706 F.3d 438
United States Court of Appeals,
District of Columbia Circuit.

AMERICANS FOR SAFE ACCESS, et al., Petitioners
v.
DRUG ENFORCEMENT ADMINISTRATION, Respondent
Carl Eric Olsen, Intervenor.

No. 11–1265.
|
Argued Oct. 16, 2012.
|
Decided Jan. 22, 2013.
|
Rehearing En Banc Denied March 11, 2013.

Synopsis

Background: Marijuana advocacy organizations and several individuals filed petition for review of final order of the United States Drug Enforcement Administration (DEA) denying their petition to initiate proceedings to reschedule marijuana.

Holdings: The Court of Appeals, Edwards, Senior Circuit Judge, held that:

[1] disabled veteran had standing to challenge DEA's order, and

[2] substantial evidence supported DEA's finding that no adequate and well-controlled studies had established that marijuana had currently accepted medical use.

Petition denied.

Karen LeCraft Henderson, Circuit Judge, dissented and filed opinion.

West Headnotes (6)

[1] **Federal Civil Procedure**
In general;injury or interest
Federal Civil Procedure
Causation;redressability

To satisfy requirements of Article III standing in case challenging government action, party must allege injury in fact that is fairly traceable to challenged government action, and it must be likely, as opposed to merely speculative, that injury will be redressed by favorable decision. U.S.C.A. Const. Art. 3, § 2, cl. 1.

16 Cases that cite this headnote

[2] **Administrative Law and Procedure**
Right of review, parties, and estoppel

When federal court of appeals reviews agency action, Article III standing must be demonstrated as it would be if such review were conducted in first instance by district court. U.S.C.A. Const. Art. 3, § 2, cl. 1.

14 Cases that cite this headnote

[3] **Administrative Law and Procedure**
Proceedings

To establish standing to seek review of agency action, petitioner's burden of production in court of appeals is same as that of plaintiff moving for summary judgment in district court: it must support each element of its claim to standing by affidavit or other evidence.

21 Cases that cite this headnote

[4] **Federal Civil Procedure**
In general;injury or interest

If parties reasonably, but mistakenly, believed that initial filings before court had sufficiently demonstrated standing, court may request supplemental affidavits and briefing to determine whether parties have met requirements for standing.

8 Cases that cite this headnote

[5] Controlled Substances
Substances regulated;definitions and schedules

Disabled veteran had standing to challenge Drug Enforcement Administration's (DEA) order denying his petition to initiate proceedings to reschedule marijuana, where Department of Veterans Affairs (VA) asked veteran to sign "Contract for Controlled Substance Prescription" that would prohibit him from using medical marijuana, separate VA policy forced him to pay for non-VA physician in Oregon to obtain referral forms required to participate in that state's medical marijuana program, VA's refusal to complete veteran's medical marijuana forms was traceable to DEA's continued decision to classify marijuana as Schedule I drug, and rescheduling marijuana would generate significant increase in likelihood that veteran could obtain completed state medical marijuana forms from VA. Controlled Substances Act, § 201(a), 21 U.S.C.A. § 811(a); 38 C.F.R. § 17.38(a)(1)(xv).

13 Cases that cite this headnote

[6] Controlled Substances
Substances regulated;definitions and schedules

Substantial evidence supported Drug Enforcement Administration's (DEA) finding that no adequate and well-controlled studies had established that marijuana had currently accepted medical use, and thus could not be rescheduled to Schedules III, IV, or V, even though there were more than two hundred peer-reviewed published studies suggesting marijuana's efficacy for various medical uses, where Department of Health and Human Services (DHHS) concluded that there had been no studies similar to what Food and Drug Administration (FDA) required for new drug applications (NDA) that had scientifically assessed efficacy of marijuana for any medical condition. Controlled Substances Act, §§ 201(b), 202(b)(3–5), 21 U.S.C.A. §§ 811(b), 812(b)(3–5).

11 Cases that cite this headnote

***439** On Petition for Review of a Final Order of the United States Drug Enforcement Administration.

Attorneys and Law Firms

Joseph D. Elford argued the cause and filed the briefs for petitioners.

Carl E. Olsen, pro se, filed briefs for intervenor.

Lena Watkins, Senior Trial Attorney, U.S. Department of Justice, argued the cause for respondent. With her on the briefs were Lanny A. Breuer, Assistant Attorney General, and Anita J. Gay, Senior Trial Attorney.

Before: HENDERSON and GARLAND, Circuit Judges, and EDWARDS, Senior Circuit Judge.

Opinion

Opinion for the Court filed by Senior Circuit Judge EDWARDS.

Dissenting opinion filed by Circuit Judge HENDERSON.

EDWARDS, Senior Circuit Judge:

****389** There is a serious debate in the United States over the efficacy of marijuana for medicinal uses. Although marijuana has been legalized in a number of states, it is classified as a "Schedule I" drug by the Drug Enforcement Administration ("DEA"), pursuant to its authority under the Controlled Substances Act of 1970 ("CSA" or "Act"). The DEA has maintained this listing because it has determined that marijuana "has no currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B). Because Schedule I is the most restricted drug classification under the CSA, the production, sale, and use of marijuana are largely banned by federal law. Petitioners in this case—Americans for Safe Access, the Coalition to Reschedule Cannabis, Patients Out of Time, and several individuals—challenge DEA's denial of its petition to initiate proceedings to reschedule marijuana.

The CSA permits the DEA to reclassify drugs to less restrictive schedules according to various statutory criteria, and interested parties can petition the DEA for such action. *See* 21 U.S.C. §§ 811, 812. In October 2002, the Coalition to Reschedule Cannabis petitioned the DEA to reschedule marijuana as a Schedule III, IV, or V drug. *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana ("*Denial* "), ****390 *440** 76 Fed.Reg. 40,552, 40,552 (July 8, 2011). The DEA denied the petition on July 8, 2011, finding that "[t]here is no currently accepted medical use for marijuana in the United States," and that "[t]he limited existing clinical evidence is not adequate to warrant rescheduling of marijuana under the CSA." *Id.* at 40,552, 40,567. On July 22, 2011, Petitioners filed a timely petition for review of the DEA action.

Petitioners claim that "[n]umerous peer-reviewed scientific studies demonstrate that marijuana is effective in treating various medical conditions, but the DEA simply ignores them to conclude that marijuana should remain in Schedule I." Pet'rs' Br. at 20. Petitioners thus contend that the DEA's denial of their petition was arbitrary and capricious and ask this court to remand the case to the agency for further consideration.

The Government, in turn, argues that we should dismiss the petition for review on jurisdictional grounds because Petitioners and Intervenor lack Article III standing. The Government also asserts that, even if the court determines that Petitioners or Intervenor have standing, the petition for review should be denied on the merits. According to the Government, in the record reviewed by the DEA, "there was no available evidence of adequate, well-controlled studies demonstrating marijuana's safety and effectiveness as a medicine and no consensus among experts as to these issues. The enactment of state laws allowing the use of marijuana for medical purposes did not constitute the required science-based evidence." Br. for Resp't at 23.

We deny the Government's jurisdictional challenge because we find that at least one of the named Petitioners, Michael Krawitz, has standing to challenge the agency's action. Krawitz, who is a disabled veteran, is entitled to medical care through the U.S. Department of Veterans Affairs ("VA"). Krawitz has suffered injury-in-fact because he must shoulder a financial cost for services he could otherwise obtain free of charge from the VA. There is a causal connection between the DEA's continuing decision to classify marijuana as a Schedule I drug and the VA's policy of refusing to provide referrals for state medical marijuana programs. And a favorable decision from this court would likely redress Krawitz's injury because, if the DEA rescheduled marijuana, the VA could no longer use the CSA to justify its policy of refusing to complete medical marijuana referral forms. Krawitz thus satisfies the requirements of Article III standing. *See Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560–61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992).

