "victims" "would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181). Assuming (as proffered) that the "victims" it advocates and litigates for allege they have each been harmed by marijuana and an NPRM that could potentially increase its societal prevalence exponentially, each of the "victims" could allege sufficient harm to justify

[28] The POR purports to contain citations for two cases where state courts have granted associational standing for CIVEL under state law. CIVEL POR at 4. While a limited, excerpted portion of an unreported New York trial court decision that was supplied by CIVEL appears to find associational standing by placing reliance on an affidavit executed by one of the plaintiffs (*Cannabis Impact Prevention Coalition and Cannabis Industry Victims Seeking Justice, et al v. Hochul, et al*, Albany County, NY, Index No. 905386-23), the other case (*Botteon and CIVEL, et. al., MID-L-001241-24*) is arguably less helpful in this regard.

associational standing for this DP. Accordingly, CIVEL has demonstrated sufficient associational standing to have that factor militate in favor of standing under SC One.

Regarding SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four, as described in the POR, CIVIL's active litigation and litigation support missions provide a sufficient basis to conclude that it would possess knowledge that could be instrumental in an accurate disposition of this NPRM determination. Furthermore, that the Administrator approved CIVEL's status as a DP is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, CIVEL has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. The substance-abuse-prevention/victim focus of this requestor may be best served by considering consolidation of its presentation with other, abuse/prevention requestors who also oppose the NPRM.

Hemp for Victory (HFV)

In its POR, HFV defines itself as "a non-profit organization dedicated to educating the public about why veterans are using medical cannabis over prescription pharmaceuticals, including dangerous and addictive opioids and other controlled substances." HFV POR at 1. The POR explains the organization's mission as "educat[ing] and bring[ing] awareness to the natural solution of cannabis as a way for veterans to manage the mental and physical challenges that often result from military service and to ensure that veterans face neither discrimination nor penalty for their use of medical marijuana." *Id.* The POR does not reference any specific or estimated number of veteran members or beneficiaries, but outlines its education and advocacy mission, and asserts that:

> Because of marijuana's [S]chedule I status under federal law, [HFV's] veteran [b]oard members and the veterans for whom they advocate currently face both discrimination and liability if they use medical marijuana. As a result, they cannot obtain access to medicine that they need from the Department of Veterans Affairs and are, in many cases, forced to rely instead on the harmful pharmaceutical drugs that are driving much of our veteran suicide epidemic.

Id. at 4.

It is not necessary to reach the issue of associational standing here. Irrespective of the size of its membership or the sincerity of the organization's commitment, HFV's POR does not specify how it or its beneficiaries would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. HFV's POR is not shy about stating that its goal is the descheduling of marijuana altogether (not part of this NPRM in any way). However, it is HFV's stated position that the placement of cannabis into Schedule III would present "an incremental step toward its ultimate goal" of removing marijuana from the list of scheduled drugs entirely. *Id.* at 5. Thus, this requestor has not demonstrated that it or those it advocates on behalf of would be adversely affected or aggrieved by promulgation of the NPRM. Actually, as conceded by its POR, rescheduling presents a potential benefit to this requestor and its veterans, and will not adversely affect any of its espoused educational and advocacy causes related to marijuana. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.[29]

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is generally within the proper scope of the NPRM (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) names a single witness, but that witness certainly presents as a potential source of authoritative information that could prove helpful in the decision the Agency must make. Additionally, the Administrator's approval of HFV as a DP warrants significant deference.

Upon a thoughtful balance of the four SC Factors, HFV has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its own interests or the interests of those on whose behalf it advocates. Placing appropriate weight on Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN**

[29] The balance of this requestor's arguments in favor of standing are wholly unpersuasive. To argue, at this procedural juncture, that the DEA is an improper advocate or sponsor of its own NPRM adds nothing to the standing equation and (at least on the present record) presents little more than an *ad hominem* distraction from the important advocacy and adjudicative work to be accomplished in these proceedings. A separate motion has been filed on this issue and it will be addressed in a separate order. Further, that HFV has been accorded associational standing in unrelated proceedings where a member had the ability to demonstrate Article III standing does not advance its argument in these proceedings regarding its APA standing.

THESE PROCEEDINGS. Consideration of the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. This requestor remains a DP, and may be well served by considering a consolidation of presentation with other veteran-access-focused participants who also favor the proposed rescheduling action.

National Drug & Alcohol Screening Association (NDASA)

In its POR, NDASA identifies itself as "a non-profit professional association representing more than 5,000 private and public sector employers and service agents, domestically and internationally, who administer and manage workplace drug and alcohol testing programs." NDASA POR at 1. Drug testing by NDASA members is carried on in the private and public sectors and regulated by various government standards. In addition to a high level of private-sector testing, the government testing includes the Nuclear Regulatory Commission (NRC) and the U.S. Department of Transportation (DOT). *Id.* at 1-2. The DOT testing is carried out in accordance with mandatory statutory and regulatory requirements. Because, according to NDASA, the authority of the U.S. Department of Health and Human Services (HHS) to test only extends to controlled substances in Schedules I and II (not III), promulgation of the NPRM would cause a cessation of marijuana drug testing in key transportation safety positions, to include the following: "airline pilots, air traffic controllers, school bus drivers, subway and train operators, ferry operators, pipeline operators, and truck drivers." *Id.* at 3. At least in the view of the requestor, this feature of the NPRM would cause its membership to suffer profound and detrimental financial and professional consequences. For these reasons, and reasons of public safety, NDASA opposes the NPRM.

As its POR is structured, standing under SC One (aggrievement, adverse impact or Article III standing) is dependent upon a determination that NDASA has associational standing. That is, that NDASA's "members would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181). Assuming (as proffered) that rescheduling marijuana to Schedule III would inflict financial and

professional harm on its members, NDASA has demonstrated sufficient associational standing to have this critical factor militate in favor of standing under SC One.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) NDASA's POR references the organization's executive director, but in view of the size and specialization of this requestor, it would seem that it would have no shortage of qualified witnesses among its five-thousand-strong membership that could prove helpful in the decision the Agency must make. Additionally, the Administrator's approval of NDASA as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, NDASA has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor could potentially benefit by considering consolidation with another requestor whose focus is founded in concerns over the potential limitations the NPRM may inflict upon testing for public safety.

The Commonwealth Project (TCP)

In its POR, TCP defines itself as an entity "committed to advocating on behalf of and prioritizing the 65+ population and integrating medical cannabis into mainstream health care for seniors." TCP POR at 1. This requestor appears to be an advocacy group focused on senior citizens and claims to be "rooted in the belief that medical cannabis could be harnessed to not only provide older Americans with an alternative to traditional prescription medications, including opioids, but to reduce soaring health care costs saddling millions of seniors." *Id.* at 2.

On the issue of SC One (aggrievement, adverse impact or Article III standing), the POR's description of TCP renders it unnecessary to reach the issue of associational standing. The POR does not specify how it or its senior-beneficiaries would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. In fact, according to its POR, the only potential aggrievement to this requestor and those seniors it advocates for would be "if rescheduling is rejected or unduly delayed." *Id.* at 3. Not only would the proposed rescheduling not adversely affect or aggrieve this organization, but it has posited that it cannot happen fast

enough for its liking. Accordingly, consideration of SC One does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR (while perhaps not altogether clear as to how the requestor executes its objectives) is generally responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is within the scope of the NPRM (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) does not identify a particular witness or source of expertise that would be particularly knowledgeable, but a source of the perspective of senior citizens added to the decisional equation would be important and potentially helpful to a resolution of the NPRM. Additionally, the Administrator's approval of TCP as a DP warrants significant deference.

Upon a thoughtful balance of the four SC Factors, TCP has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its own interests or the interests of those on whose behalf it advocates (just the opposite in fact). Placing appropriate weight on Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Consideration of the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. This requestor's access-for-seniors focus may by enhanced by consideration of presentation consolidation with other requestors focused on seeking marijuana access for specific groups (*e.g.*, veterans).

The National Transportation Safety Board (NTSB)

The POR filed by the NTSB provides the following account of its background, status, and mission:

> The NTSB is an independent federal agency charged by Congress with investigating every civil aviation accident in the United States and significant events in the other modes of transportation—railroad, transit, highway, marine, pipeline, and commercial space.

NTSB POR at 1. According to NTSB, under current law, rescheduling marijuana to Schedule III would place it outside the parameters of authorized drug testing, "prevent[ing] testing for marijuana use by safety-sensitive employees in commercial transportation operations, such as truck drivers, rail conductors, pipeline/hazardous materials operators, air traffic controllers, flight attendants, and airline pilots, among many others." *Id.* at 2. In NTSB's view, this result would "create a safety blind spot that could endanger the public, contrary to NTSB's public safety mission." *Id.* at 3. NTSB's POR expresses additional concerns related to the effect of increasing marijuana use in public, due to what it characterizes as "performance-impairing effects" on humans who operate by, with, and in the public transportation sphere. *Id.*

Inasmuch as its representations depict the potential for (in its view) a profound impact on its mission and its ability to safeguard the public in the transportation space, this requestor has established standing under Article III, and its position militates strongly in favor of standing under SC One (aggrievement, adverse impact or Article III standing).

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is squarely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) as the lead agency in evaluating major traffic incidents and the relevance and extent of any attendant impairment issues, it is likely that this requestor has access to experts in the field that could meaningfully assist in the adjudication of this NPRM. Additionally, the Administrator's approval of NTSB as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, NTSB has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor could potentially benefit by considering consolidation with another requestor whose focus is concerns over the potential limitations the NPRM may inflict upon testing for public safety.

<u>The Doc App, Inc., d/b/a My Florida Green (DocApp)</u>

In its POR, DocApp describes itself as "a company that supports over 43,000 medical marijuana patients in Florida [which] provides a HIPAA-compliant platform offering real-time analytics, data-driven insights, and treatment support for marijuana patients." DocApp POR at 2.

Even a cursory reading of this Designated Participant's POR reveals that the DocApp's primary interest in these proceedings' rests solely on the utilization of its platform in future actions involving the possible rescheduling of marijuana to Schedule III. To be sure, input into the process is only enhanced by entities with a potential commercial perspective in the proposed rescheduling action. Here, however, in place of expressing a position on the NPRM, the POR characterizes the NPRM as a "positive step," and emphasizes that it is essential that marijuana patients maintain "flexibility to select what best meets their needs, guided by real-time data on strain options, effects, and availability." *Id.* at 3. This emphasis stands in some tension with the CSA's implementing regulations, which unambiguously provide that "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a). Furthermore, the Supreme Court has made clear that medical standards are a function of a state's police powers, not the DEA. *Gonzales*, 546 U.S. at 274. Patient control (as contrasted with input to his/her prescriber/pharmacist) is inconsistent with the regulatory dynamic of prescribing controlled substances, and setting a federal standard for the dispensing and prescribing of controlled substances is well beyond the CSA's statutory mandate. *Id.* at 272, 274-75.

A reading of this DP's POR reflects, at best, mild positivity regarding the NPRM and does not indicate any manner in which it, its customers, or its business interests would be even marginally affected by the proposed rescheduling. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit in any perceivable way.

Under SC Two (compliance with procedural directives), the RFH was apparently timely, and POR provided identifying and mission information. Beyond that, this DP did not comply with the DEA Administrator's directives to state with particularity its interest in the proceeding, state with particularity the objections or issues concerning which it desires to be heard, and state its position regarding objections or issues. 89 Fed. Reg. at 70149. Likewise although responding to the Preliminary Order, the POR did not state "why/how the DP would be sufficiently 'adversely affected or aggrieved' by the proposed scheduling action to qualify as an 'interested person' under the regulations." Prelim. Ord. at 3. Thus, SC Two does not militate in favor of APA standing.

With respect to SC Three (within the scope of the NPRM), as discussed, *supra*, inasmuch as this POR seeks relief that is beyond the NPRM (*to wit*, the adoption of regulations focused on the inclusion of its software or something like it), and even beyond the regulations and the proper scope of the CSA as determined by the Supreme Court, consideration of this factor does not at all support APA Standing.

Regarding SC Four (Meaningful Assistance/Consolidation Potential), as also discussed, *supra*, input from commercial interests are a proper and valuable area of consideration in deciding whether to reschedule marijuana or any other drug, but this DP is not raising a single issue that could or should be addressed by the NPRM. To be sure, the Administrator has identified this requestor as a DP, but the POR filed is so bereft of any demonstration of standing (or even relevance) has **NOT DEMONSTRATED STANDING AND MAY NOT INDEPENDENTLY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor should expeditiously consider potential consolidation with another, similarly aligned, commercially-motivated requestor. The Administrator's designation is an essential element to be afforded (as evident in the balance of this order) to powerful (and generally controlling) deference regarding participation. But the Administrator did not have the benefit of the POR filed by this DP, and deserves, at a minimum, the analysis offered here. To be clear, based on the content of its POR, this DP has not demonstrated a sufficient (standing or evidentiary) basis to participate in this hearing in the absence of sponsorship by or consolidation with a DP who has demonstrated at least sufficient grounds to be heard.

The State of Nebraska (Nebraska)

In its POR, pertinent to SC One (aggrievement, adverse impact or Article III standing) Nebraska asserts that because under state law, marijuana is "illegal in all circumstances," rescheduling to Schedule III will "supercharge the marijuana industry" and "will increase the many costs and expenditures by Nebraska's law enforcement agencies, its judiciary, and its penal system directly related to or arising from marijuana industry." Neb. POR at 1-2. Inasmuch as its representations depict the potential for pecuniary costs and (in its view) public safety challenges,

this requestor has established standing under Article III, and this militates strongly in favor of standing under SC One.[30]

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) it is self-evident that the official view of a state regarding the impact of the NPRM on its pecuniary and enforcement issues is a vital consideration that could benefit the NPRM process. Additionally, the Administrator's approval of Nebraska as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, Nebraska has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor's enforcement-related interests may by best served by considering presentation consolidation with other enforcement-motivated requestors.

Ari Kirshenbaum, PhD

In his POR, Dr. Kirshenbaum identifies himself as a PhD researcher and Psychology professor emeritus who is presently engaged in "research related to cannabis-related impairment of the skills needed for motor vehicle operation." Kirshenbaum POR at 1. The requestor indicates that the current placement of marijuana in Schedule I presents mandatory procedural steps that can result in delays in conducting research. *Id.* at 2. Dr. Kirshenbaum's POR states that he is currently "co-leading a research study out of the University of California San Francisco (Medical School) that has been delayed for over a year due to the regulatory hurdles necessitated by [marijuana's] Schedule I designation." *Id.*

[30] Nebraska's alternative argument that standing under the APA, the CSA, and the CSA's implementing regulations is satisfied exclusively by virtue of the fact that the Administrator designated it as a participant misperceives the recommended decision hearing structure. Analogously, although all DEA immediate suspension enforcement hearings commence with the issuance of a charging document by the Administrator, assigning controlling weight to that preliminary decision and binding the ALJ thereby would render the hearing process under the APA as illusory. 21 U.S.C. § 811(a). That cannot be the intent of Congress. To be sure, decisions regarding standing (like all rulings and decisions made by an ALJ) are subject to the Administrator's review, but a final order that is consistent with the recommended decision is stronger than when the contrary occurs. *See generally, Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) ("The Agency's departures from the ALJ's findings are vulnerable if they fail to reflect attentive consideration to the ALJ's decision.").

Dr. Kirshenbaum supports the rescheduling of marijuana into Schedule III so that his studies can be conducted more expeditiously. On the issue of SC One (aggrievement, adverse impact or Article III standing), Dr. Kirshenbaum does not specify how he would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. Not only would the proposed rescheduling not adversely affect or aggrieve this requestor, but he wants it to happen quickly. Accordingly, consideration of SC One does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is within the scope of the NPRM (SC Three). Under SC Four (Meaningful Assistance/Consolidation Potential) Dr. Kirshenbaum offers his own testimony, which could potentially bring a knowledgeable and relevant perspective from academia. Additionally, the Administrator's approval of Dr. Kirshenbaum as a DP warrants significant deference.

Upon a thoughtful balance of the four SC Factors, Dr. Kirshenbaum has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve him. Placing appropriate weight on Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Consideration of the other SC Factors (in particular, SC Four, in light of the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to his presentation in this recommended decision. Dr. Kirshenbaum may wish to consider the prospect of presentation consolidation with other academic/medical professional requestors who are supportive of the NPRM.

Office of Cannabis Ombudsman, State of Connecticut (OCO)

In its POR, OCO defines itself as "the first-in-the-nation independent state agency with a mission to protect and preserve the needs of medical cannabis patients." OCO POR at 1-2. The POR explains that OCO is statutorily created and its focus is to provide assistance to

> Connecticut residents [as] they navigate the [m]edical cannabis system through direct assistance; outreach and educational activities; meetings, facility visits and continuous communication with current and future suppliers; assessing and implementing needed improvements; and working with research centers,

> universities and advocates to monitor and improve [the state] system and bring best-in-class standards to [Connecticut].

Id. at 2. OCO represents that it "generally supports the [NPRM] and removing marijuana from [S]chedule I" due to criminal and other consequences that stem from that designation. But it also says that it "has concerns with a [S]chedule III placement" because state residents seeking medical marijuana could be "confused if cannabis becomes akin to Tylenol 3 and other pharmaceuticals in [S]chedule III." *Id.* at 3. Confusingly, OCO also expresses additional "concerns" that existing regulations (which apply to all Schedules) "could increase the price and decrease the availability of medicinal cannabis if enforced by DEA, which is currently not the case."[31] *Id.* Lastly, OCO is apparently also opposed to quotas and other controls that could be required to bring a Schedule III-marijuana in line with the terms of the Single Convention. *Id.* Thus, OCO is apparently "generally" supportive of rescheduling marijuana, but not supportive of controls that could be required to comply with U.S. treaty obligations.

While Connecticut is doubtless a relatively populous state, the true number of OCO's beneficiaries cannot be readily ascertained from its POR. Consequently, OCO's position on the NPRM renders the issue of associational standing irrelevant. The POR does not specify how OCO or any of the state residents that utilize its services would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. In fact, although OCO has taken an arguably nuanced view of the NPRM, it has made it clear that it is "generally" supportive. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is generally within the proper scope of the NPRM (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) supplies little insight into whether it has sources of authoritative information at its disposal that could prove helpful in the decision the Agency must make beyond the perspective of this independent agency within the State of Connecticut,[32] but as an independent agency with a mission that is so closely aligned with the

[31] Enforcement (or past/future Congressional riders precluding enforcement) is not an issue within the scope of the NPRM.

[32] It is unclear as to whether OCO is authorized to speak on behalf of the State of Connecticut.

subject of the NPRM, its input certainly carries with it the potential to render a valuable contribution. Beyond all that, the Administrator's approval of OCO as a DP warrants significant deference.

Upon a thoughtful balance of the four SC Factors, OCO has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its own interests or the interests of those on whose behalf it advocates. Placing appropriate weight on Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Consideration of the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. This requestor may wish to consider presentation consolidation with other DPs focused on enhancing marijuana access to specific groups and who support promulgation of the NPRM.

Tennessee Bureau of Investigation (TBI)

> TBI's POR provides the following account of its duties and mission:
>
> The [TBI] is Tennessee's lead investigative agency with original jurisdiction over drug enforcement and the primary agency for forensic science services for law enforcement in the State. This includes operating the Tennessee Dangerous Drugs Task Force, which collaborates with federal agencies (including the DEA) to combat drug crimes across the State. TBI both investigates and enforces federal and state drug-related offenses, including marijuana offenses.

TBI POR at 1. Additionally, TBI represents that its forensic crime labs process over 30,000 drug submissions annually, many of which involve marijuana. *Id.* at 2. TBI posits that the proposed rescheduling would increase the prevalence of marijuana, would strain its drug-enforcement activities, and result in an immediate and adverse impact on TBI's mission. More specifically, according to TBI, the promulgation of the NPRM would result in "significant time and resources to reassess enforcement priorities, personnel assignments, and adjust asset allocations …." *Id.* at 3.

Inasmuch as its representations depict the potential for pecuniary costs and (in its view) public safety challenges, this requestor has established standing under Article III, and its position militates strongly in favor of standing under SC One (aggrievement, adverse impact or Article III standing).

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is squarely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) it is self-evident that the official view of the primary drug law enforcement entity in a state regarding the impact of the NPRM on its pecuniary, training and enforcement issues is a vital consideration that could benefit the NPRM process. Additionally, the Administrator's approval of TBI as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, TBI has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor may be well served to consider presentation consolidation with other enforcement focused DPs who oppose the proposed rescheduling.

Village Farms International (VFI)

According to its POR, VFI is a large-scale supplier of products who either is or seeks to be a supplier of marijuana. The requestor broadly describes its mission as seeking "to improve life's journey for the wellbeing of humankind and the earth on which we live." VFI POR at 1. Very broad, to be sure. As its basis for APA standing, VFI represents that it intends to enter the U.S. marijuana market and that the proposed rescheduling of marijuana to Schedule III would "facilitate its goals of researching, manufacturing, importing, and exporting marijuana for scientific and medical purposes consistent with state and federal law …" and that those goals are hindered by the current Schedule I placement. *Id.* at 4. In VFI's view, numerous, specific regulatory barriers would soften if the NPRM succeeds, and those barriers would include easier access to research, gentler requirements for inventory, export, and ordering. *Id.* at 4-5. These ameliorations, in this requestor's opinion, would result in higher profits and more efficiencies.

The POR has convincingly outlined how placing marijuana in Schedule III would be helpful to its commercial interests, and is likewise clear that its ultimate objective is descheduling or scheduling to an even less restrictive level than Schedule III. The requestor views the NPRM as "an incremental step toward optimizing the U.S.'s legal approach to marijuana" (read: legalization). *Id.* at 6. None of VFI's expanded objectives are contemplated by the present NPRM. The POR regarding this requestor does not specify how it would be

"adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule, but rather, outlines how its research and pecuniary interests would be advanced by rescheduling. This is a requestor who aspires to pursue the purported benefits of marijuana for commercial use. Thus, this requestor has not demonstrated that it would be adversely affected or aggrieved by promulgation of the NPRM, but that it will not accrue the potential benefits it aspires to upon the failure of the NPRM. Rescheduling presents a potential benefit to this requestor, but declining to do so will not adversely affect its interests beyond the status quo. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

Under SC Two (compliance with procedural directives), the RFH was apparently timely, and the POR is clear in its support of the proposed rescheduling (albeit as an incremental measure), discusses the issues upon which it desires to be heard, and adequately outlines its position. On the whole, this requestor has complied with the relevant Preliminary Order and the procedural directives of the Agency in the NPRM. Thus, SC Two does not disfavor APA standing. Similarly, inasmuch as the POR is mostly focused on the rescheduling depicted in the NPRM and its potential impact on its commercial interests, SC Three (within the scope of the NPRM) militates in favor a grant of APA standing for this requestor.

Regarding SC Four (Meaningful Assistance/Consolidation Potential), a reasonable reading of the POR depicts an enterprise with considerable experience in supplying agricultural products on a large scale, a likely result of rescheduling marijuana into medicine. Such input has the potential to bring valuable perspectives to the rescheduling equation. Beyond that, the Administrator has identified this requestor as a DP.

Upon a thoughtful balance of the four SC Factors, VFI has certainly not adequately demonstrated that promulgation of the NPRM will adversely affect or aggrieve its interests within the unambiguous, directive terms of the regulations. Upon consideration of the powerful Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**.[33] Analyzing the other SC Factors (in particular, SC Four, as evidenced by the nature and scale of this requestor's business,

[33] VFI's unsupported accusation that the DEA is an improper advocate or sponsor of its own NPRM adds nothing to the standing equation (at least on the present record and at this procedural juncture). The issues at stake in these proceedings are too important to devote time and attention to *ad hominem* distractions. This accusation has also been set forth in a separate motion, which will be addressed in a separate order.

as well as the Administrator's designation) militate in favor of VFI's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. Inasmuch as VFI shares a pecuniary and commercial concerns with other requestors, it may be prudent for this requestor to a consolidation of presentations with other commercially-motivated DPs who also support the NPRM.

Smart Approaches to Marijuana (SAM)

SAM's POR describes the organization as "a bipartisan alliance of organizations and individuals dedicated to a health-first approach to marijuana … comprised of medial doctors, lawmakers, treatment providers, preventionists, teachers, law enforcement officers who seek a middle road between incarceration and legalization." SAM POR at 1. It defines its mission as "equip[ing] policymakers with commonsense proposals, based in reputable science, to promote public health and decrease marijuana use and its consequences." *Id.*

By the terms of its POR, SAM presents itself as an advocacy organization. The POR references "organizations," but has made no representations that would sustain associational standing. Thus, the standing justification of this requestor are exclusively founded in its claim that it would be aggrieved and adversely affected by the potential affect rescheduling would have on its training and advocacy expenditures as a marijuana-skeptical material and lecturing source.[34] Inasmuch as this requestor has adequately demonstrated that promulgation of this

[34] SAM's alternate theory, *to wit*, that it is somehow magically endowed with APA standing by virtue of the fact that the Administrator sent a DP letter is singularly unpersuasive. SAM POR at 2. First, the regulations apply to DEA – all of DEA. While it is possible to apply to the Administrator "for an exception to the application of any [regulation] by filing a written request . . . stating the reasons for such an exception," no such written request granted by the Administrator is part of the present record. 21 C.F.R. § 1307.03. Beyond that, SAM's theory misperceives the structure of adjudications under the APA, the CSA, and the CSA's implementing regulations. As discussed elsewhere in this order, Congress was crystal clear in placing APA proceedings as a condition precedent to rescheduling by the Agency. 21 U.S.C. § 811(a). Determinations as to standing fixed by the Administrator at the outset of the hearing would obstruct the ALJ's authority to issue a report including a statement of all "findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion as presented on the record [and] the appropriate rule …." 5 U.S.C. § 557(c). Analogously, although all DEA immediate suspension enforcement hearings commence with the issuance of a charging document by the Administrator, assigning controlling weight to that preliminary decision and binding the ALJ thereby would render the hearing process under the APA as illusory. 21 U.S.C. § 811(a). That cannot be the intent of Congress. To be sure, decisions regarding standing (like all rulings and decisions made by an ALJ) are subject to the Administrator's review, but a final order that is consistent with the recommended decision is stronger than when the contrary occurs. *See generally, Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) ("The Agency's departures from the ALJ's findings are vulnerable if they fail to reflect attentive consideration to the ALJ's decision.").

NPRM would adversely affect its budget and mission, SC One (aggrievement, adverse impact or Article III standing) militates in favor of APA standing.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) it is self-evident that the official view of an advocacy entity that purports to have wide-ranging, bipartisan support and can show adverse impact as a direct result of the proposed rescheduling action has the potential for significant, relevant input here. Further, the Administrator's approval of SAM as a DP (while not necessarily controlling) warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, SAM has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor may wish to consider the option of presentation consolidation with other DP advocacy groups who do not favor the proposed rescheduling.