On the merits, the question before the court is not whether marijuana could have some medical benefits. Rather, the limited question that we address is whether the DEA's decision declining to initiate proceedings to reschedule marijuana under the CSA was arbitrary and capricious. These questions are not coterminous. "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983). On the record before us, we hold that the DEA's denial of the rescheduling petition survives review under the deferential arbitrary and capricious standard. The petition asks the DEA to reclassify marijuana as a Schedule III, IV, or V drug, which, under the terms of the CSA, requires a "currently accepted medical use." The DEA's regulations, which we approved in *Alliance for Cannabis Therapeutics v. DEA,* 15 F.3d 1131 (D.C.Cir.1994), define "currently accepted medical use" to require, *inter alia,* "adequate ****391 *441** and well-controlled studies proving efficacy." *Id.* at 1135. We defer to the agency's interpretation of these regulations and find that substantial evidence supports its determination that such studies do not exist.

I. Background

A. The Controlled Substances Act

We have previously described marijuana's listing as a Schedule I drug under the CSA as follows:

> The [CSA] places hazardous drugs in five categories, or schedules, which impose varying restrictions on access to the drugs. *See* 21 U.S.C. § 812 (1988). Marijuana is assigned by statute to Schedule I, the

most restrictive of these. Schedule I drugs may be obtained and used lawfully only by doctors who submit a detailed research protocol for approval by the Food and Drug Administration and who agree to abide by strict recordkeeping and storage rules.

The CSA allows the Attorney General to reschedule a drug if he finds that it does not meet the criteria for the schedule to which it has been assigned. 21 U.S.C. § 811(a). The Attorney General has delegated this authority to the [DEA] Administrator. In rescheduling a drug, the Administrator must consider, *inter alia,* "[s]cientific evidence of [the drug's] pharmacological effect, if known," and "[t]he state of current scientific knowledge regarding the drug or other substance." 21 U.S.C. § 811(c)(2), (3).

A drug is placed in Schedule I if (1) it "has a high potential for abuse," (2) it has "no *currently accepted medical use* in treatment in the United States," and (3) "[t]here is a lack of accepted safety for use of the drug ... under medical supervision." 21 U.S.C. § 812(b)(1) (1988) (emphasis added).

Alliance for Cannabis Therapeutics, 15 F.3d at 1133.

A criterion for Schedule III, IV, and V drugs is the existence of "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(3)–(5). To assess whether there is a "currently accepted medical use," the DEA looks for five necessary elements: "(1) The drug's chemistry must be known and reproducible; (2) There must be adequate safety studies; (3) There must be adequate and well-controlled studies proving efficacy; (4) The drug must be accepted by qualified experts; and (5) The scientific evidence must be widely available." *See Denial,* 76 Fed.Reg. at 40,579. Unlike Schedule I drugs, federal law permits individuals to obtain Schedule II, III, IV, or V drugs for personal medical use with a valid prescription. *See* 21 U.S.C. § 829(a)–(c).

Under the CSA, "any interested party" may petition the DEA to reschedule a drug. 21 U.S.C. § 811(a). In reaching a final scheduling decision, the DEA must request from the Department of Health & Human Services ("DHHS") a "scientific and medical evaluation," as well as a recommendation for the drug's appropriate schedule. 21 U.S.C. § 811(b). These recommendations are binding on the DEA insofar as they rest on scientific and medical determinations. *Id.*

B. Procedural History

As noted above, Petitioners in this case include three advocacy organizations and several individuals. On September 1, 2011, Carl Olsen intervened on behalf of Petitioners. He asserts a religious interest in the use of marijuana.

On October 9, 2002, the Coalition to Reschedule Cannabis petitioned the DEA to reschedule marijuana as a Schedule III, IV, or V drug. *See Petition to Reschedule Cannabis (Marijuana), reprinted in* Joint ****392 *442** Appendix ("J.A.") 46–162. Petitioners assert that marijuana's Schedule I status is inappropriate because, *inter alia,* it "has an accepted medical use in the United States." The petition to reschedule supported this assertion with citations to alleged peer-reviewed, published studies on the potential medical applications of marijuana. *See, e.g., id.* at 38–56, *reprinted in* J.A. 86–104. The DEA submitted Petitioner's rescheduling request to DHHS. *Denial,* 76 Fed.Reg. at 40,552.

In its scientific and medical evaluation, DHHS concluded that marijuana lacks a currently accepted medical use in the United States. In reaching this conclusion, DHHS applied the DEA's established five-prong test, which requires a known and reproducible drug chemistry, adequate safety studies, adequate and well-controlled studies demonstrating efficacy, acceptance of the drug by qualified experts, and widely available scientific evidence. *See id.* at 40,559–60. DHHS stated that there are approximately 483 known components of the cannabis plant. *Id.* at 40,554. The components include 66 compounds called cannabinoids, and marijuana is the only plant in which these compounds are known to exist. *Id.* DHHS stated, however, that marijuana's chemistry was not "known and reproducible" as there had not been "a complete scientific analysis" of its components. *Id.* at 40,552, 40,560. In addition, although there was ongoing research, there were no studies of sufficient quality to assess "the efficacy and full safety profile of marijuana for any medical condition." *Id.* at 40,560. Further, there was "a material conflict of opinion among experts" as to medical safety and efficacy, thereby precluding a finding that qualified experts accepted marijuana as a medicine. *Id.* Additionally, the raw research data typically were not available in a format that would allow "adequate scientific scrutiny of whether the data demonstrate safety or efficacy." *Id.*

DHHS gave the DEA its evaluation and scheduling recommendation on December 6, 2006. *See id.* at 40,552–66. The DEA subsequently denied the petition to reschedule on July 8, 2011, finding that "[t]he limited existing clinical evidence is not adequate to warrant rescheduling of marijuana under the CSA." *Id.* at 40,567.

On July 22, 2011, Petitioners filed a timely petition for review of the DEA's decision. Petitioners argue that the DEA acted arbitrarily and capriciously when it concluded that marijuana lacks a "currently accepted medical use" and has a "high potential for abuse." They ask this court to remand the case to the DEA for reconsideration of its decision. The Government contests these assertions and responds further that Petitioners, for various reasons, lack standing to challenge the DEA's determination in court.

After oral argument, "mindful of our independent obligation to be sure of our jurisdiction," we requested supplemental filings on Petitioners' standing. *Sierra Club v. EPA,* 292 F.3d 895, 898 (D.C.Cir.2002); *see also Am. Library Ass'n v. FCC,* 401 F.3d 489, 492, 496 (D.C.Cir.2005) (requesting supplemental filings on standing where the parties reasonably believed that the initial filings had sufficiently addressed the issue).

II. Analysis

A. Standing

[1] "To satisfy the requirements of Article III standing in a case challenging government action, a party must allege an injury in fact that is fairly traceable to the challenged government action, and 'it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.' " *Nat'l Wrestling* ****393** ***443** *Coaches Ass'n v. U.S. Dep't of Educ.,* 366 F.3d 930, 937 (D.C.Cir.2004) (quoting *Defenders of Wildlife,* 504 U.S. at 560–61, 112 S.Ct. 2130). Petitioners have advanced several theories of standing in this case for each of the various parties. However, to proceed to the merits of their claims, we need only find one party with standing. *See Tozzi v. U.S. Dep't of Health and Human Servs.,* 271 F.3d 301, 310 (D.C.Cir.2001) (declining to address standing of remaining appellants after finding one appellant with standing). Because we conclude that petitioner Michael Krawitz has individual standing, we need not address the issue for the other Petitioners.

1. *Petitioners' Burden of Production*

[2] Before seeking review in this court, Petitioners were under no obligation to establish Article III standing. *See Pfizer Inc. v. Shalala,* 182 F.3d 975, 980 (D.C.Cir.1999) ("An administrative agency, which is not subject to Article III of the Constitution of the United States and related prudential limitations, may issue a declaratory order in mere anticipation of a controversy or simply to resolve an uncertainty."). However, when a federal court of appeals reviews an agency action, Article III standing must be demonstrated "as it would be if such review were conducted in the first instance by the district court." *Sierra Club,* 292 F.3d at 899.