National Cannabis Industry Association (NCIA)

The POR filed by NCIA describes itself as "the oldest, largest, and most inclusive [tax-exempt non-profit] trade association representing the legal cannabis industry." NCIA POR at 2. The POR further represents that NCIA's "membership is composed of hundred of businesses from all sectors of the industry—from state-licensed cannabis businesses to legal hemp product manufacturers to the wide range of ancillary businesses serving the industry" and styles itself as "the voice of Main Street Cannabis." *Id.*

NCIA has put forward its APA standing argument in essentially two prongs. The first is not persuasive, but much of the second prong is. Both prongs are underpinned by an associational standing theory. That is, that its standing derives from its theory that one or more of its members would have standing to sue in their own right, the interests to be protected are germane to the organization's purpose, and the result the organization is pursing requires the participation of individual members in the lawsuit. *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181).

The first prong is that it (and presumably its members) support rescheduling into Schedule III because that action "would both lessen criminal penalties and preclude the application of [Internal Revenue Code § 280E] … to marijuana businesses" that are not currently operating in violation of applicable state laws. NCIA POR at 6. Inasmuch as this prong supports the proposed rescheduling action, it would not, at least in this regard adversely affect or aggrieve its membership, and does not further its standing argument under SC One (aggrievement, adverse impact or Article III standing).

The other theory of standing is both more nuanced and more persuasive. NCIA posits that a number of its members would be adversely affected by a new definition of tetrahydrocannabinol which is incorporated into the NPRM. Without engaging in a deep dive into the merits of this issue, NCIA argues that the NPRM definition "could cause currently unscheduled [n]on-[i]ntoxicating [c]annabinoids to be designated as prohibited Scheduled I controlled substances without [additional] scheduling actions" on the part of DEA. NCIA POR at 4. A significant weakness in this position is that NCIA has not specifically alleged that any of its members are currently utilizing any particular substances that would be affected (a deficit that could conceivably undermine its standing argument in this regard). However, NCIA's POR contains the following representation:

> NCIA is adversely affected or aggrieved by the [NPRM] because the simultaneous scheduling of certain [n]on-intoxicating [c]annabinoids as Schedule I substances through the [NPRM's] proposed revisions to the definition of THC would make one or more NCIA members' businesses federally illegal for the first time.

Id. at 3 (internal quotation marks omitted). Thus, based on the fact that this requestor has alleged that it is properly in a position to exercise associational standing with several of its members who could potentially have their present business enterprises rendered illegal by promulgation of the NPRM, SC One favors standing on this narrow issue.[35]

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is somewhat within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful

[35] Contrariwise, NCIA's more speculative arguments regarding what the Agency may do in the future, based on its pronouncements in the past and other interpretations, are unpersuasive and beyond the scope of the NPRM. See e.g., *Id.* at 5.

Assistance/Consolidation Potential), as described in its POR, it seems that NCIA would have the means at its disposal to provide qualified witnesses among its large and diverse membership, and that the commercial perspective available to it would be helpful to the adjudication of this NPRM. That said, its commercial perspective may lend itself readily and effectively to a consolidation with other DPs. Additionally, the Administrator's approval of NCIA as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, NCIA has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Inasmuch as this requestor shares a pecuniary and commercial concerns with other requestors, it may by prudent to a consolidation of presentations with other commercially-motivated DPs who also support the NPRM.

Ellen Brown

While Ellen Brown's POR references her position as Research Subcommittee Chair of the Massachusetts Cannabis Advisory Board (MCAB), there is no indication therein that she is authorized (or seeking) to speak for that body.[36] Indeed, the POR is written in the first person, and focuses, not on the MCAB, but on her own experiences. Ms. Brown indicates that her position on the MCAB Research Subcommittee has provided her with some exposure to veterans, but evidently, she is not in a group authorized to speak on any behalf beyond her own. Ms. Brown further provides that she is a veteran, and as one under the care of the Veteran's Administration (the VA), she has "personally been aggrieved" by marijuana's current Schedule I placement and is in favor of the proposed rescheduling action set forth in the NPRM. Brown POR at 2.

Ms. Brown's POR does not specify how she would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. It is her stated position that she and other veterans would markedly benefit by DEA's embracement of the NPRM and rescheduling of marijuana to Schedule III, thereby opening marijuana treatment avenues. *Id.* Thus, this requestor has not demonstrated that she would be adversely affected or aggrieved by

[36] To the extent this conclusion is incorrect and Ms. Brown is indeed authorized to speak for MCAB, that body or Ms. Brown may file a clarification within five (5) business days from the receipt of this order with a request to reconsider.

promulgation of the NPRM. Rescheduling presents a potential benefit to this requestor and (at least in her view) other veterans. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is generally responsive, and in some respects consistent with the Preliminary Order as well as the procedural directives of the Agency. Likewise, the subject matter of the POR is within the proper scope of the NPRM to some extent (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) is difficult to gauge. Although Ms. Brown represents that she has spoken to some veterans interested in exploring the benefits of marijuana as medicine, there is no indication about the number of veterans or anything beyond some limited anecdotal, generalized representations. That the Administrator approved Ms. Brown status as DP's is entitled to significant deference, but balancing the powerful SC One and the other SC Factors, Ms. Brown has not made a sufficient (standing or evidentiary) presentation to warrant her participation in these proceedings.

Upon a thoughtful balance of the four SC Factors Ms. Brown has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve her own interests and has noticed little beyond her own experience and expectations about the potential benefits of rescheduling marijuana as sought by the DEA. Placing appropriate regulatory emphasis on the powerful Factor One, this requestor has **NOT DEMONSTRATED STANDING AND MAY <u>NOT INDEPENDENTLY</u> CONTINUE TO PARTICIPATE IN THESE PROCEEDNGS**. Ms. Brown's POR efforts and input may be better suited to consolidation with another DP who has presented a sufficient showing to warrant participation.

<u>Drug Enforcement Association of Federal Narcotics Agents (DEAFNA)</u>

The POR filed on behalf of DEAFNA describes the association as a "[l]aw [e]nforcement [f]raternal [o]rganization representing active and retired DEA Special Agents, Diversion Investigators, Intelligence Research Specialists, and other DEA [p]ersonnel." DEAFNA POR at 2.

DEAFNA's basis for standing is that the rescheduling "has a direct impact on [its] members' ability to implement the necessary regulatory controls which will take years to implement and will come at an unreasonable financial cost." *Id.* This requestor is against the proposed rescheduling because it would present "a significant shift in federal drug policy with

significant implications for … the ability of law enforcement agencies to protect the public." *Id.* at 3. As noted *supra*, "[a]n association only has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181). Here, inasmuch as DEAFNA's members, as specialized public servants engaged in the regulation and enforcement actions under the CSA, could potentially demonstrate adverse effect from the promulgation of the NPRM, the action is clearly germane to DEAFNA's purpose, and the members of the organization are not required participants in the action. Here, the interests cited by DEAFNA, at least as articulated as adverse (that is—at least in its view—the potentially adverse impact rescheduling could have on the law enforcement efforts to enforce driving and other impairment-related and fit-for-duty laws regularly enforced by many of its members), could conceivably be adversely impacted by promulgation of the NPRM. Accordingly, SC One favors standing in this case.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order as well as the procedural directives of the Agency. Likewise, the subject matter of the POR is within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential), this requestor organization (at least as noticed in its POR) specializes in law enforcement in the field of controlled substances. It would be reasonable to assume that this requestor has access to members with the potential to speak authoritatively on the listed issues of concern, a law enforcement perspective (particularly this highly-specialized law enforcement perspective) is quite valuable, and even beyond all that, that the Administrator approved DEAFNA's status as DP's is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, this DP has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor should strongly consider the option of presentation consolidation with other enforcement-motivated DPs who also disfavor the NPRM.

On Procedure

In accordance with my authority to regulate the course of the hearing,[37] the following procedures are herein implemented to ensure fair and orderly proceedings. While the Government, as the burdened party, may present multiple witnesses, each of the remaining DPs (absent leave to the contrary granted by this tribunal) may present the testimony of a single witness. Documentary evidence and proposed witnesses from all the Parties must be disclosed in advance in a written disclosure (Prehearing Statement) as outlined below. No evidence will be admitted to the record without a proper foundation presented at the hearing on the merits.

Within the discretion of the tribunal, and to the extent practicable, each of the Parties will present testimonial and documentary evidence as set forth below.

The Government, as the burdened party, will present its evidence first. Those DPs who support the NPRM (Pro-Rescheduling DPs) will present evidence following the conclusion of the Government's case. The DPs who oppose the NPRM (Anti-Rescheduling DPs) will present evidence following the conclusion of the Pro-Rescheduling DPs' presentations. All DPs (Pro and Anti) will be limited to a single witness each, with direct examination limited to no more than approximately ninety (90) minutes (excluding cross-examination). Anti-Rescheduling DPs may cross-examine all Government witnesses and all Pro-Rescheduling witnesses. Witnesses presented by the Anti-Rescheduling DPs may be cross-examined by the Government and Pro-Rescheduling DPs. In all cases, cross-examination will be limited to approximately twenty (20) minutes per witness for each authorized cross-examiner. Within the further discretion of the tribunal, presentations may be grouped (or even consolidated) by the tribunal in accordance with commonly-expressed viewpoints as set forth in the Parties' respective PORs.

Any Party (to include the Government) who is unprepared to proceed on the date(s) scheduled at the preliminary hearing (with the input of that Party) may forfeit his/her/its ability to present the scheduled evidence or examination.

It is herein **ORDERED** that the Parties, no later than **2:00 p.m. Eastern Time (ET) on November 26, 2024**, shall electronically file with this tribunal and serve on each other, a Prehearing Statement[38] containing the following sections:

[37] 5 U.S.C. § 556(c)(5); 21 C.F.R. § 1316.52.

[38] Absent advance leave by this tribunal on a motion supported by good cause, all filed documents (other than noticed proposed exhibits offered by either party on the merits) *shall be limited to fifty (50) pages* (utilizing 12-point characters and 1-inch margins).

1. **Witnesses.** Names, *curriculum vitae*, and current addresses of all witnesses whose testimony is sought to be presented by each of the Parties.

2. **Summary of Testimony.** Brief summary of the testimony of each witness. The summaries are to state what the testimony will be, rather than merely list the areas to be covered. Testimony not disclosed may be subject to exclusion.

3. **Documents.** A list noticing all documentary evidence, including affidavits and other proposed exhibits, intended to be offered into evidence, specifying the number of pages in each. Each proposed exhibit is to be marked for identification and numbered as follows: ("[name of Party]-Exh. No. ## (ID)").

4. **Hearing Date Availability.** The NPRM and GNoH in this matter fixes the place of hearing as the DEA Hearing Facility in Arlington, Virginia. The Government and the Parties are expected to provide their representatives' and their witnesses' availability for the months of January through February 2025[39] at the Preliminary Hearing.

5. **District Court Intervention**. To the extent practicable, each Party should indicate whether he/she/it presently intends to seek the intervention of a U.S. District Court in accordance with *Axon Enterprise, Inc. v. FTC*, 598 U.S. 175 (2023).

It is further **ORDERED** that, in accordance with 21 C.F.R. § 1316.64, **a Preliminary Hearing[40] in this matter will be conducted on December 2, 2024, at 9:30 a.m. ET in the North Courtroom[41] at the DEA Hearing Facility**, at 700 Army Navy Drive, Arlington, Virginia, 22202.[42]

It is further **ORDERED** that all proceedings will be governed by the provisions of 21 C.F.R. §§ 1316.41-1316.68.[43] Your attention is specifically directed to 21 C.F.R. § 1316.45, which provides, *inter alia*, that "[d]ocuments shall be dated and deemed filed upon receipt by the

[39] 21 C.F.R. § 1301.45.
[40] 21 C.F.R. § 1316.
[41] As set forth in the Preliminary Order, the courtrooms at the DEA Hearing Facility are spacious and modern, but not unlimited. Accordingly, in view of the potentially high number of hearing participants, it is anticipated that admission to the preliminary hearing will be limited to representatives (no more than two, preferably one) and credentialled media as designated by the Agency. The Administrator has directed the proceedings will be livestreamed to afford those physically outside the courtroom an opportunity to observe the proceedings. Naturally, witnesses will be admitted to the courtroom to testify at the merits hearings at times where their testimony is scheduled. No cell phone use by anyone will be permitted in the courtroom at any hearing conducted in this matter. The highest level of decorum will be maintained at all times during all hearings, and court attire is required for anyone participating in any capacity. All representative appearances will be live (not virtual) throughout, and all representatives must plan to arrive sufficiently early to allow security processing through the DEA Visitor Center, which is collocated with the DEA Hearing Facility at 700 Army Navy Drive, Arlington, Virginia, 22202.
[42] Logistical issues will be coordinated by Law Clerk Laila Mogharabi, Esq., who can be contacted at (202) 307-8188 and at ECF-DEA@dea.gov.
[43] Additional helpful information regarding DEA administrative proceedings may be found at the OALJ website, https://www.dea.gov/administrative-law-judges.

Hearing Clerk." Documents (other than proposed exhibits) may be filed electronically or by hard copy. Only one method of document filing may be utilized.

Electronic Filing: The strongly preferred method of filing correspondence in these proceedings is as a PDF attachment via email to the DEA Judicial Mailbox (**ECF-DEA@dea.gov**). The forwarding email on all electronically filed correspondence must indicate that it was simultaneously served on the opposing party via email. The Respondent must ensure that all documents filed with the DEA Judicial Mailbox are simultaneously served on the Government Mailbox at (**dea.registration.litigation@dea.gov**). Any request(s) to modify email addresses of a party or counsel must be made on notice to this tribunal and the opposing party. The email receipt date reflected by the DEA Judicial Mailbox server shall conclusively control all issues related to the date of service of all filed correspondence, provided however, that correspondence received after 5:00 p.m., local Washington, D.C. time, will be deemed to have been received on the following business day. Note: While email is utilized as the method to forward documents for filing—as attachments—no substantive matter communicated through the body of a forwarding email will be considered. The parties are directed to refrain from including social security numbers or personally identifiable information in electronically-filed documents. Proposed evidentiary exhibits will not be accepted via electronic filing. Details regarding evidentiary exhibit filing will be the subject of a subsequent order.

Hard Copy Filing: Alternatively, correspondence may be filed in hard-copy form. Hard-copy filings must be served in triplicate and addressed to my attention at: **The DEA Office of Administrative Law Judges, 8701 Morrissette Drive, Springfield, Virginia 22152**. Because the DEA Hearing Facility is not physically collocated with the DEA mailing address, hard copy filings must be posted sufficiently in advance of the due date to assure timely receipt by this office.

Failure to timely file a prehearing statement that complies with the directions provided above may result in a sanction, including (but not limited to) a waiver of hearing and an implied withdrawal of a request for participation. Prehearing statements should not include motions, which should be filed separately.[44]

[44] A prehearing ruling setting deadlines will be issued after the prehearing conference.

It is further **ORDERED** that any requests for extension of time to file must be made by written motion sufficiently in advance of scheduled deadlines to be considered and ruled upon.

Dated: November 19, 2024

JOHN MULROONEY

Digitally signed by JOHN MULROONEY
Date: 2024.11.19 17:25:51 -05'00'

JOHN J. MULROONEY, II
Chief Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on November 19, 2024 caused a copy of the foregoing to be delivered to the following recipients: (1) James J. Schwartz, Esq., Counsel for the Government, via email at james.j.schwartz@dea.gov; Jarrett T. Lonich, Esq., Counsel for the Government, via email at jarrett.t.lonich@dea.gov; and S. Taylor Johnston, Esq., Counsel for the Government, via email at stephen.t.johnston@dea.gov; (2) the DEA Government Mailbox, via email at dea.registration.litigation@dea.gov; (3) Shane Pennington, Esq., Counsel for Village Farms International, via email at spennington@porterwright.com; and Tristan Cavanaugh, Esq., Counsel for Village Farms International, via email at tcavanaugh@porterwright.com; (4) Nikolas S. Komyati, Esq., Counsel for National Cannabis Industry Association, via email at nkomyati@foxrothschild.com; William Bogot, Esq., Counsel for National Cannabis Industry Association, via email at wbogot@foxrothschild.com; and Khurshid Khoja, Esq., Counsel for National Cannabis Industry Association, via email at khurshid@greenbridgelaw.com; (5) John Jones and Dante Picazo for Cannabis Bioscience International Holdings, via email at ir@cbih.net; (6) Andrew J. Kline, Esq., Counsel for Hemp for Victory, AKline@perkinscoie.com; and Abdul Kallon, Esq., Counsel for Hemp for Victory, via email at and AKallon@perkinscoie.com; (7) Erin Gorman Kirk for the State of Connecticut, via email at erin.kirk@ct.gov; (8) Ellen Brown for Massachusetts Cannabis Advisory Board, via email at ellen@greenpathtraining.com; (9) Shanetha Lewis for Veterans Initiative 22, via email at info@veteransinitiative22.com; (10) Jason Castro, Esq., Counsel for The Doc App., Inc. d/b/a My Florida Green, via email at jasoncastro@myfloridagreen.com; (11) Kelly Fair, Esq., Counsel for The Commonwealth Project, via email at Kelly.Fair@dentons.com; (12) Rafe Petersen, Esq., Counsel for Ari Kirshenbaum, via email at Rafe.Petersen@hklaw.com; (13) David G. Evans, Esq., Counsel for Cannabis Industry Victims Educating Litigators, Community Anti-Drug Coalitions of America, Phillip Drum, Kenneth Finn, International Academy on the Science and Impacts of Cannabis, and National Drug and Alcohol Screening Association, via email at thinkon908@aol.com; (14) Patrick Philbin, Esq., Counsel for Smart Approaches to Marijuana, via email at pphilbin@torridonlaw.com; and Chase Harrington, Esq., Counsel for Smart Approaches to Marijuana, via email at charrington@torridonlaw.com; (15) Stephanie E. Masker, Esq., Counsel for National Transportation Safety Board, via email at stephanie.masker@ntsb.gov; (16) Eric Hamilton, Esq., Counsel for the State of Nebraska, via email at eric.hamilton@nebraska.gov; and Zachary Viglianco, Esq., for the State of Nebraska, via email at zachary.viglianco@nebraska.gov; (17) Gene Voegtlin for International Association of Chiefs of Police, via email at voegtlin@theiacp.org; (18) Gregory J. Cherundolo for Drug

Enforcement Association of Federal Narcotics Agents, via email at executive.director@afna.org; (19) Reed N. Smith, Esq., Counsel for the Tennessee Bureau of Investigation, via email at Reed.Smith@ag.tn.gov; and Jacob Durst, Esq., Counsel for Tennessee Bureau of Investigation, via email at Jacob.Durst@ag.tn.gov; and (20) Jim Skinner for National Sheriff's Association, via email at sheriffskinner@collincountytx.gov and ykaraman@sheriffs.org.

QUINN FOX

Digitally signed by QUINN FOX
Date: 2024.11.19 17:27:19 -05'00'

Quinn Fox
Staff Assistant to the Chief Judge
Office of Administrative Law Judges

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiff(s)

v.

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

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Robert F. Kennedy, JR., in his official capacity as Secretary of Health and Human Services, 200 Independence Avenue, S.W., Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Smart Approaches to Marijuana, Cannabis Industry Victims Educating Litigators, North Carolinians Against Legalizing Marijuana, Cannabis Impact Prevention Coaliation, LLC, Cannabis Industry Victims Seeking Justics, Drug Free America Foundation, Save Our Society From Drugs, Drug Watch International, Hillsborough County Anti-Drug Alliance, Illinois Family Institute, and David Evans.

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiff(s)

v.

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

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W., Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Smart Approaches to Marijuana, Cannabis Industry Victims Educating Litigators, North Carolinians Against Legalizing Marijuana, Cannabis Impact Prevention Coaliation, LLC, Cannabis Industry Victims Seeking Justics, Drug Free America Foundation, Save Our Society From Drugs, Drug Watch International, Hillsborough County Anti-Drug Alliance, Illinois Family Institute, and David Evans.

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiff(s)

v.

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

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* MEHMET OZ, M.D., in his official capacity as Administrator of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Smart Approaches to Marijuana, Cannabis Industry Victims Educating Litigators, North Carolinians Against Legalizing Marijuana, Cannabis Impact Prevention Coaliation, LLC, Cannabis Industry Victims Seeking Justics, Drug Free America Foundation, Save Our Society From Drugs, Drug Watch International, Hillsborough County Anti-Drug Alliance, Illinois Family Institute, and David Evans.

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

SMART APPROACHES TO MARIJUANA, et al.,

Plaintiff(s)

v.

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

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* THE CENTERS FOR MEDICARE & MEDICAID SERVICES, 7500 Security Boulevard, Baltimore, MD 21244-1850

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Smart Approaches to Marijuana, Cannabis Industry Victims Educating Litigators, North Carolinians Against Legalizing Marijuana, Cannabis Impact Prevention Coaliation, LLC, Cannabis Industry Victims Seeking Justics, Drug Free America Foundation, Save Our Society From Drugs, Drug Watch International, Hillsborough County Anti-Drug Alliance, Illinois Family Institute, and David Evans.

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS

Smart Approaches to Marijuana, et al.

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF DC
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

Robert F. Kennedy, Jr, in his official capacity as Secretary of Health and Human Services, et al.

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT DC
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Patrick Kenneally; Connor W. Mighell
BURKE LAW GROUP, PLLC; 1000 Main Street, Suite 2300; Houston, Texas 77002; (832) 987-2214

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	◉ 1	Incorporated or Principal Place of Business in This State	◉ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A. *Antitrust***

- ☐ 410 Antitrust

○ **B. *Personal Injury/ Malpractice***

- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

○ **C. *Administrative Agency Review***

- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ **D. *Temporary Restraining Order/Preliminary Injunction***

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

◉ **E. *General Civil (Other)*** OR ○ **F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ **G. *Habeas Corpus/ 2255*** ☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	○ **H. *Employment Discrimination*** ☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	○ **I. *FOIA/Privacy Act*** ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ **J. *Student Loan*** ☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ **K. *Labor/ERISA (non-employment)*** ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ **L. *Other Civil Rights (non-employment)*** ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	○ **M. *Contract*** ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ **N. *Three-Judge Court*** ☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

CMS did not comply with 5 U.S.C. 553; action is arbitrary, capricious, and not in accordance with law under 5 U.S.C. 706.

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint **YES** ☐ **NO** ☒

VIII. RELATED CASE(S) IF ANY (See instruction) **YES** ☐ **NO** ☒ If yes, please complete related case form

DATE: 03/30/2026 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Connor W. Mighell

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

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

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW

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I. INTRODUCTION

On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") announced the Substance Access Beneficiary Engagement Incentive ("BEI"). The BEI is a program to allow access to hemp-derived products containing the Schedule I substance delta-9 tetrahydrocannabinol ("THC") and other cannabinoids to Medicare beneficiaries through participating health care organizations. It takes effect on April 1, 2026 and is available to Medicare patients participating in Medicare Innovation Center models ACO REACH, the Enhancing Oncology Model ("EOM"), and, on January 1, 2027, the Long-term Enhanced ACO Design Model ("LEAD").

CMS published no Notice of Proposed Rulemaking. It solicited no public comments. It offered no reasoned explanation. It bypassed the Federal Register entirely. It effectively reversed, *sub silentio*, its own April 2025 final rule declaring cannabis products ineligible for supplemental Medicare coverage. 90 Fed. Reg. 15792, 15867 (Apr. 15, 2025).

In short, CMS coopted Section 1115A, a statutory vehicle Congress created to test payment and healthcare delivery models, to make THC products available by fiat to millions of Medicare beneficiaries. It did so without any congressional authorization, lacking the procedural safeguards Congress mandated, and devoid of any analysis of whether these products are legal or safe for the elderly Americans who will receive them. This is precisely the kind of agency overreach that the major questions doctrine prohibits and that the APA was designed to prevent.

Plaintiffs respectfully request that this Court: (1) issue a temporary restraining order under Federal Rule of Civil Procedure 65(b); (2) issue a preliminary injunction under Federal Rule of Civil Procedure 65(a); and (3) stay the effective date of the BEI pending judicial review under 5 U.S.C. § 705. This relief would preserve the pre-March 20 *status quo*, until CMS complies with the law.

II. STATEMENT OF FACTS

Plaintiffs incorporate by reference the Statement of Facts set forth in the Complaint, and set forth herein the following facts most relevant to emergency relief.

A. The CMS Innovation Center and Section 1115A Authority

Section 1115A of the Social Security Act, 42 U.S.C. § 1315a, established the Center for Medicare & Medicaid Innovation within CMS. Its statutory purpose is to test "innovative payment and service delivery models" to reduce program expenditures "while preserving or enhancing the quality of care" for "defined populations with deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. § 1315a(a)(1). It was not designed to create access to over-the-counter consumer products with highly questionable medical applications. The models at issue, ACO REACH and EOM, are payment and delivery models.

The ACO Reach brings together doctors, hospitals, and other healthcare providers into a single team called an Accountable Care Organization ("ACO"). *See Innovation Models: ACO REACH*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/priorities/innovation/innovation-models/aco-reach. These teams coordinate patient care, ensuring patients get the right tests, follow-up, and preventative services to reduce duplication or unnecessary medical procedures. *Id.* If the

ACO keeps costs below a benchmark while meeting quality standards, the team shares in the savings, thereby encouraging providers to work together efficiently to focus on preventive care, chronic disease management, and patient outcomes rather than simply the number of services delivered. *Id.* Currently, there are approximately 74 ACOs made up of approximately 126,000 providers and organizations providing care to approximately 1.7 million Medicare beneficiaries. *Id.*

The EOM focuses on Medicare patients with certain cancers and tests a new way of paying oncology practices. *See Innovation Models: EOM*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/priorities/innovation/innovation-models/eom. Participating clinics are given bundled payments or target budgets for patients' entire course of cancer treatment, rather than being paid separately for every test or procedure. *Id.* The incentive is that if the clinic keeps costs within the target and meets quality and outcome goals, it can earn shared savings bonuses. *Id.* Based on the most recent publicly available information, the total number of Medicare participants is unknown. *Id.* However, 28 physician group practices and one commercial payer are participating, accounting for approximately 2,000 practitioners across more than 350 care sites. *Id.*

The BEI also applies to another payment model, LEAD, which does not begin until January 1, 2027. *See LEAD (Long-Term Enhanced ACO Design) Model*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/priorities/innovation/innovation-models/lead.