[3] A "petitioner's burden of production in the court of appeals is accordingly the same as that of a plaintiff moving for summary judgment in the district court: it must support each element of its claim to standing 'by affidavit or other evidence.' " *Id.* (quoting *Defenders of Wildlife,* 504 U.S. at 561, 112 S.Ct. 2130). "Its burden of proof is to show a 'substantial probability' that it has been injured, that the defendant caused its injury, and that the court could redress that injury." *Id.* (quoting *Am. Petroleum Inst. v. EPA,* 216 F.3d 50, 63 (D.C.Cir.2000)). "In assessing [Petitioners'] standing, we must assume they will prevail on the merits of their claims." *NB ex rel. Peacock v. District of Columbia,* 682 F.3d 77, 82 (D.C.Cir.2012).

[4] If the parties reasonably, but mistakenly, believed that the initial filings before the court had sufficiently demonstrated standing, the court may—as it did here, *see* Order, Oct. 16, 2012—request supplemental affidavits and briefing to determine whether the parties have met the requirements for standing. *See, e.g., Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.,* 489 F.3d 1279, 1296–97 (D.C.Cir.2007) (noting that it was "prudent" for the court to seek supplemental submissions where there was a question about standing); *Am. Library Ass'n,* 401 F.3d at 492, 496. Petitioners submitted supplemental filings on October 25, 2012, offering factual information in support of Krawitz's standing. *See generally* Supp. Krawitz Aff; Pet'rs' Supp. Br. The Government was afforded an opportunity to respond to Petitioners' supplemental filing and did so on November 1, 2012.

The dissenting opinion argues that we should decline to consider Petitioners' supplemental filings because they

allegedly rest on a new theory of standing and, thus, violate the commands of Circuit Rule 28(a)(7) and, relatedly, *Sierra Club* and its progeny. We disagree.

Circuit Rule 28(a)(7) states:

> In cases involving direct review in this court of administrative actions, the brief of the appellant or petitioner must set forth the basis for the claim of standing.... When the appellant's or petitioner's standing is not apparent from the administrative record, the brief must include arguments and evidence establishing the claim of standing.

***444** ****394** D.C.Cir. R. 28(a)(7). In this case, Petitioners obviously made a serious effort to satisfy the requirements of the rule by setting forth their evidence and arguments in support of standing in their opening brief to the court. *See* Pet'rs' Br. at 5–7. In addition, Circuit Rule 28(a)(7) does not itself impose any jurisdictional requirements. So even assuming, *arguendo,* that Petitioners failed to adhere to the briefing requirements of the rule—which has not been shown in this case—this would not compel *sua sponte* dismissal by the court.

Because the briefing requirements of Circuit Rule 28(a)(7) are not jurisdictional, they have no relevance here unless the Government raised a viable objection pursuant to the rule. The Government raised no such objection to Petitioners' opening brief to the court. Likewise, in its response to Petitioners' supplemental filings, the Government did not contend that Petitioners had infringed Circuit Rule 28(a)(7) or *Sierra Club* and its progeny. Rather, the Government merely noted that Petitioners' supplemental filings stated, "for the first time, that [Krawitz] participates in the 'Oregon Medical Marijuana Program.' " Supp. Br. for Resp't at 1. The Government did not "protest that Krawitz raised a new standing theory," as the dissenting opinion argues. Nor did the Government claim that Petitioners' supplemental submissions on standing should not be addressed by the court because they failed to satisfy the requirements of Circuit Rule 28(a)(7) or the controlling law of the circuit. Indeed, the Government did not even suggest that it was disadvantaged in the adversarial process because of the nature of Petitioners' supplemental filings. *See Sierra Club,* 292 F.3d at 901. The Government's arguments in response to Petitioners' supplemental filings focused on its claim that Petitioners had failed to demonstrate Krawitz's Article III standing.

Although Petitioners made a reasonable effort to satisfy the command of Circuit Rule 28(a)(7) in their opening brief by advancing evidence and arguments in support of standing, the court still had questions regarding whether the facts asserted by Petitioners were sufficient to satisfy the requirements of Article III standing. Therefore, the panel majority, adhering to well-established circuit law, requested supplemental briefing after oral arguments. Nothing in the text of the rule bars the court from requesting such filings. As Judge Kavanaugh noted in *Public Citizen, Inc. v. National Highway Traffic Safety Administration:*

> This Court "retains the discretion to seek supplemental submissions from the parties if it decides that more information is necessary to determine whether petitioners, in fact, have standing." *Am. Library Ass'n v. FCC,* 401 F.3d 489, 494 (D.C.Cir.2005); *see, e.g., Am. Chemistry Council v. Dep't of Transp.,* 468 F.3d 810, 815 (D.C.Cir.2006) ("[W]e raised the issue of standing at oral argument and requested supplemental briefing."); *Action on Smoking & Health v. Dep't of Labor,* 100 F.3d 991, 992 (D.C.Cir.1996) (petitioner "furnished post-argument affidavits at our request"); *see also Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach,* 469 F.3d 129, 132 (D.C.Cir.2006) (supplemental briefing sought where agency first challenged standing after panel opinion issued).

489 F.3d at 1296.

The point here is simple: under the law of this circuit, the members of a panel retain discretion to seek supplemental submissions on standing to fulfill the obligation of the court to determine whether the requirements of Article III have been met. Circuit Rule 28(a)(7) does not preclude ****395** ***445** this, nor does the law of the circuit. The reason is clear. Circuit Rule 28(a)(7) says only that "[w]hen the appellant's or petitioner's standing is not apparent from the administrative record, the brief must include arguments and evidence establishing the claim of

standing." D.C. CIR. R. 28(a)(7). This language is hardly free from ambiguity because what may be "apparent from the administrative record" to one reasonable person may seem less clear to another. And some parties may be unsure whether to explore every conceivable avenue of standing in the first instance in light of the admonition in *Sierra Club* cautioning advocates to submit only "a *concise* recitation of the basis [for standing]." 292 F.3d at 901 (emphasis added); *see also Am. Library Ass'n,* 401 F.3d at 494 (noting that a "gotcha" construction of Circuit Rule 28(a)(7) and *Sierra Club* "is inconsistent with our precedent and would have the undesirable effect of causing parties to include long jurisdictional statements in practically all opening briefs for fear that the court might find their standing less than self-evident"). So it is hardly surprising that it sometimes happens, as it did in this case, that a party advances plausible arguments and offers concrete evidence in support of standing in its opening brief, reasonably assuming that nothing more is necessary, and the members of the panel still have questions. In such circumstances, as our case law shows, the court acts with prudence in applying Circuit Rule 28(a)(7) and in determining whether supplemental submissions are necessary. That is what was done in this case.

2. *The Elements of Standing in this Case*

[5] Petitioners' strongest theory of standing is that Krawitz, a veteran of the United States Air Force, is harmed by the DEA's continued classification of marijuana as a Schedule I drug because it deprives him of services that he is entitled to receive free of charge from the VA. The record indicates that, as a condition of his pain management treatment, Krawitz was asked by VA officials to sign a "Contract for Controlled Substance Prescription" that would prohibit him from, *inter alia,* using medical marijuana. *See* Supp. Krawitz Aff ¶ 7; *see also* Krawitz Aff. Ex.1. Krawitz claims that, because he refused to sign this contract, he is now required to seek pain treatment outside the VA system. *See* Supp. Krawitz Aff. ¶¶ 8–10. Petitioners also contend that Krawitz suffers injury because a separate VA policy forces him to pay for a non-VA physician in Oregon to obtain the referral forms required to participate in that state's medical marijuana program. *See id.* ¶¶ 11–15. Petitioners argue that both of these injuries are caused by the DEA's continued decision to classify marijuana as a Schedule I drug and would be redressed by a favorable decision from this court. In response, the Government argues that Petitioners cannot prove redressability because their conclusion that rescheduling will result in any relief from the VA is too speculative.

The first element of the "irreducible constitutional minimum of standing" is injury in fact, meaning "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Defenders of Wildlife,* 504 U.S. at 560, 112 S.Ct. 2130 (citations omitted) (internal quotation marks omitted). Petitioners clearly establish injury in fact here and Respondents do not seriously question it. As a veteran, Krawitz is entitled to free medical care from the VA system. This care normally includes the "[c]ompletion of forms ... by healthcare professionals based on an examination or knowledge of the veteran's ****396** ***446** condition." 38 C.F.R. § 17.38(a) (1)(xv) (2012). This policy is implemented by VHA Directive 2008–071, which states that "clinicians must honor all requests by patients for completion of non-VHA medical forms." Supp. Krawitz Aff. Ex. 2. However, pursuant to VHA Directive 2011–004: "It is VHA policy to prohibit VA providers from completing forms seeking recommendations or opinions regarding a Veteran's participation in a State marijuana program." Supp. Krawitz Aff. Ex. 1. Thus, to participate in Oregon's medical marijuana program, Krawitz consults with a non-VA physician in Oregon at an annual cost of approximately $140.00. *See* Supp. Krawitz Aff. ¶ 15. In being forced to pay out-of-pocket for care that he could otherwise receive freely from the VA system, Krawitz clearly suffers an " actual" and "concrete" injury to his "legally protected interest." *Defenders of Wildlife,* 504 U.S. at 560, 112 S.Ct. 2130; *cf. Peacock,* 682 F.3d at 83 (holding that "procedural violations that threaten an individual's ability to obtain Medicaid coverage of prescription medications" constitute injury in fact).

Beyond injury in fact, we must determine whether Krawitz's injuries have been caused by the DEA's decision to continue listing marijuana as a Schedule I drug and whether there is a "substantial probability" that the relief requested would redress the injury. *See Nat'l Wrestling Coaches Ass'n,* 366 F.3d at 944. The modest complexity of these questions arises from the fact that the agency action challenged by Petitioners—*i.e.* the DEA's continued classification of marijuana as a Schedule I drug —is not the direct cause of Krawitz's injury. Rather, his injury is caused by the actions of the VA system, which has decided as a matter of policy not to assist patients in

obtaining substances illegal under federal law. This court has addressed standing under analogous circumstances in at least four previous decisions. In those cases, we looked for whether "the record presented substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress." *Id.* at 941. In two of those decisions, we found standing. In the other two, we denied standing. This case more strongly resembles the former two.

In *Block v. Meese,* 793 F.2d 1303, 1308 (D.C.Cir.1986), the plaintiff's company owned exclusive distribution rights to a film that the Justice Department classified as "political propaganda." The plaintiff alleged injury to his economic interests because the classification deterred potential customers. *Id.* To support this assertion, the plaintiff submitted declarations and affidavits from potential customers who were dissuaded from purchasing the film because of its status as "propaganda." *Id.* We held that there was sufficient factual evidence on the record to establish that the harm was "attributable to the classification." *Id.*

In *Tozzi v. U.S. Department of Health and Human Services,* 271 F.3d 301 (D.C.Cir.2001), a manufacturer of PVC plastic challenged a decision by the Secretary of Health and Human Services to list dioxin, a chemical released through the incineration of PVC plastic, as a "known" carcinogen. Though this triggered no new federal regulation, the manufacturer sued on the theory that the classification had prompted state and local entities to regulate to the detriment of the manufacturer. *Id.* at 309. Looking carefully at the record, we found several reasons to conclude that the government action was "at least a substantial factor motivating the third parties' actions." *Id.* at 308. We noted that Congress intended the Secretary's determination "to serve as the federal government's authoritative statement on ****397 *447** the current state of knowledge regarding the carcinogenicity of various chemicals." *Id.* at 309 (citing H.R.Rep. No. 95–1192, at 28, 1978 U.S.C.C.A.N. 9042 (1978) (describing the Secretary's list as a "comprehensive document" containing "all known or suspected carcinogenic agents")). We also noted that the Secretary's list of carcinogens "is widely disseminated and highly influential," and we pointed to several local government restrictions on the use of PVC plastic that explicitly cited the Secretary's determination that dioxin is a "known" carcinogen. *Id.* We also found it significant that the term "carcinogen" is "inherently pejorative and damaging," noting that this increased the probability of an economically harmful third party response. *Id.*

In at least two other cases, we have denied standing when a non-party's conduct was the most direct cause of the alleged injury. In *National Wrestling Coaches Ass'n,* 366 F.3d at 933, "several membership organizations that represent[ed] the interests of collegiate men's wrestling coaches, athletes, and alumni" challenged the government's Title IX enforcement policy, alleging that it had caused several schools to cancel their men's wrestling programs. We denied standing, reasoning that the plaintiffs "offer[ed] nothing but speculation to substantiate their claim that a favorable decision from this court [would] redress their injuries by altering these schools' independent decisions." *Id.* at 937. And in *Renal Physicians Ass'n v. U.S. Department of Health & Human Services,* 489 F.3d 1267 (D.C.Cir.2007), a medical association challenged a government regulation that allegedly depressed their compensation for in-house patient referrals. Once again, this court denied standing, concluding it was "speculative," not "likely," that rescinding the regulation would increase the rate of compensation. *Id.* at 1277.

Turning to the facts of this case, the causation element is satisfied because Krawitz's injury is fairly traceable to the Government's decision to continue listing marijuana as a Schedule I drug. As with the statute in *Tozzi,* Congress made clear when it passed the CSA that the agency's scheduling decisions should serve as the federal government's "authoritative statement" on the legitimacy of particular narcotics and dangerous drugs. 271 F.3d at 309. The House Report for the CSA explains that Congress had already enacted "more than 50 pieces of legislation" relating to the regulation of dangerous drugs. H.R.Rep. No. 91–1444, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571. Congress intended the CSA and its scheduling program to "collect[ ] and conform [ ] these diverse laws in one piece of legislation." *Id.* Furthermore, the Government's classification of marijuana under Schedule I is "inherently pejorative." *Tozzi,* 271 F.3d at 309. Under the terms of the Act, a Schedule I drug "has a high potential for abuse," "has no currently accepted medical use," and has "a lack of accepted safety for use." 21 U.S.C. § 812(b)(1). When the DEA classified marijuana as a Schedule I drug, pursuant to its delegated authority under

the CSA, it announced an authoritative value judgment that surely was meant to affect the policies of third-party federal agencies.

Unsurprisingly, the VA has heeded the DEA's judgment regarding marijuana, thus making the question of causation relatively easy in this case. The record before the court clearly shows that the VA's refusal to complete Krawitz's medical marijuana forms is traceable to the DEA's continued decision to classify marijuana as Schedule I. VHA Directive 2011–004, which prohibits VA providers from completing state medical marijuana forms, cites three times to marijuana's Schedule I ****398** ***448** status. *See* Supp. Krawitz Aff. Ex. 1. Indeed, compliance with the CSA is the only justification the Directive cites for this policy. *See id.* ("[VA] providers must comply with all Federal laws, including the Controlled Substances Act. Marijuana is classified as a Schedule I drug under the Controlled Substances Act."). In light of this evidence, the Government, in its brief to the court, offers nothing more than a perfunctory challenge to causation. This case is nothing like the situations in *National Wrestling* and *Renal Physicians,* where the records contained only weak evidence of causal links between the claimants' injuries and the contested actions of third-party defendants.

The Government focuses most on redressability in contesting Krawitz's standing in this case. The Government argues that rescheduling marijuana would not "generate a significant increase in the likelihood" that the VA would authorize its physicians to recommend marijuana in Oregon. *See Town of Barnstable v. FAA,* 659 F.3d 28, 32 (D.C.Cir.2011). In support of this argument, the Government suggests that, based on the current scientific evidence, there would be no approval by the Food & Drug Administration of medical marijuana, and, absent such approval, VA physicians would be unlikely to recommend a substance that could not be prescribed or readily subjected to supervised use.

The Government's argument against redressability fails. The issue is not whether VA physicians would recommend marijuana usage to patients. The issue is only whether rescheduling marijuana would "generate a significant increase in the likelihood" that Krawitz could obtain completed state medical marijuana forms from the VA. *See id.* Under existing regulations and VHA Directive 2008–071, VA clinicians are subject to a non-discretionary duty to "honor all requests by patients for completion of non-VHA medical forms." *See* 38 C.F.R. § 17.38(a)(1)(xv) (2012); Supp. Krawitz Aff. Ex. 2. The only thing stopping VA clinicians from performing this duty with respect to Krawitz's request is VHA Directive 2011–004. *See* Supp. Krawitz Aff. Ex. 1. The only reason the VA cites for implementing VHA Directive 2011–004 is the classification of marijuana as a Schedule I drug. *Id.* Therefore, were marijuana rescheduled to reflect its potential for medical use, the VA would have no expressed reason to retain VHA Directive 2011–004 and VA clinicians would likely be subject to a non-discretionary duty to complete Krawitz's state medical marijuana forms.