B. The BEI's Structure and Terms

CMS published the BEI on its website on March 20, 2026, and nowhere else. *See Substance Access: Beneficiary Engagement Incentive*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/priorities/innovation/substance-access-beneficiary-engagement-incentive. The BEI is incorporated into the participation agreements governing ACO REACH and EOM and becomes effective on April 1, 2026. *Id.* By its terms, ACO REACH and EOM providers can offer eligible "hemp" products to patients. *Id.* To be eligible, products must be taken orally and contain no more than 0.3% delta-9 THC by weight and no more than 3 mg of total tetrahydrocannabinols per serving, including delta-8, delta-10, and THCA. *Id.* Depending on the serving size, the product could contain up to 3 mg of delta-9 THC per serving, as long as the 0.3% by weight limit is not exceeded. *Id.* Other program requirements include: (a) formal election of the BEI by the participating ACO or EOM; (b) submission of a CMS-required Implementation Plan by the participating ACO or EOM; (c) CMS approval of that plan, with CMS retaining authority to reject or suspend participation; (d) physician determination of beneficiary eligibility, including that the beneficiary is over 18 years of age and does not have a disqualifying condition, although CMS has not publicly specified those conditions that are disqualifying; (e) shared decisionmaking with beneficiaries; (f) product eligibility and dosing requirements; (g) a $500 annual cap per beneficiary; and (h) quarterly reporting obligations. *Id.* CMS claims Medicare does not pay for the products directly, but the limited information available makes it unclear whether this is true.

C. CMS's Prior Position on Cannabis Products

In April 2025, only one year prior, CMS took the near inverse position to the one it now maintains. Specifically, after notice-and-comment rulemaking and in full compliance with the APA, CMS issued a final rule, effective June 3, 2025, stating 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. 15792, 15867 (Apr. 15, 2025). CMS has not rescinded this rule. Moreover, CMS found that "cannabis" products "do not have a reasonable expectation of improving or maintaining the health of the chronically ill." *Id.* "Hemp" and "marijuana" are both forms of cannabis, come from the *Cannabis sativa L.* plant, and share the same chemical constituents; the sole difference between them is the concentration of delta-9 THC, discussed further below. *See also* Agriculture Improvement Act of 2018 ("2018 Farm Bill"), Pub. L. No. 115-334, § 10113, 132 Stat. 4490, 4908 (codified at 7 U.S.C. § 1639o); *see generally* Cong. Rsch. Serv., Changes to the Federal Definition of Hemp: Legal Background and Pending Legislation, LSB11381 (Dec. 22, 2025). This law banned cannabis-derived hemp products.

D. Executive Order No. 14370

On December 18, 2025, President Trump signed Executive Order No. 14370, titled "Increasing Medical Marijuana and Cannabidiol Research." 90 Fed. Reg. 60541 (Dec. 23, 2025). At the signing ceremony, CMS Administrator Dr. Mehmet Oz publicly stated that "millions of Americans on Medicare" would become eligible to receive cannabis and hemp-derived products "as early as April of next year, and at no charge, if their doctors recommend them." *Excerpts From President Trump's Historic Executive Order*, Cannabis Indus. J. (Dec. 18, 2025), https://cannabisindustryjournal.com/news_article/excerpts-

from-president-trumps-historic-executive-order/. This announcement predated the BEI by three months and signaled a predetermined outcome.

Charlotte's Web, a major hemp company, likely collaborated with CMS in shaping the BEI. Charlotte's Web co-founder Jared Stanley confirmed in February 2026 that the BEI program was "internally finalized" by CMS weeks before publication and referred to a "briefing" that he and other hemp industry insiders had received weeks prior. Kyle Jaeger, *Federal Agency Finalized Rule for CBD Medicare Coverage Pilot Program Weeks Ago, Key Hemp Stakeholder Says*, Marijuana Moment (Feb. 13, 2026), https://www.marijuanamoment.net/federal-agency-finalized-rule-for-cbd-medicare-coverage-pilot-program-weeks-ago-key-hemp-stakeholder-says/.

E. Absence of Notice-and-Comment Rulemaking

CMS issued no Notice of Proposed Rulemaking. It solicited no public comments. It provided no formal administrative record. It offered no reasoned explanation for creating the BEI or for reversing its April 2025 final rule. The BEI was not published in the Federal Register. It was announced on March 20, 2026 with a rushed effective date of April 1, 2026, only 11 days later.

F. Conflict with the FY2026 Agriculture Appropriations Act and Controlled Substances Act

The U.S. Drug Enforcement Administration (DEA) currently classifies marijuana as a Schedule I controlled substance. *Drug Scheduling*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/drug-scheduling. For all legal purposes, sale and possession of marijuana and all derivatives is illegal. 21 U.S.C. §§ 801–901.

The Controlled Substances Act ("CSA") defines "marijuana" as "all parts of the plant *Cannabis sativa L.*, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin." 21 U.S.C. § 802(16)(A).

The 2018 Farm Bill amended the definition of "marijuana" to exclude "hemp." *See* Pub. L. No. 115-334, § 12619, 132 Stat. 4490, 5018 (2018). The bill defined "hemp" as "[t]he 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, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

The FY2026 Agriculture Appropriations Act ("2026 Agriculture Appropriations Act"), signed by President Trump, further clarified statutory limits on hemp-derived products by establishing a total THC limit of 0.4 mg per container, effective November 2026. This represents a substantive change from the 2018 Farm Bill, which regulated hemp based on the percentage of delta-9 THC by dry weight rather than total THC per container.

G. The Health Risks CMS Failed to Consider

As discussed in detail in the Complaint, the scientific evidence documenting health risks from cannabis and hemp-derived THC products for older adults is substantial. Representative studies include:

- A June 2025 meta-analysis published in *Heart*, encompassing 24 studies and approximately 200 million participants, found that cannabis use was associated

with a two-fold risk of cardiovascular death, a 29% higher risk of acute coronary syndrome, and a 20% higher risk of stroke. *See* Wilhelm Storck et al., *Cardiovascular Risk Associated with the Use of Cannabis and Cannabinoids: A Systematic Review and Meta-Analysis*, 111 Heart 1047 (2025).

- A 2024 study in the *Journal of the American Heart Association*, analyzing data from approximately 434,000 U.S. adults, found that daily cannabis users had a 25% higher risk of heart attack and a 42% higher risk of stroke. *See* Abra M. Jeffers et al., *Association of Cannabis Use with Cardiovascular Outcomes Among US Adults*, 13 J. Am. Heart Ass'n e030178 (2024).
- A May 2025 study in *JAMA Cardiology* found that chronic cannabis use, whether smoked or consumed as THC-containing edibles, was associated with vascular endothelial dysfunction comparable to that observed in tobacco smokers. *See* Leila Mohammadi et al., *Association of Endothelial Dysfunction with Chronic Marijuana Smoking and THC-Edible Use*, JAMA Cardiology (May 28, 2025).
- A peer-reviewed 2022 study analyzing 516 U.S. CBD products found that only 42% fell within ±10% of the CBD content claimed on the label. Among 121 edible CBD products tested, lead was detected in 42%, mercury in 37%, and arsenic in 28%. *See* Hannah Gardener et al., *Heavy Metal and Phthalate Contamination and Labeling Integrity in a Large Sample of US Commercially Available Cannabidiol (CBD) Products*, 851 Sci. Total Env't 158110 (2022).

The FDA has not approved hemp-derived THC products for medical use. While Epidiolex, a CBD product used to treat rare seizures, has been approved by the FDA, it has not been tested for safety in people over 55. *See EPIDIOLEX New Drug Application Letter*, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/210365orig1s000ltr.pdf. The FDA has stated that no federal regulatory framework for CBD exists and that it has "not found adequate information showing how much CBD can be consumed, and for how long, before causing harm." *HFP Constituent Updates*, U.S. Food & Drug Admin. (Nov. 21, 2022), https://www.fda.gov/food/hfp-constituent-updates/fda-warns-companies-illegally-selling-food-and-beverage-products-contain-cbd. Lastly, neither the FDA nor the BEI imposes any meaningful safeguards to prevent product adulteration, ensure quality control, or require independent testing.

III. LEGAL STANDARD

A plaintiff seeking a preliminary injunction must demonstrate "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." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

Section 705 of the APA provides that "on such conditions as may be required and to the extent necessary to prevent irreparable injury," a reviewing court "may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. The factors for granting a stay under Section 705 "substantially overlap with the

Winter factors." *Immigrant Defs. L. Ctr. v. Noem*, 145 F.4th 972, 986 (9th Cir. 2025) (cleaned up). Moreover, where (as here) the government is a party, the third and fourth factors, balance of equities and public interest, merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

IV. ARGUMENT

A. This Challenge Is Reviewable

Section 1115A of the Social Security Act bars judicial review of certain Innovation Center decisions, including "selection of models for testing," "selection of organizations, sites, or participants," and "the elements, parameters, scope, and duration" of models. 42 U.S.C. § 1315a(d)(2). Plaintiffs do not challenge these decisions. Rather, they fault CMS for its lack of procedural faithfulness and *ultra vires* action when creating and adopting the BEI. As such, this suit is reviewable. *See Regeneron Pharms., Inc. v. United States HHS*, 510 F. Supp. 3d 29, 42 (S.D.N.Y. 2020) (holding that Section 1115A "does not bar review of the propriety of the procedures used" to establish models); *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986) (finding a "strong presumption favoring judicial review of administrative action").

Additionally, the BEI is final agency action. It marks the consummation of CMS's decision-making process, it has been published, it has a fixed implementation date, and is not tentative or interlocutory. Second, it is an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). The BEI imposes binding eligibility and reporting requirements, along with product specifications, on all participating organizations. As such, it produces concrete legal consequences for their aligned Medicare beneficiaries. *See Sackett v. EPA*,

566 U.S. 120, 127 (2012) (agency action is final where it determines rights or obligations and produces direct legal consequences); *see also Bennett*, 520 U.S. at 178.

B. Plaintiffs Have Standing

Plaintiffs attach several declarations establishing their standing to bring this lawsuit. *See* Exhibits A–G. Plaintiffs have standing on three independent bases.

a. Individual and Associational Standing.

David Evans is a 78-year-old Medicare beneficiary who receives care from an ACO REACH participating provider. *See* Exhibit B (declaration of David Evans). His relationship with his health care provider will be negatively affected by imminent implementation of the BEI beginning April 1, 2026. His right to participate in notice-and-comment rulemaking was denied.

SAM, CIVEL, NCALM, CIPC, CIVSJ, DFAF, SOS, and DWI have associational standing under *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333 (1977). At least one identified member of each of these Plaintiffs, David Evans, is injured by the BEI and has independent standing to sue. *See* Exhibit B (declaration of David Evans). The interests these Plaintiffs seek to protect, namely public health, product safety, and lawful agency procedure, are germane to these organizations' respective purposes of public education about the dangers of cannabis and hemp-derived products and assisting victims of these products. Neither the claims asserted nor the declaratory and injunctive relief requested requires Mr. Evans's participation.

b. Procedural standing.

Plaintiffs were denied their right to participate in notice-and-comment rulemaking under 5 U.S.C. § 553. *See* Exhibits A–G. Plaintiffs are all organizations engaged in victim

advocacy and public education about the dangers of cannabis products, hemp-derived products, THC, CBD, and other cannabinoids. The BEI represents a reasonable risk of injury to Plaintiffs' particularized interests in educating the public, and in protecting the victims of these harmful substances. *See Cap. Area Immigrants' Rts. Coal. v. Trump*, 471 F. Supp. 3d 25, 38 (D.D.C. 2020). The BEI will increase access to these substances, particularly for a vulnerable elderly population, increasing the burden on Plaintiffs to oppose their use and advocate for those harmed. *See Mendoza v. Perez*, 754 F.3d 1002, 1010 (D.C. Cir. 2014) (outlining elements of procedural standing).

c. Organizational standing.

All Plaintiffs except David Evans and Illinois Family Institute have organizational standing. *See* Exhibits A, C-F. The BEI has forced these Plaintiff organizations to divert resources from their core programmatic activities, which include direct patient education, clinician training programs, community health intervention, and victim advocacy, in order to monitor, analyze, and counteract the BEI. This constitutes concrete, demonstrable injury. *See People for the Ethical Treatment of Animals v. United States Dep't of Agriculture*, 797 F.3d 1087, 1094 (D.C. Cir. 2015); *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982).

C. Plaintiffs Are Likely To Succeed on the Merits

a. CMS Violated the APA's Notice-and-Comment Requirements.

Legislative rules are those that impose "legally binding obligations or prohibitions on regulated parties" and carry "the force and effect of law." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302–303 (1979)). A rule is legislative when it "effects a substantive regulatory change to the statutory or

regulatory regime." *Mendoza v. Perez*, 754 F.3d 1002, 1006 (D.C. Cir. 2014) (quotation omitted).

The BEI is such a policy. It imposes binding obligations on participating organizations. It creates a new benefit structure for Medicare beneficiaries that conflicts with CMS's prior rule on medical marijuana as well as the CSA, the 2018 Farm Bill, and the Agriculture Appropriations Act. It establishes detailed eligibility criteria. It has the force and effect of law. And as such, the BEI is a legislative rule subject to 5 U.S.C. § 553's notice-and-comment requirements. The BEI applies broadly to a vast number of Medicare beneficiaries, far exceeding the narrow populations envisioned by Section 1115A, which is limited to testing models for "defined populations." No exemption to notice and comment applies. The BEI is not an interpretive rule that clarifies an existing statute or regulation. It is not a general policy statement, nor is it a rule of agency organization, procedure, or practice. It is an agency action with legal force and effect that directly affects the rights and obligations of participating organizations and their aligned Medicare beneficiaries, creating entirely new programmatic requirements for ACO REACH and EOM organizations.

CMS cannot evade the APA's requirements by disguising its rulemaking as a participation agreement amendment. Courts look to "the *contents* of the agency's action, not the agency's self-serving *label*, when deciding whether statutory notice-and-comment demands apply." *Azar v. Allina Health Servs.*, 587 U.S. 566, 575 (2019) (emphasis in original). An agency "may not hide behind its authority to contract in order to evade the APA." *American Hospital Ass'n v. Bowen*, 834 F.2d 1037, 1054 (D.C. Cir. 1987) (quoting

district court). "[A]ny contract provisions that are legislative [in character] are subject to § 553's notice and comment requirements." *Id.* Moreover, Section 1115A contains no express exemption from the APA rulemaking requirements. *See* 5 U.S.C. § 559; *see also Asiana Airlines v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998) (exemption is express only when Congress "has established procedures so clearly different from those required by the APA that it must have intended to displace the norm").

CMS's failure to publish the BEI, which is a generally applicable policy with legal effect—*i.e.*, a substantive rule—in the Federal Register violates 5 U.S.C. § 552(a)(1) and the Federal Register Act, 44 U.S.C. § 1505. This independently violates the APA. *See Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000). Moreover, CMS's procedural violations render the BEI invalid. *See* 5 U.S.C. § 706(2)(D).

b. The BEI is arbitrary, capricious, and not reasonably explained.

Agency action must be "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). An "unexplained inconsistency" renders a changed policy arbitrary and capricious. *Children's Hosp. Ass'n of Texas v. Azar*, 933 F.3d 764, 773 (D.C. Cir. 2019). When an agency reverses course, it must provide "a reasoned explanation for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009)).

The BEI flunks this requirement. CMS gave no explanation whatsoever for its action, which conflicts with its April 2025 final rule categorically excluding medical cannabis from supplemental Medicare Advantage coverage. By attempting this "end-

around" and inserting the BEI into participation agreements without any analysis or justification for its change in position, CMS violated the APA by engaging in arbitrary action. *See Encino Motorcars, LLC*, 579 U.S. at 222.

CMS also failed to consider important aspects of the problem. *See Motor Vehicles Mfrs. Ass'n v. State Farm Mut.*, 463 U.S. 29, 43 (1983) (finding such action arbitrary and capricious). CMS did not address the legal status under the CSA of the products it makes more available. CMS also did not account for the voluminous peer-reviewed evidence of cardiovascular harm, liver injury, drug interactions, and cognitive harm from cannabis and hemp-derived products. It failed to address the known pervasive contamination and mislabeling of commercially available CBD products. It ignored the absence of any FDA regulatory framework for cannabinoids, including CBD. It disregarded the near-total lack of clinical research on cannabis use in populations over 65. Each failure independently renders the BEI arbitrary and capricious. *Id.*

CMS's THC limit of 3mg per serving also directly conflicts with the CSA, the 2018 Farm Bill and 2026 Agriculture Appropriations Act. CMS's dubious promise that it "will adjust its definition in accordance with the law," despite having inexplicably drafted the definition in violation of the law in the first instance, is of little comfort and itself an acknowledgement that the BEI as constituted conflicts with enacted federal law.

CMS also failed to explain how this rule complies with its own statutory responsibility under Section 1115A, which limits testing to "defined populations with deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." CMS provides no basis for concluding that individuals, currently capable of purchasing

hemp-derived cannabis on their own, suffer from deficits in care, nor does it provide any information regarding patient outcomes for those deprived of hemp-derived cannabis or evidence of any expenditures that would be avoided as a result of this program.

c. The BEI exceeds CMS's statutory authority.

Where an agency asserts authority of vast economic and political significance, like authority to increase access to cannabinoids, "the agency must point to clear congressional authorization for the power it claims." *West Virginia v. EPA*, 597 U.S. 697, 723 (2022) (quotation omitted) (detailing the major questions doctrine). CMS has not done so. Using a statutory provision designed to test payment and delivery models to create *de facto* federal health insurance access to Schedule I substances for millions of Medicare beneficiaries is precisely the kind of action that demands clear statutory authority. But CMS has no statutory authority, under Section 1115A or otherwise, to create a program that allows access to harmful, dangerous, and illegal substances without APA rulemaking.

No precedent exists for using Innovation Center models to distribute specific consumer products to beneficiaries, because those models are not intended for that purpose. These models are pilot or demonstration projects designed to test new payment and care delivery approaches for Medicare and Medicaid. Their purpose is to improve care quality, lower costs, and promote value-based care by encouraging best medical and financial practices through financial incentives or shared savings/risk arrangements—not to serve as a distribution system for specific consumer products.

Not only that, but the political, economic, and public health significance of the BEI is profound. By effectively creating a nationwide pathway for Medicare beneficiaries to access Schedule I cannabinoids, the program implicates federal law, healthcare spending of billions of taxpayer dollars, and regulatory oversight of controlled substances. Moreover, the program has been explicitly championed at the highest levels by the executive and powerful special interests. The Trump Administration has ordered its implementation, Administrator Oz has made public statements in its favor, and the cannabis industry has celebrated its arrival. These factors demonstrate that the BEI is not a routine administrative action, but a sweeping policy with broad economic, health, and political consequences. Given the unprecedented scope of this initiative, which is entirely beyond and out of step with past initiatives, the major questions doctrine applies in full force. *West Virginia*, 597 U.S. at 716 (applying doctrine to questions of "vast economic and political significance"), 721 (applying doctrine when "the sheer scope of . . . claimed authority" and the "unprecedented" nature of action provide reason for pause). An agency, manifestly subject to extraordinary political pressures, cannot appropriate such transformative authority without a clear and specific grant of congressional authorization.

d. The BEI conflicts with federal law.

The BEI is plainly "not in accordance with law" and therefore violates 5 U.S.C. § 706(2)(A). Its THC limits conflict with the 2018 Farm Bill and 2026 Agriculture Appropriations Act. Moreover, the BEI facilitates widespread access to substances that remain Schedule I under the CSA.

No hemp-derived nor THC-bearing product has been approved by FDA for medical use, and the agency has identified significant safety risks associated with cannabinoid consumption. *See Consumer Updates*, Fed. Drug Admin. (Mar. 5, 2020), https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis; *Public Health Focus*, Fed. Drug Admin. (July 16, 2024), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd. CMS conducted no compliance analysis before issuing the BEI. *See PDK Labs., Inc. v. DEA*, 362 F.3d 786, 797–98 (D.C. Cir. 2004) (agency must "bring its experience and expertise to bear" and evaluate statutory status of drug-related product when status was unclear). In fact, a prior APA compliant process completed less than one year prior determined that the health effects of medical marijuana, containing the same or comparable ingredients as hemp-derived cannabinoids, were not sufficient to justify use by Medicare patients. *See* 90 Fed. Reg. 15792, 15867 (Apr. 15, 2025). An agency does not act reasonably when it creates a program to allow distribution of substances that are dangerous, illegal, or harmful to health and disregards its own very recent comprehensive analysis.

D. Plaintiffs Will Suffer Irreparable Harm Absent Relief

Plaintiffs have suffered and will continue to suffer irreparable harm if this Court does not act. This harm is not speculative. It is certain.

First, Plaintiffs will suffer procedural injury if the BEI goes into effect without notice or comment. When an agency flouts the APA in this way, the deprivation of the

right to participate in the rulemaking process is a harm that cannot be remedied after the fact. "It is well established that the harm suffered by those who would otherwise participate in agency rulemaking under the APA is to be considered irreparable when the agency fails to afford them their rights to such participation." *Nat'l Treasury Emps. Union v. Newman*, 768 F. Supp. 8, 10 (D.D.C. 1991) (quotation omitted). Plaintiffs are organizations opposed to public access to cannabis, hemp-derived products, and cannabinoids. Every single Plaintiff would have filed comments with CMS, had the BEI proceeded through proper notice-and-comment rulemaking. This harm will become irreparable if the BEI is allowed to take effect without an opportunity for comment.

Second, David Evans is a Medicare beneficiary aligned with an organization that participates in ACO REACH—his primary care medical office. He faces imminent implementation of a program that will make hemp-derived THC products available through his healthcare provider. If his provider attempts to convince him to use hemp-derived, THC, CBD, or other cannabinoid products or offers them in any way to its patients, Mr. Evans would lose all faith in them and would be forced to seek out a different medical provider. This program was developed and adopted without any opportunity for his participation in the rulemaking process, and without any analysis of the safety of hemp-derived products for American seniors like him.

Third, many of the Plaintiffs will suffer concrete, ongoing injury to their core programmatic activities. They have been required to divert significant resources from their educational and care-focused missions, which include expenditures for community health, physician training, and victim assistance, to monitor and counteract the BEI's

harmful effects on their target populations. The BEI will also create more victims of cannabinoids and a more intractable educational problem, requiring further expenditures. As long as the BEI is in effect, this diversion of resources will continue.

Fourth and finally, Plaintiffs will suffer irreparable injury due to the public health catastrophe the BEI will unleash. The FDA has identified safety risks associated with CBD, and scientific evidence suggests these risks are particularly acute for Medicare beneficiaries who are elderly, take multiple medications, and are at high risk of drug interactions. By making Schedule I substances available to seniors without any examination of health risks, CMS has committed grievous harm that cannot be remedied without the requested relief.

E. The Balance of the Equities and Public Interest Favor Relief

Because the government is a party, the balance of equities and public interest merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

There is a strong public interest in agencies following the law. *See League of Women Voters of the United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (finding "generally no public interest in the perpetuation of unlawful agency action"). The APA's notice-and-comment requirements ensure public participation, transparency, and deliberative decisionmaking. Requiring CMS to follow the procedures Congress established serves the public interest.

There is also a strong public interest in protecting vulnerable Americans from products distributed without adequate safety analysis and without an established federal regulatory framework. Heart disease is the leading cause of death among Americans over

65. Peer-reviewed research documents that cannabis use is associated with a two-fold increase in risk of cardiovascular death. CMS has not acknowledged this evidence, much less analyzed it.

A stay merely preserves the *status quo* in which the BEI did not exist. Maintaining this state of things pending a decision on the merits imposes no cognizable harm on anyone. It only requires CMS to continue operating without the BEI while the Court reviews whether the BEI was lawfully adopted. The government has no legitimate interest in implementing an unlawfully adopted rule. *See generally Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89 (D.C. Cir. 2002) (rejecting government's claim of harmless error where agency bypassed notice-and-comment procedures entirely).

F. The Court Should Issue Relief Under Rule 65 and 5 U.S.C. § 705

Given the serious and stark nature of CMS's error, and the imminence of the harm associated with the BEI, which takes effect on April 1, 2026, a temporary restraining order under Rule 65(b) is appropriate. A preliminary injunction under Rule 65(a) is likewise appropriate given the overwhelming strength of Plaintiff's claims on the merits. This Court also has authority under the APA to stay this action pending review and provide relief to all persons subject to the BEI, not just Plaintiffs. 5 U.S.C. § 705.

Plaintiffs would prefer that this Court issue a stay under 5 U.S.C. § 705. "To the extent the district court considers the public interest and the conveniences of the parties, the court is limited to evaluating how such interest and conveniences are affected by the selection of an injunction over other enforcement mechanisms." *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 498 (2001). A stay is preferable for the Plaintiffs

because Section 705 does not authorize courts to condition stays on the posting of a bond, whereas Rule 65(c) does authorize courts to condition preliminary injunctions on the posting of a bond. This is an APA challenge seeking to maintain the *status quo*, with no monetary harm to the defendants that will result from a stay. As such, should this Court issue relief under Rule 65, Plaintiffs request a nominal or zero bond given the nature of the claims.

V. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court enter an order:

a. Temporarily restraining Defendants from implementing, applying, or enforcing the BEI pending a hearing on the motion for preliminary injunction pursuant to Rule 65(b);

b. Preliminarily enjoining Defendants from implementing, applying, or enforcing the BEI pending resolution of this action on the merits pursuant to Rule 65(a);

c. Staying the effective date of the BEI pending conclusion of judicial review under 5 U.S.C. § 705;

d. Expediting briefing and a hearing on this motion; and

e. Granting such other and further relief as the Court deems just and proper.

Date: March 30, 2026

Respectfully submitted,

/s/ Patrick Kenneally

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Attorneys for Plaintiffs

EXHIBIT A

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. _____

DECLARATION OF LUKE NIFORATOS
IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW

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

1. I am over eighteen years of age and am competent to testify as to the matters stated herein. I make this declaration based on my personal knowledge.

2. I am Executive Vice President of Smart Approaches to Marijuana, Inc. ("SAM"). In my role, I have personal knowledge of SAM's organizational structure, operations, mission, programs, finances, and the impact of the Substance Access Beneficiary Engagement Incentive ("BEI") on SAM's activities.

3. I submit this declaration in support of Plaintiffs' Emergency Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review, and in support of the Memorandum of Points and Authorities filed in connection therewith.

4. SAM is a corporation headquartered at 220 Maryland Ave NE, Washington, D.C. 20002, and incorporated in Virginia.

5. SAM's mission includes education and advocacy regarding the public health and safety impacts of marijuana and cannabis policy.

6. SAM operates concrete programmatic activities that go beyond general issue advocacy. These activities include public health education campaigns directed at healthcare providers and patients, direct information services regarding cannabis-related health risks, and research and policy analysis programs. These are not merely lobbying or public relations efforts; they are ongoing, resource-intensive programs that serve specific populations and produce tangible informational outputs.

7. SAM is a participant in the ongoing administrative process opposing the rescheduling of cannabis before the Drug Enforcement Administration ("DEA").