This case is fully distinguishable from *National Wrestling* and *Renal Physicians,* where we found redressability lacking. In both those cases, in addition to a tenuous showing of causation, there were reasons beyond the challenged government action for the third parties to continue the conduct that caused injury to the plaintiffs. In *National Wrestling* there were many factors that led each school to cancel its men's wrestling program, such as "the absence of league sponsorship for wrestling, budgetary concerns, and the need to balance the athletic program with other University priorities." 366 F.3d at 942. Furthermore, Title IX and its accompanying regulations would have remained in force regardless of the case's outcome. *See id.* at 943. Indeed the plaintiffs in *National Wrestling* did not even contest the legality of the Title IX regulations. *Id.* In *Renal Physicians* the court found that the plaintiffs had failed to demonstrate redressability in part because, even if the challenged regulation were struck down, market forces might drive the injurious conduct to continue. *See* 489 F.3d at 1277.

***449** ****399** In contrast, this case is more like *Tozzi.* There we found it significant for redressability that the Secretary's listing of dioxin as a "known" carcinogen was the only such pronouncement by the federal government. *See* 271 F.3d at 309–10. Therefore, if we had set aside that listing, "dioxin activists could no longer point to an authoritative determination by the United States government that dioxin is 'known' to cause cancer in humans.... State and local governments would be less likely to regulate dioxin, and healthcare companies would in turn be less likely to stop using PVC plastic." *Id.* at 310. Here, the Schedule I listing is the authoritative federal declaration of marijuana's illegality and unfitness for medical use. The VA is a federal agency and thus surely

inclined to subscribe to such a federal declaration. Were the substance rescheduled, the VA would lose the only express justification for its policy against completing state medical marijuana forms. Therefore, it is "likely" instead of merely "speculative" that Krawitz's injury would be redressed.

Because Krawitz has Article III standing due to his inability to have the VA system complete his state medical marijuana forms, we need not consider whether his alleged inability to obtain pain management services from the VA in Virginia warrants standing. We also need not consider whether the other Petitioners have standing as well. *See Watt v. Energy Action Educ. Found.,* 454 U.S. 151, 160, 102 S.Ct. 205, 70 L.Ed.2d 309 (1981) ("Because we find [one plaintiff] has standing, we do not consider the standing of the other plaintiffs."); *see also Tozzi,* 271 F.3d at 310 (same).

B. The DEA's Denial of the Petition to Initiate Proceedings to Reschedule Marijuana

[6] On the merits, Petitioners claim that the DEA's final order denying their request to initiate proceedings to reschedule marijuana was arbitrary and capricious. Under the terms of the CSA, marijuana cannot be rescheduled to Schedules III, IV, or V without a "currently accepted medical use." 21 U.S.C. § 812(b)(3)–(5). To assess whether marijuana has such a medical use, the agency applies a five-part test: "(1) The drug's chemistry must be known and reproducible; (2) There must be adequate safety studies; (3) There must be adequate and well-controlled studies proving efficacy; (4) The drug must be accepted by qualified experts; and (5) The scientific evidence must be widely available." *See Denial,* 76 Fed.Reg. 40,552, 40,579. The DEA's five-part test was expressly approved by this court in *Alliance for Cannabis Therapeutics,* 15 F.3d at 1135. Because the agency's factual findings in this case are supported by substantial evidence and because those factual findings reasonably support the agency's final decision not to reschedule marijuana, we must uphold the agency action.

Under the Administrative Procedure Act, a court may set aside an agency's final decision only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "We will not disturb the decision of an agency that has 'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.' " *MD Pharm. Inc. v. DEA,* 133 F.3d 8, 16 (D.C.Cir.1998) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)). Furthermore, the agency's interpretation of its own regulations "must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." ****400** ***450** *Thomas Jefferson Univ. v. Shalala,* 512 U.S. 504, 512, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994). The CSA also directs this court to review the agency's findings of fact for substantial evidence. *See* 21 U.S.C. § 877. Under this standard, we must "ask whether a reasonable mind might accept a particular evidentiary record as adequate to support a conclusion." *Dickinson v. Zurko,* 527 U.S. 150, 162, 119 S.Ct. 1816, 144 L.Ed.2d 143 (1999).

Petitioners do not seriously dispute the propriety of the five-part test approved in *Alliance for Cannabis Therapeutics.* Thus, they are left with the difficult task of showing that the DEA has misapplied its own regulations. Petitioners challenge the agency's reasoning on each of the five factors. However, "[a] drug will be deemed to have a currently accepted medical use for CSA purposes only if all five of the foregoing elements are demonstrated." *Denial,* 76 Fed.Reg. at 40,579. In this case, we need only look at one factor, the existence of "adequate and well-controlled studies proving efficacy," to resolve Petitioners' claim.

In its scientific and medical evaluation, DHHS concluded that "research on the medical use of marijuana ha[d] not progressed to the point that marijuana [could] be considered to have a 'currently accepted medical use' or a 'currently accepted medical use with severe restrictions.' " *Id.* at 40,560. As noted above, DHHS' recommendations are binding on the DEA insofar as they rest on scientific and medical determinations. 21 U.S.C. § 811(b). After an exhaustive examination of the issue, the DEA, adhering to DHHS' recommendation, reached the following conclusion:

> To establish accepted medical use, the effectiveness of a drug must be established in well-controlled, well-designed, well-conducted, and well-documented scientific studies, including studies performed in a large number of patients (57 FR

> 10499, 1992). To date, such studies have not been performed. The small clinical trial studies with limited patients and short duration are not sufficient to establish medical utility. Studies of longer duration are needed to fully characterize the drug's efficacy and safety profile. Scientific reliability must be established in multiple clinical studies. Furthermore, anecdotal reports and isolated case reports are not adequate evidence to support an accepted medical use of marijuana (57 FR 10499, 1992). The evidence from clinical research and reviews of earlier clinical research does not meet this standard.

Denial, 76 Fed.Reg. at 40,579.

Petitioners contest these findings, arguing that their petition to reschedule marijuana cites more than two hundred peer-reviewed published studies demonstrating marijuana's efficacy for various medical uses, and that those studies were largely ignored by the agency. As we explain below, Petitioners' singular reliance on "peer-reviewed" studies misses the mark. It is also noteworthy that Petitioners' brief to this court fails to convincingly highlight any significant studies allegedly ignored by DHHS or the DEA.

Petitioners' argument focuses at length on one study—the March 1999 report from the Institute of Medicine ("IOM")—that was clearly addressed by the DEA. The IOM report does indeed suggest that marijuana might have medical benefits. *See, e.g.,* INST. OF MEDICINE, MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE 177 (Janet E. Joy et al. eds., 1999), *reprinted in* J.A. 208 ("For patients such as those with AIDS or who are undergoing chemotherapy, and who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad-spectrum relief not found in any other single medication."). However, the DEA ****401 *451** fairly construed this report as calling for "more and better studies to determine potential medical applications of marijuana" and not as sufficient proof of medical efficacy itself. *Denial,* 76 Fed.Reg. at 40,580. In other words, "while the IOM report did support further research into therapeutic uses of cannabinoids, the IOM report did not *'recognize marijuana's accepted medical use'* but rather the potential therapeutic utility of cannabinoids." *Id.*

At bottom, the parties' dispute in this case turns on the agency's interpretation of its own regulations. Petitioners construe "adequate and well-controlled studies" to mean peer-reviewed, published studies suggesting marijuana's medical efficacy. The DEA, in contrast, interprets that factor to require something more scientifically rigorous. In explaining its conclusion that there is a lack of clinical evidence establishing marijuana's "currently accepted medical use," the agency said the following:

> [A] limited number of Phase I investigations have been conducted as approved by the FDA. Clinical trials, however, generally proceed in three phases. See 21 C.F.R. 312.21 (2010). Phase I trials encompass initial testing in human subjects, generally involving 20 to 80 patients. *Id.* They are designed primarily to assess initial safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary studies of potential therapeutic benefit. (62 FR 66113, 1997). Phase II and Phase III studies involve successively larger groups of patients: usually no more than several hundred subjects in Phase II and usually from several hundred to several thousand in Phase III. 21 C.F.R. 312.21. These studies are designed primarily to explore (Phase II) and to demonstrate or confirm (Phase III) therapeutic efficacy and benefit in patients. (62 FR 66113, 1997). No Phase II or Phase III studies of marijuana have been conducted. Even in 2001, DHHS acknowledged that there is "suggestive evidence that marijuana may have beneficial therapeutic effects in relieving spasticity associated with multiple sclerosis, as an analgesic, as an antiemetic, as an appetite stimulant and as a bronchodilator." (66 FR 20038, 2001). But there is still no data from adequate and well-controlled clinical trials that meets the requisite standard to warrant rescheduling.

Id. at 40,579–80.

The DEA interprets "adequate and well-controlled studies" to mean studies similar to what the Food and Drug Administration ("FDA") requires for a New Drug Application ("NDA"). *See id.* at 40,562. DHHS found that "there have been no NDA-quality studies that

have scientifically assessed the efficacy of marijuana for any medical condition." *Id.* It is well understood that, under FDA protocols, "adequate and well-controlled investigations" require "clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. § 355(d). This is a rigorous standard. *See, e.g., Edison Pharm. Co. v. FDA,* 600 F.2d 831, 843 (D.C.Cir.1979) (holding that substantial evidence supported the FDA's conclusion that double-blind testing of a new drug was necessary before the drug could be administered to cardiac patients); *Holland–Rantos Co. v. U.S. Dep't of Health, Educ. and Welfare,* 587 F.2d 1173, 1174 (D.C.Cir.1978) (refusing to construe the requirement of a "well-controlled investigation" in a "self-defeating fashion").

***452** ****402** Contrary to what Petitioners suggest, something more than "peer-reviewed" studies is required to satisfy DEA's standard, and for good reason. "[S]cientists understand that peer review per se provides only a minimal assurance of quality, and that the public conception of peer review as a stamp of authentication is far from the truth." Charles Jennings, *Quality and Value: The True Purpose of Peer Review,* Nature.com (2006), http://www. nature.com/nature/peerreview/debate/nature05032.html; *see also* Lynn S. McCarty et al., *Information Quality in Regulatory Decision Making: Peer Review versus Good Laboratory Practice,* 120 ENVTL. HEALTH PERSP. 927, 930 (2012) ("It is difficult to extract from the extensive body of work and commentary published over the last 25–30 years that scientific journal peer review is a coherent, consistent, reliable, evaluative procedure.... [T]he opposite conclusion may be more accurate."). Petitioners may have cited some peer-reviewed articles in support of their position, but they have not pointed to "adequate and well-controlled studies" confirming the efficacy of marijuana for medicinal uses. If, as is the case here, "there is substantial evidence to support the [agency's] finding that the[ ] studies [offered by petitioner] are not helpful, then petitioner must fail." *Unimed, Inc. v. Richardson,* 458 F.2d 787, 789 (D.C.Cir.1972). In making this assessment, we must "remind ourselves that our role in the Congressional scheme is not to give an independent judgment of our own, but rather to determine whether the expert agency entrusted with regulatory responsibility has taken an irrational or arbitrary view of the evidence assembled before it." *Id.*

The DEA's construction of its regulation is eminently reasonable. Therefore, we are obliged to defer to the agency's interpretation of "adequate and well-controlled studies." *See Thomas Jefferson Univ.,* 512 U.S. at 512, 114 S.Ct. 2381 (deferring to "an agency's interpretation of its own regulations"). Judged against the DEA's standard, we find nothing in the record that could move us to conclude that the agency failed to prove by substantial evidence that such studies confirming marijuana's medical efficacy do not exist.

Finally, Petitioners suggested during oral argument that the Government had foreclosed the research that would be necessary to create sufficiently reliable clinical studies of marijuana's medical efficacy. Because Petitioners did not properly raise this issue with the DEA and there is nothing in the record to support it, we do not consider it here. We note, however, that DHHS' recommendation explained that "[t]he opportunity for scientists to conduct clinical research with marijuana exists under the [D]HHS policy supporting clinical research with botanical marijuana." *Denial,* 76 Fed.Reg. at 40,562. Thus, it appears that adequate and well-controlled studies are wanting not because they have been foreclosed but because they have not been completed.

III. Conclusion

For the reasons discussed above, we hereby deny the petition for review.

KAREN LeCRAFT HENDERSON, Circuit Judge, dissenting:

Over a decade ago, our court was compelled to remind all petitioners of first principles, namely, they must assure us that they meet Article III's case or controversy requirement if their standing is not "self-evident" from the record. *Sierra Club v. EPA,* 292 F.3d 895, 900 (D.C.Cir.2002). We subsequently transformed the holding into D.C. Circuit Rule 28(a)(7) to tell the litigating world we really meant ****403** ***453** what we said in *Sierra Club.* Since then, our precedent and our Rule

seem to have been honored more in the breach than in compliance. We have issued pre-argument orders alerting the parties to be prepared to address standing at oral argument because of our uncertainty regarding standing based on the briefing. *See, e.g.,* Order, *Cherry v. FCC,* No. 10–1151 (Feb. 23, 2012). We have allowed a second —late—opportunity to establish standing at the reply brief stage. *See Exxon Mobil Corp. v. FERC,* 571 F.3d 1208, 1219 (D.C.Cir.2009). We have even asked for post-argument briefs based on the petitioner's failure theretofore to establish standing. *See Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.,* 489 F.3d 1279, 1297 (D.C.Cir.2007); *see also id.* at 1297–99 (Sentelle, J., dissenting). Some of us have been more forgiving than others. *See, e.g., Am. Library Ass'n v. FCC,* 401 F.3d 489, 492 (D.C.Cir.2005) (Edwards, J.) (articulating *Sierra Club* exception if petitioners "reasonably [but mistakenly] believed their standing [was] self-evident"); *Communities Against Runway Expansion, Inc. v. FAA,* 355 F.3d 678, 685 (D.C.Cir.2004) (Edwards, J.) (excusing belated submissions attached to reply brief because they made standing "patently obvious"); *KERM, Inc. v. FCC,* 353 F.3d 57, 60–61 (D.C.Cir.2004) (noting petitioner's belated assertion of standing but nonetheless analyzing standing arguments) (Edwards, J.). Perhaps it is too late to blow the whistle but I do not share the solicitude my colleagues show the petitioners—no novices on their merits claim [1] —here, especially in view of the fact that their standing theory for the lone petitioner *with standing* is, post-argument, brand new.

Petitioners Americans for Safe Access (ASA), Coalition for Rescheduling Cannabis (CRC), Patients Out of Time (POT), Kathy Jordan, Michael Krawitz, Richard Steeb and William Britt (petitioners) petition for review of the decision of the Drug Enforcement Administration (DEA or Agency), *Denial of Petition To Initiate Proceedings To Reschedule Marijuana,* 76 Fed.Reg. 40,552 (Jul. 8, 2011), denying their petition to initiate rulemaking proceedings to reschedule marijuana as a Schedule I substance under the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.* The majority determines—based on his post-argument submission—that Krawitz has standing and thus proceeds to the merits. I believe the post-argument submission should not have been allowed. Once allowed, it should not have been considered because it asserts a new theory of standing. The remaining petitioners also lack standing and therefore the petition for review should have been dismissed.

I.

To press their claim, the petitioners must establish that at least one of them has standing. *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.,* 547 U.S. 47, 52 n. 2, 126 S.Ct. 1297, 164 L.Ed.2d 156 (2006). Article III standing has three elements: "(1) injury-in-fact, (2) causation, and (3) redressability." *Sierra Club,* 292 F.3d at 898. Reviewing administrative action, we require that the petitioner "either identify in that record evidence sufficient to support its standing to seek review or, if there is none because standing was not an issue before the agency, submit additional evidence to the court of appeals." ****404 *454** *Id.* at 899. Three of the seven petitioners—ASA, CRC and POT—are organizations. The remaining petitioners—Jordan, Krawitz, Steeb and Britt—are members of ASA (ASA Members). Neither CRC nor POT has attempted to establish its standing. The remaining petitioners assert three theories of standing: ASA's standing as an association, the individual standing of the four ASA Members and ASA's standing representing its members. I begin with Krawitz's standing as he is the one whose standing the majority affirms.