8. On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") published the BEI on its website. The BEI takes effect on April 1, 2026 for ACO REACH participants and on the same date for Enhancing Oncology Model ("EOM") participants. The BEI creates a framework for distributing hemp-derived THC products and other cannabis-derived products to Medicare beneficiaries through participating healthcare providers.

9. The BEI directly affects and interferes with SAM's core programmatic activities beyond its issue-advocacy or mission by requiring SAM to divert 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.

10. SAM's injury is not abstract policy disagreement but concrete impairment of specific programmatic activities with a consequent drain on organizational resources. SAM's interest in preventing the expansion of access to cannabis products has been directly and demonstrably harmed by the BEI.

11. The BEI provides marijuana products via a medical source, meaning that SAM's significant expenditure of resources opposing the DEA's notice of proposed rulemaking rescheduling marijuana has been rendered essentially moot by this program, which did not proceed through notice and comment.

12. CMS published no Notice of Proposed Rulemaking for the BEI, solicited no public comments, offered no reasonable explanation for its action, and bypassed the Federal Register.

13. SAM would have submitted detailed comments to CMS opposing the BEI had the agency complied with the notice-and-comment requirements of 5 U.S.C. § 553. SAM possesses extensive expertise and data regarding the public health and safety risks of cannabis- and hemp-derived products, which it would have submitted to the agency as part of a formal rulemaking proceeding. SAM's expertise derives from years of public education, advocacy, reporting federal law violations to agencies, and participation in regulatory proceedings, including the ongoing DEA rescheduling proceeding.

14. SAM has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal notice-and-comment

rulemaking. No formal administrative record was developed or made available. SAM has been deprived of its participatory interest in shaping the regulatory outcome through the procedures Congress established.

15. SAM is also an interested party in the ongoing DEA proceedings opposing the rescheduling of marijuana from Schedule I to Schedule III under the Controlled Substances Act. SAM is injured by its inability to comment on the BEI, which seeks to expand access to marijuana for certain Americans by circumventing marijuana's Schedule I status, and which directly implicates SAM's ongoing participation in the related DEA proceeding. The BEI's implementation without notice and comment deprives SAM of the ability to develop a record connecting the BEI to the rescheduling proceeding in which SAM has invested substantial resources.

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

Executed on March 30, 2026.

Luke Niforatos

EXHIBIT B

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. _____

DECLARATION OF DAVID EVANS IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW

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

1. I am over eighteen years of age and am competent to testify as to the matters stated herein. I make this declaration based on my personal knowledge.

2. I submit this declaration in support of Plaintiffs' Emergency Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review, and in support of the Memorandum of Points and Authorities filed in connection therewith.

3. I am the Senior Counsel and Executive Director of Cannabis Industry Victims Educating Litigators ("CIVEL"). I am the Executive Director of North Carolinians Against Legalizing Marijuana, Cannabis Impact Prevention Coalition, LLC, and Cannabis Industry Victims Seeking Justice ("CIVSJ"). I am a donor, consultant, and

volunteer for Smart Approaches to Marijuana, Inc. ("SAM"). I am a consultant and volunteer of Drug Free America Foundation ("DFAF") and Save Our Society from Drugs ("SOS"). I am a member of Drug Watch International ("DWI").

4. I am a Medicare beneficiary. I receive Medicare benefits and primary care through Hopscotch Primary Care, PLLC. Hopscotch Primary Care has joined ACO REACH as part of Physicians Healthcare Collaborative ACO. As such, I am aligned with an ACO REACH participant provider.

5. On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") published the Substance Access Beneficiary Engagement Incentive ("BEI") on its website. The BEI takes effect on April 1, 2026 for ACO REACH participants. Because my primary care provider participates in ACO REACH, I face imminent implementation of a program that will make hemp-derived THC products and other cannabis-derived products available through my healthcare provider beginning April 1, 2026.

6. I am 78 years old, and I am a three-time cancer survivor. I was treated for two forms of cancer while on Medicare, as well as a concussion due to a fall.

7. As a senior citizen enrolled in Medicare, I am a member of the population most vulnerable to the cardiovascular, neurological, cognitive, and drug-interaction harms documented in the peer-reviewed literature regarding these products. I am opposed to expanded access to cannabis and hemp-derived products, and I do not want them provided by or through my Medicare provider, due to their serious and well-documented health risks. This program will allow individual doctors to determine which products to provide to Medicare patients and the dosing of those products, and then

conduct detailed research on these patients. This will turn these medical professionals into "bedside bureaucrats" by delegating to them millions of decisions each year about which services the Medicare program will provide.

8. I have extensive personal knowledge of and experience with the harms caused by cannabis and hemp-derived products. I used cannabis and alcohol and other drugs in high school and in college and became addicted by the time I was 19. In my senior year in college, I sought help from a 12 Step self-help group. I was able to stop drinking before I stopped using cannabis. I experienced hallucinations while using cannabis. I have been abstinent since 1970. Since 1970 I have worked as a volunteer or a professional to help others who are addicted. In that time I have compiled a great deal of scientific data and heard many personal stories about the dangers of cannabis, hemp-derived products, and cannabinoids.

9. I would have submitted evidence of these harms to CMS had I been afforded the opportunity to participate in notice-and-comment rulemaking for the BEI. CMS published no Notice of Proposed Rulemaking, solicited no public comments, and bypassed the Federal Register entirely. As a result, I was deprived of my right to participate in the rulemaking process as an interested party under 5 U.S.C. § 553.

10. The BEI was announced on March 20, 2026, with an effective date of April 1, 2026. I had no opportunity to submit comments, evidence, or objections to CMS regarding the BEI before it was finalized and set for implementation.

11. My individual injuries described above, including the alteration of my healthcare relationship due to the BEI and the denial of my right to participate in notice-and-comment rulemaking, establish that I have standing to sue in my own right.

12. I am a donor, consultant, and volunteer for SAM. The interests that SAM seeks to protect in this action, including public health, product safety, and lawful agency procedure, are germane to SAM's mission of education and advocacy regarding the public health and safety impacts of marijuana and cannabis policy. Neither the claims asserted nor the declaratory and injunctive relief requested requires my individual participation.

13. I am the Senior Counsel and Executive Director of CIVEL. The interests that CIVEL seeks to protect in this action are germane to CIVEL's mission of educating legal professionals and the public about the harms caused by the cannabis industry. Neither the claims asserted nor the declaratory and injunctive relief requested requires my individual participation.

14. I am the Executive Director of North Carolinians Against Legalizing Marijuana. The interests that North Carolinians Against Legalizing Marijuana seeks to protect in this action are germane to its organizational mission. Neither the claims asserted nor the declaratory and injunctive relief requested requires my individual participation.

15. I am the Executive Director of CIPC. The interests that CIPC seeks to protect in this action are germane to its organizational mission. Neither the claims asserted nor the declaratory and injunctive relief requested requires my individual participation.

16. I am the Executive Director of CIVSJ. The interests that CIVSJ seeks to protect in this action are germane to CIVSJ's organizational mission. Neither the claims asserted nor the declaratory and injunctive relief requested requires my individual participation.

17. I am a consultant and volunteer of DFAF. The interests that DFAF seeks to protect in this action are germane to DFAF's organizational mission. Neither the claims asserted nor the declaratory and injunctive relief requested requires my individual participation.

18. I am a consultant and volunteer of SOS. The interests that SOS seeks to protect in this action are germane to SOS's organizational mission. Neither the claims asserted nor the declaratory and injunctive relief requested requires my individual participation.

19. I am a member of DWI. The interests that DWI seeks to protect in this action are germane to DWI's organizational mission. Neither the claims asserted nor the declaratory and injunctive relief requested requires my individual participation.

20. As Senior Counsel and Executive Director of CIVEL, I have personal knowledge of CIVEL's operations, programs, and the impact of the BEI on CIVEL's activities. CIVEL is an organization based in Flemington, New Jersey, and is incorporated in New Jersey, whose mission includes educating legal professionals and the public about the harms caused by the cannabis industry. CIVEL represents the victims of the marijuana industry who have been, are being, or will actually be harmed by the challenged actions of CMS because the CMS hemp-cannabis distribution program will

increase the use of marijuana, reduce the perception of its dangerousness, and lower medical standards for determining what constitutes a medicine. CIVEL operates concrete programmatic activities including legal education seminars, victim assistance programs, and community outreach. CIVEL is a participant in the ongoing administrative process opposing the rescheduling of cannabis before the Drug Enforcement Administration, and was granted association standing by DEA Chief Administrative Law Judge John J. Mulrooney on November 19, 2024 in the matter of *Schedules of Controlled Substances: Proposed Rescheduling of Marijuana*, DEA Docket No. 1362, Hearing Docket No. 24-44. CIVEL was also recognized as having association standing in *Botteon v. Murphy*, NJ Superior Court MID-L-002293 (2020), a New Jersey case concerning federal law preemption and the state marijuana law.

21. The BEI has directly impaired CIVEL's core programmatic activities by requiring CIVEL to divert staff time and resources from its victim assistance and legal education programs to monitor, analyze, and respond to the BEI and its implications for vulnerable seniors. This diversion of resources constitutes a concrete and demonstrable injury to CIVEL's organizational interests.

22. CIVEL has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal notice-and-comment rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments. CIVEL would have submitted comments to CMS opposing the BEI had the agency complied with 5 U.S.C. § 553.

23. As Executive Director of North Carolinians Against Legalizing Marijuana, I have personal knowledge of that organization's operations and the impact of the BEI on its activities. North Carolinians Against Legalizing Marijuana has been registered with the North Carolina Secretary of State for lobbying purposes in opposing "medical" marijuana and hemp cannabis products such as what CMS is proposing in the BEI. North Carolinians Against Legalizing Marijuana only recognizes medicines that are produced and distributed with standard best-practice pharmaceutical protocols and that are approved by the U.S. Food and Drug Administration. Unless a marijuana, cannabis, or hemp product has been approved for marketing as a medicine by the FDA under the federal Food, Drug and Cosmetic Act, North Carolinians Against Legalizing Marijuana maintains it is neither safe nor effective and puts patients at risk. The BEI has directly affected and interfered with North Carolinians Against Legalizing Marijuana's core programmatic activities beyond its issue-advocacy or mission. The organization has been required to divert resources from its programs and lobbying efforts to monitor and respond to the BEI, constituting a concrete organizational injury.

24. North Carolinians Against Legalizing Marijuana has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

25. As Executive Director of CIPC, I have personal knowledge of that organization's operations and the impact of the BEI on its activities. CIPC is a corporation organized under the laws of the State of New York whose mission is to prevent the

negative social, health, public safety, and environmental impacts of marijuana. CIPC was granted standing in *Cannabis Impact Prevention Coalition and Cannabis Industry Victims Seeking Justice, et al. v. Hochul*, Index No. 905386-23 (Albany County, NY), a case involving state laws regarding "medical" marijuana. The BEI has directly affected and interfered with CIPC's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs. This diversion constitutes a concrete organizational injury.

26. CIPC has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been deprived of its participatory interest in shaping the regulatory process through providing comments.

27. As Executive Director of CIVSJ, I have personal knowledge of CIVSJ's operations and the impact of the BEI on its activities. CIVSJ is a corporation organized under the laws of the State of New York whose mission is to make the marijuana industry legally accountable to its victims. CIVSJ was granted standing alongside Cannabis Impact Prevention Coalition, LLC in *Cannabis Impact Prevention Coalition and Cannabis Industry Victims Seeking Justice, et al. v. Hochul,* Index No. 905386-23 (Albany County, NY). The BEI has directly affected and interfered with CIVSJ's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs. This diversion constitutes a concrete organizational injury.

28. CIVSJ has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal rulemaking, and has been

deprived of its participatory interest in shaping the regulatory process through providing comments.

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

Executed on March 30, 2026.

David G. Evans

EXHIBIT C

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. _____

DECLARATION OF AMY RONSHAUSEN IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW

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

1. I am over eighteen years of age and am competent to testify as to the matters stated herein. I make this declaration based on my personal knowledge.

2. I am Executive Director of Drug Free America Foundation ("DFAF"). In my role, I have personal knowledge of DFAF's organizational structure, operations, mission, programs, finances, and the impact of the Substance Access Beneficiary Engagement Incentive ("BEI") on DFAF's activities.

3. I submit this declaration in support of Plaintiffs' Emergency Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review, and in support of the Memorandum of Points and Authorities filed in connection therewith.

4. DFAF is a nonprofit organization based in St. Petersburg, Florida. DFAF is a drug prevention and policy organization committed to developing strategies and educational programs that prevent drug use and promote sustained recovery.

5. DFAF operates concrete programmatic activities that go beyond general issue advocacy. These activities include drug prevention education programs, student assistance initiatives, community outreach, workplace drug prevention programs, and related operational activities.

6. On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") published the BEI on its website. The BEI takes effect on April 1, 2026 for ACO REACH participants and on the same date for Enhancing Oncology Model ("EOM") participants. The BEI creates a framework for distributing hemp-derived THC products and other cannabis-derived products to Medicare beneficiaries through participating healthcare providers.

7. The BEI has directly affected and interfered with DFAF's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its educational programs, student assistance initiatives, community outreach, workplace drug prevention programs, and related operational activities to oppose and counter the BEI.

8. DFAF's injury is not abstract policy disagreement but concrete impairment of specific programmatic activities with a consequent drain on organizational resources. DFAF's interest in preventing the expansion of access to cannabis products has been directly and demonstrably harmed by the BEI.