II.

A. Krawitz's Standing

In their opening brief, the petitioners did not distinguish Krawitz from the other ASA Members. With that brief, the petitioners submitted an affidavit executed by Krawitz. Krawitz declared therein that he was a disabled veteran and that he used marijuana to alleviate his pain. Krawitz explained that he received medical benefits from the United States Department of Veterans Affairs (VA) but that

> [b]ecause of my medical cannabis use, *I am currently being denied my prescription pain treatment by the VA* based upon their illegal drug policy that routinely, administratively, denies pain treatment as punishment for using cannabis by veterans

> that do not live in a state with legal medical cannabis, based on VA's policy regarding medical cannabis, which, among other things, prohibits VA physicians from discussing therapeutic uses of cannabis with me. A true and correct copy of that policy is attached hereto as Exhibit 1. Although the bulk of my medical care still occurs at VA hospital I am now seeing an outside M.D. for my pain treatment under the VA's fee basis program.

Krawitz Aff. ¶ 4 (bracketed text omitted) (emphasis added). To his affidavit, Krawitz attached a document entitled "CONTRACT FOR CONTROLLED SUBSTANCE PRESCRIPTION." Krawitz Aff. Ex. 1 at 1. The document is confusing at best, and, at worst, makes it appear as if the VA itself could be providing Krawitz with marijuana. *See, e.g.,* Krawitz Aff. Ex. 1 at 1 ("I will not request or accept controlled substance medication from any other physician or individual while I am receiving such medication from my physician at the Salem VAMC Clinic"). The petitioners, unhelpfully, provided no explanation of the contract in either their opening or their reply briefs.

Krawitz's affidavit and exhibit failed to establish standing. His affidavit boiled down to the averment that he was injured because the VA had a drug policy that "denies pain treatment as punishment for using cannabis by veterans that do not live *in a state with legal medical cannabis,*" Krawitz Aff. ¶ 4 (emphasis added). But Krawitz challenges federal, not state law, and he has provided no evidence or argument that rescheduling marijuana under the CSA will change the way any state regulates marijuana. Indeed, state marijuana legislation in recent years has distinctly diverged from federal law. *See, e.g., Gettman v. DEA,* 290 F.3d 430, 435 (D.C.Cir.2002) ("[S]peculative claims dependent upon the actions of third parties do not create standing.").

Notwithstanding the failure of the petitioners' showing regarding standing—specifically, Krawitz's affidavit with attachment—we issued a post-argument order, giving them yet another opportunity[2] to ***455 **405** "clarify and amplify the assertions made in paragraph 4 of the Affidavit of Michael Krawitz regarding his individual standing." I dissented from the order because our precedent unequivocally directs the method by which a petitioner must establish standing, a method the petitioners ignored. In 2002, we explained:

> Henceforth, therefore, a petitioner whose standing is not self-evident should establish its standing by the submission of its arguments and any affidavits or other evidence appurtenant thereto *at the first appropriate point in the review proceeding.* In some cases that will be in response to a motion to dismiss for want of standing; in cases in which no such motion has been made, it will be with the petitioner's opening brief—and not, as in this case, in reply to the brief of the respondent agency. In either procedural context the petitioner may carry its burden of production by citing any record evidence relevant to its claim of standing and, if necessary, appending to its filing additional affidavits or other evidence sufficient to support its claim. In its opening brief, the petitioner should also include in the "Jurisdictional Statement" a concise recitation of the basis upon which it claims standing.
>
> .... [A]ll too often the petitioner does not submit evidence of those facts with its opening brief and the respondent is therefore left to flail at the unknown in an attempt to prove the negative, or the court raises its own question about the petitioner's standing and ends up having to direct the parties to file supplemental briefs in order to ensure that the issue is joined in a fair and thorough adversarial process.

Sierra Club, 292 F.3d at 900–01 (emphasis added). We cautioned that "[a]bsent good cause shown ... a litigant should not expect the court" to depart from the above procedure. *Id.* at 900. *Sierra Club* does not make the petitioner's showing optional—it instead constitutes binding Circuit law. As noted earlier, we codified *Sierra Club* in our Circuit Rules as follows:

> In cases involving direct review in this court of administrative actions, the brief of the appellant or petitioner must set forth the basis for the claim of standing. This section, entitled "Standing," must follow the summary

> of argument and immediately precede the argument. When the appellant's or petitioner's standing is not apparent from the administrative record, the brief must include arguments and evidence establishing the claim of standing. *See Sierra Club v. EPA,* 292 F.3d 895, 900–01 (D.C.Cir.2002). If the evidence is lengthy, and not contained in the administrative record, it may be presented in a separate addendum to the brief.

D.C.Cir. R. 28(a)(7); *see also Int'l Bhd. of Teamsters v. Transp. Sec. Admin.,* 429 F.3d 1130, 1134–35 & n. 2 (D.C.Cir.2005) (dismissing petition for review because petitioner "first addressed its standing at oral argument, in response to questioning by the court"); *Exxon Mobil,* 571 F.3d at 1220 (declining to consider standing theory first articulated at oral argument). The petitioners had made no effort to show "good cause" [3] for their initial failure to establish standing. And, this being so, I ****406 *456** opposed giving them yet another opportunity to establish standing.

In response to the order, the petitioners filed a supplemental brief with a new Krawitz affidavit, featuring a new theory of standing. He avers, *for the first time,* that he spends one or two months per year in Oregon, where he obtains marijuana for medical use. To obtain medicinal marijuana in Oregon, a person must apply for a registration card, which requires him to submit annually "[v]alid, written documentation from the person's attending physician stating that the person has been diagnosed with a debilitating medical condition and that the medical use of marijuana may mitigate the symptoms or effects of the person's debilitating medical condition." *See* Or. Rev. Stat § 475.309(2), (7)(C)(i). Krawitz complains that the VA has a policy —VHA Directive 2011–004—prohibiting its physicians from providing such documentation, thus forcing him to pay $140.00 per year to consult an Oregon physician who can so provide.

Unlike his original affidavit—in which Krawitz declared that the VA denied him pain treatment—Krawitz's new affidavit states that the VA is *not* denying him treatment for pain based on his marijuana use. Moreover, VHA Directive 2011–004 makes plain that the VA does *not* have a policy of denying pain treatment to veterans who are using marijuana, instead declaring: "VHA policy does not administratively prohibit Veterans who participate in State marijuana programs from also participating in VHA ... pain control programs ... [D]ecisions to modify treatment plans in those situations need to be made by individual providers in partnership with their patients." VHA Directive 2011–004 (Jan. 31, 2011), *available at* http://www.va.gov/VHAPUBLICATIONS/View Publication.asp?pub—ID=2362.

In other words, Krawitz asserts a new injury-in-fact—a $140.00 per year pocketbook injury—that is nowhere to be found in even the most generous reading of his original affidavit. As we have earlier held, however, "we are aware of no authority which permits a party to assert an entirely new injury (and thus, an entirely new theory of standing) in its *reply* brief." *Coal. for Responsible Regulation, Inc. v. EPA,* 684 F.3d 102, 147 (D.C.Cir.2012) (per curiam) (emphasis added). And plainly—until today—we have *never* permitted a petitioner to assert an entirely new injury and theory of standing in a post-argument submission. [4]

Because my colleagues found that Krawitz has standing, they proceeded directly to the merits. *Rumsfeld,* 547 U.S. at 52 n. 2, 126 S.Ct. 1297 ("[T]he presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement."). Because I believe Krawitz lacks standing, I must consider the other petitioners' standing.