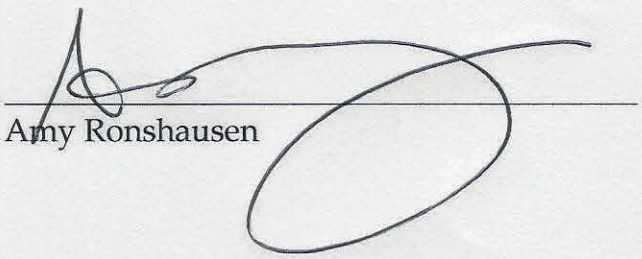
9. CMS published no Notice of Proposed Rulemaking for the BEI, solicited no public comments, offered no reasonable explanation for its action, and bypassed the Federal Register.

10. DFAF would have submitted detailed comments to CMS opposing the BEI had the agency complied with the notice-and-comment requirements of 5 U.S.C. § 553. DFAF possesses extensive expertise and data regarding the public health risks of cannabis- and hemp-derived products and the impact of expanded drug access on communities, which it would have submitted to the agency as part of a formal rulemaking proceeding.

11. DFAF has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal notice-and-comment rulemaking. No formal administrative record was developed or made available. DFAF has been deprived of its participatory interest in shaping the regulatory outcome through the procedures Congress established.

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

Executed on March 30, 2026.



Amy Ronshausen

EXHIBIT D

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. _____

DECLARATION OF AMY RONSHAUSEN
IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW

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

1. I am over eighteen years of age and am competent to testify as to the matters stated herein. I make this declaration based on my personal knowledge.

2. I am Executive Director of Save Our Society From Drugs ("SOS"). In my role, I have personal knowledge of SOS's organizational structure, operations, mission, programs, finances, and the impact of the Substance Access Beneficiary Engagement Incentive ("BEI") on SOS's activities.

3. I submit this declaration in support of Plaintiffs' Emergency Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review, and in support of the Memorandum of Points and Authorities filed in connection therewith.

4. SOS is a nonprofit organization based in St. Petersburg, Florida. SOS is a committed to establishing, promoting, and enabling sound drug laws and policies that will reduce illegal drug use, drug addiction and drug-related illness and death.

5. SOS operates concrete programmatic activities that go beyond general issue advocacy. These activities include drug prevention education programs, public awareness campaigns, community intervention initiatives, support and resources for professionals working in fields impacted by drug use and abuse, and related operational activities.

6. On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") published the BEI on its website. The BEI takes effect on April 1, 2026 for ACO REACH participants and on the same date for Enhancing Oncology Model ("EOM") participants. The BEI creates a framework for distributing hemp-derived THC products and other cannabis-derived products to Medicare beneficiaries through participating healthcare providers.

7. The BEI has directly affected and interfered with SOS's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its drug prevention education programs, public awareness campaigns, community intervention initiatives, support and resources for professionals working in fields impacted by drug use and abuse, and related operational activities.

8. SOS's injury is not abstract policy disagreement but concrete impairment of specific programmatic activities with a consequent drain on organizational resources.

SOS's interest in preventing the expansion of access to cannabis products has been directly and demonstrably harmed by the BEI.

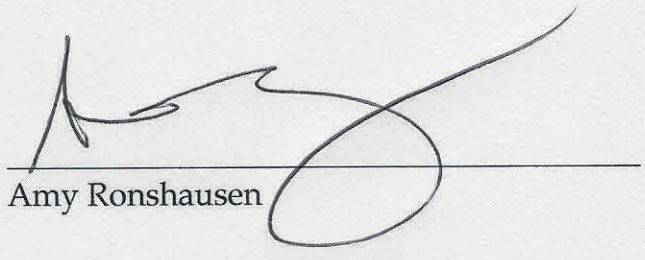
9. CMS published no Notice of Proposed Rulemaking for the BEI, solicited no public comments, offered no reasonable explanation for its action, and bypassed the Federal Register.

10. SOS would have submitted detailed comments to CMS opposing the BEI had the agency complied with the notice-and-comment requirements of 5 U.S.C. § 553. SOS possesses extensive expertise and data regarding the public health risks of cannabis- and hemp-derived products and the impact of expanded drug access on communities, which it would have submitted to the agency as part of a formal rulemaking proceeding.

11. SOS has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal notice-and-comment rulemaking. No formal administrative record was developed or made available. SOS has been deprived of its participatory interest in shaping the regulatory outcome through the procedures Congress established.

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

Executed on March 30, 2026.



Amy Ronshausen

EXHIBIT E

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. _____

DECLARATION OF JOHN COLEMAN, PH.D.
IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW

I, John Coleman, Ph.D., hereby declare under penalty of perjury pursuant to 28 U.S.C. § 1746 as follows:

1. I am over eighteen years of age and am competent to testify as to the matters stated herein. I make this declaration based on my personal knowledge.

2. I am President of Drug Watch International ("DWI"). In my role, I have personal knowledge of DWI's organizational structure, operations, mission, programs, finances, and the impact of the Substance Access Beneficiary Engagement Incentive ("BEI") on DWI's activities.

3. I submit this declaration in support of Plaintiffs' Emergency Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review, and in support of the Memorandum of Points and Authorities filed in connection therewith.

4. DWI is a nonprofit organization based in Clifton, Virginia. DWI is a volunteer drug information network promoting "healthy drug-free cultures" globally. We advocate for the prohibition of and abstinence from all drugs, including alcohol and tobacco, and oppose the legalization of drugs prohibited by national and international laws.

5. DWI operates concrete programmatic activities that go beyond general issue advocacy. These activities include international drug policy research and analysis, public education campaigns, expert consultation and technical assistance to government agencies, and related operational activities.

6. On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") published the BEI on its website. The BEI takes effect on April 1, 2026 for ACO REACH participants and on the same date for Enhancing Oncology Model ("EOM") participants. The BEI creates a framework for distributing hemp-derived THC products and other cannabis-derived products to Medicare beneficiaries through participating healthcare providers.

7. The BEI has directly affected and interfered with DWI's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs.

8. Specifically, since the BEI was announced on March 20, 2026, DWI's board and members have spent considerable time on collecting and disseminating information about cannabis- and hemp-derived products and the BEI to its stakeholders and constituents, thus diverting members from the mission of Drug Watch International, Inc.,

which seeks to prevent the abuse of all drugs, not just cannabis, through education, prevention, and treatment.

9. DWI's injury is not abstract policy disagreement but concrete impairment of specific programmatic activities with a consequent drain on organizational resources. DWI's interest in preventing the expansion of access to drugs has been directly and demonstrably harmed by the BEI.

10. CMS published no Notice of Proposed Rulemaking for the BEI, solicited no public comments, offered no reasonable explanation for its action, and bypassed the Federal Register.

11. DWI would have submitted detailed comments to CMS opposing the BEI had the agency complied with the notice-and-comment requirements of 5 U.S.C. § 553. DWI possesses extensive expertise and data regarding the public health risks of cannabis- and hemp-derived products and the impact of expanded drug access on communities, which it would have submitted to the agency as part of a formal rulemaking proceeding.

12. Moreover, DWI would have commented that the growing power of the Executive Branch to make laws through rulemaking is considered by some to be both unconstitutional and anti-democratic. The APA was intended to ameliorate these deficiencies by requiring notice and comment before final agency rulemaking can occur. Over the years, practical considerations have introduced exceptions and waivers to the APA requirements. The BEI does not meet any conditions for a waiver or exemption of the notice-and-comment feature of the APA, and deprives the public of what little input the law allows for rulemaking.

13. DWI has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal notice-and-comment rulemaking. No formal administrative record was developed or made available. DWI has been deprived of its participatory interest in shaping the regulatory outcome through the procedures Congress established.

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

Executed on MARCH 30, 2026.

John Coleman, Ph.D.

EXHIBIT F

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. _____

DECLARATION OF ELLEN SNELLING
IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW

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

1. I am over eighteen years of age and am competent to testify as to the matters stated herein. I make this declaration based on my personal knowledge.

2. I am Board Chairperson of Hillsborough County Anti-Drug Alliance("HCADA"). In my role, I have personal knowledge of HCADA's organizational structure, operations, mission, programs, finances, and the impact of the Substance Access Beneficiary Engagement Incentive ("BEI") on HCADA's activities.

3. I submit this declaration in support of Plaintiffs' Emergency Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review, and in support of the Memorandum of Points and Authorities filed in connection therewith.

4. HCADA is a nonprofit organization based in Tampa, Florida.HCADAhas been in existence, active in the community, and supportive of law enforcement, the court system, prevention agencies, and substance abuse treatment providers since its inception in 1989. In 2003, HCADA restructured as a 501(c)(3) and expanded its community-based alcohol, tobacco, and substance abuse education and prevention activities, as well as participation in the development of related planning strategies statewide, for the betterment of the Hillsborough County community.

5. HCADA operates concrete programmatic activities that go beyond general issue advocacy. These activities include addressing alcohol issues on college campuses; supporting passage of Prescription Drug Monitoring Program Legislation; preventing underage drinking and impaired driving; supporting responsible vendor training regarding alcohol and "safe rides" programs; working in the areas of smoking prevention, cessation, second hand smoke, smoking effects on pets, smoking in multi-unit housing, retail sales to minors, and support for Students Working Against Tobacco (SWAT) clubs in middle-and high schools, reaching 3,000+ students during the school year; opposing legislation to legalize marijuana; and providing volunteers to assist the Drug Enforcement Agency during its "Drug Take Back Days."

6. On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") published the BEI on its website. The BEI takes effect on April 1, 2026 for ACO REACH participants and on the same date for Enhancing Oncology Model ("EOM") participants. The BEI creates a framework for distributing hemp-derived THC products

and other cannabis-derived products to Medicare beneficiaries through participating healthcare providers.

7. The BEI has directly affected and interfered with HCADA's core programmatic activities beyond its issue-advocacy or mission by requiring diversion of resources from its programs.

8. Specifically, since the BEI was announced on March 20, 2026, HCADA's board and members have spent considerable time on collecting and disseminating information about cannabis- and hemp-derived products and the BEI to its stakeholders and constituents, thus diverting members from the mission of HCADA which seeks to prevent the abuse of all drugs, not just cannabis, through its educational and volunteer efforts.

9. HCADA's injury is not abstract policy disagreement but concrete impairment of specific programmatic activities with a consequent drain on organizational resources. HCADA's interest in preventing the expansion of access to drugs has been directly and demonstrably harmed by the BEI.

10. CMS published no Notice of Proposed Rulemaking for the BEI, solicited no public comments, offered no reasonable explanation for its action, and bypassed the Federal Register.

11. HCADA would have submitted detailed comments to CMS opposing the BEI had the agency complied with the notice-and-comment requirements of 5 U.S.C. § 553. HCADA possesses extensive expertise and data regarding the public health risks of cannabis- and hemp-derived products and the impact of expanded drug access on

communities, which it would have submitted to the agency as part of a formal rulemaking proceeding.

12. HCADA has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal notice-and-comment rulemaking. No formal administrative record was developed or made available. HCADA has been deprived of its participatory interest in shaping the regulatory outcome through the procedures Congress established.

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

Executed on _____, 2026.

_____
Ellen Snelling

EXHIBIT G

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. _____

DECLARATION OF KATHY VALENTE IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND STAY OF AGENCY ACTION PENDING JUDICIAL REVIEW

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

1. I am over eighteen years of age and am competent to testify as to the matters stated herein. I make this declaration based on my personal knowledge.

2. I am the Director of Operations of Illinois Family Institute ("IFI"). In my role, I have personal knowledge of IFI's organizational structure, operations, mission, programs, finances, and the impact of the Substance Access Beneficiary Engagement Incentive ("BEI") on IFI's activities.

3. I submit this declaration in support of Plaintiffs' Emergency Motion for Temporary Restraining Order, Preliminary Injunction, and Stay of Agency Action Pending Judicial Review, and in support of the Memorandum of Points and Authorities filed in connection therewith.

4. IFI is a nonprofit organization based in Tinley Park, Illinois. Since 1992, IFI has worked to advance public policy initiatives consistent with Judeo-Christian teachings and traditions, educating citizens so that they can better influence their local communities and the state. To accomplish this goal, IFI works to educate Christians and the general public on matters of moral concern; to initiate, promote, encourage and coordinate activity designed to safeguard and advance public morality consistent with Biblical Christianity. This educational work includes opposition to further access to drugs, including cannabis- and hemp-derived products.

5. On March 20, 2026, the Centers for Medicare & Medicaid Services ("CMS") published the BEI on its website. The BEI takes effect on April 1, 2026 for ACO REACH participants and on the same date for Enhancing Oncology Model ("EOM") participants. The BEI creates a framework for distributing hemp-derived THC products and other cannabis-derived products to Medicare beneficiaries through participating healthcare providers.

6. CMS published no Notice of Proposed Rulemaking for the BEI, solicited no public comments, offered no reasonable explanation for its action, and bypassed the Federal Register.

7. IFI would have submitted detailed comments to CMS opposing the BEI had the agency complied with the notice-and-comment requirements of 5 U.S.C. § 553. IFI possesses extensive expertise and data regarding the public health and moral risks of cannabis- and hemp-derived products and the impact of expanded drug access on

communities, which it would have submitted to the agency as part of a formal rulemaking proceeding.

8. IFI has an informational interest in the administrative record that would have been developed had the BEI proceeded through formal notice-and-comment rulemaking. No formal administrative record was developed or made available. IFI has been deprived of its participatory interest in shaping the regulatory outcome through the procedures Congress established.

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

Executed on March 30, 2026.

Kathy Valente

Kathy Valente