457 **407** ***B. Other Petitioners' Standing

ASA's Organizational Standing

In their opening brief, the petitioners asserted that ASA has standing as an organization because it must expend "significant resources combatting the DEA's positions respecting marijuana's medical use and abuse potential, which would be redressed by a favorable decision." Pet'rs' Opening Br. 6. In their reply brief, they argue "ASA has been unable to employ a full-time California Director to interface with government agencies in California and those of other medical marijuana states to implement state law, in particular, the regulation of medical marijuana

dispensaries." Pet'rs' Reply Br. 3 (citing Sherer Supp. Aff. ¶ 2).

An organization does not have standing based on a mere " 'setback to [its] abstract social interests.' " *Nat'l Ass'n of Home Builders v. EPA,* 667 F.3d 6, 11 (D.C.Cir.2011) (quoting *Nat'l Taxpayers Union, Inc. v. United States,* 68 F.3d 1428, 1433 (D.C.Cir.1995)). An association's "self-serving observation that it has expended resources to educate its members and others regarding [a challenged statutory provision] does not present an injury in fact," particularly if "[t]here is no evidence that [the challenged provision] has subjected [the association] to operational costs beyond those normally expended to review, challenge, and educate the public." *Nat'l Taxpayers Union,* 68 F.3d at 1434. Nor is standing found "when the only 'injury' arises from the effect of the regulations on the organizations' lobbying activities." *Ctr. for Law & Educ. v. Dep't of Educ.,* 396 F.3d 1152, 1161 (D.C.Cir.2005).

The petitioners support ASA's organizational standing by relying on *Havens Realty Corp. v. Coleman,* 455 U.S. 363, 102 S.Ct. 1114, 71 L.Ed.2d 214 (1982). In *Havens,* a nonprofit corporation sued the owner of an apartment complex for damages under the Fair Housing Act because "the [discriminatory] practices of [the apartment complex] had frustrated the organization's counseling and referral services, with a consequent drain on resources." *Id.* at 369, 102 S.Ct. 1114. The Supreme Court upheld the nonprofit's standing because the "practices have perceptibly impaired [its] ability to provide counseling and referral services for low-and moderate-income homeseekers.... Such concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources—constitutes far more than simply a setback to the organization's abstract social interests." *Id.* at 379, 102 S.Ct. 1114.

We considered a similar standing issue in *Spann v. Colonial Vill., Inc.,* 899 F.2d 24 (D.C.Cir.1990), where we found two organizations had standing to assert a claim for injunctive relief and damages under the Fair Housing Act because the discriminatory conduct "required [plaintiffs] to devote more time, effort, and money to endeavors designed to educate not only black home buyers and renters, but the D.C. area real estate industry and the public that racial preference in housing is indeed illegal." *Id.* at 27; *see also id.* at 28–29 ("increased education and counseling could plausibly required"). We emphasized "the difference between this suit and one presenting only abstract concerns or complaints about government policy;" specifically, the plaintiffs "do not seek to compel government action, [or] to involve the courts in a matter that could be resolved in the political branches" but rather "are private actors suing other private actors, traditional grist for the judicial mill." *Id.* at 30.

Unlike *Havens* and *Spann,* this case does not involve "private actors suing other ****408** ***458** private actors, traditional grist for the judicial mill." *Id.* Nor does it involve a suit for damages under a federal statute (like the Fair Housing Act) that creates a cause of action. Instead, it serves "to compel government action, [and] to involve the courts in a matter that could be resolved in the political branches." [5] *Id.* Moreover, ASA's asserted injury—that it must spend money to "educate the public about the true benefits of marijuana" and to "lobby[ ] local, state and federal governments," Sherer Aff. ¶¶ 8, 12—is essentially an argument that ASA cannot allocate issue advocacy expenses in the way it would prefer, which is insufficient to establish standing. *See Ctr. for Law & Educ.,* 396 F.3d at 1162 ("The only 'service' impaired is pure issue-advocacy—the very type of activity distinguished by *Havens*."). Nor have the petitioners explained how ASA would be able to avoid these expenditures if marijuana were rescheduled. For example, ASA would still need to meet the substantial scientific evidence—identified by DEA—that rejects its position regarding marijuana's medical efficacy. Similarly, ASA would need to counter statements made by entities other than DEA (including the very state and local governments they are lobbying) that oppose legalization of marijuana for medical use. *See Nat'l Taxpayers Union,* 68 F.3d at 1434 ("There is no evidence that [the challenged statutory provision] has subjected [the association] to operational costs beyond those normally expended to review, challenge, and educate the public").

The closest the petitioners come to establishing an injury to ASA as an organization is their statement that "[s]ince 2006, due to expenditures made by ASA to offset the false statements made by the [DEA and HHS] that marijuana has no medical use and is extremely dangerous, ASA has been unable to hire a full-time California Director." Sherer Supp. Aff ¶ 2. But whatever happened in 2006 that prevented ASA from hiring a full-time California Director, it could not have been marijuana's Schedule I listing because marijuana has been so listed *since 1970.*

See 21 U.S.C. § 812(c) (establishing initial schedules of controlled substances).

ASA Members' Individual Standing

The petitioners also assert that the three ASA Members other than Krawitz have their own individual standing. In their opening brief, they assert that if marijuana were removed from Schedule I, the three would no longer be "deterred from cultivating their own medicine ... since they would likely be afforded a medical necessity defense in federal court." Pet'rs' Opening Br. 7. Nevertheless, "speculative claims dependent upon the actions of third parties do not create standing." *Gettman,* 290 F.3d at 434–35 (dismissing petition—for lack of standing—of marijuana researcher who argued DEA decision not to reschedule marijuana decreased his potential customers and diminished his ability to conduct research). Here, the causal chain is even more speculative. ASA's Members allege that their injury could be redressed by a favorable ruling because (1) if marijuana were rescheduled; *and* (2) if they chose to cultivate marijuana; *and* (3) if the federal government detected the cultivation; *and* (4) if the federal government prosecuted the cultivators; *and* (5) if the cultivators asserted a medical necessity defense; *and* (6) if the court accepted the medical necessity defense; ***459 **409** *then* (7) they would avoid criminal liability for cultivation. [6]

Moreover, the existence of a medical necessity defense for marijuana cultivation is tenuous at best. The petitioners assert that marijuana's Schedule I status is the only thing preventing courts from recognizing the defense, citing *United States v. Oakland Cannabis Buyers' Coop.,* 532 U.S. 483, 121 S.Ct. 1711, 149 L.Ed.2d 722 (2001), which held that no medical necessity defense exists for the illegal distribution of various controlled substances, including marijuana, because the CSA "reflects a determination that marijuana has no medical benefits worthy of an exception." *Id.* at 491, 121 S.Ct. 1711. The Court's reasoning made clear, however, that rescheduling marijuana would not necessarily produce a medical necessity defense because "it is an open question whether federal courts ever have authority to recognize a necessity defense not provided by statute." *Id.* at 490, 121 S.Ct. 1711 ("Even at common law, the defense of necessity was somewhat controversial.").

Assuming *arguendo* the three ASA Members decide to cultivate marijuana, it is far from likely that a federal prosecutor would exercise his discretion to prosecute. In fact, the Department of Justice recently suggested that it did not consider it an efficient use of resources to prosecute "individuals with cancer or other serious illnesses who use marijuana as part of a recommended treatment regimen consistent with applicable law, or those caregivers in clear and unambiguous compliance with existing state law who provide such individuals with marijuana." David W. Ogden, Deputy Attorney General, U.S. Dep't of Justice, *Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana* (Oct 19, 2009), *available at* http://www.justice. gov/opa/documents/medical-marijuana.pdf. [7]

ASA's Representational Standing

Finally, I believe that ASA lacks standing to bring this action on behalf of its members because ASA has failed to establish that one of its members has standing to sue in his own right. *Fund Democracy, LLC v. SEC,* 278 F.3d 21, 25 (D.C.Cir.2002) ("An association only has standing to bring suit on behalf of its members when[, *inter alia,*] its members would otherwise have standing to sue in their own right....") [8]

***460 **410** Because I believe that no petitioner possesses Article III standing, I respectfully dissent. [9]

All Citations

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Footnotes

1 Two individuals who joined the petitioners' quest to reschedule marijuana at the administrative stage—Jon Gettman and High Times—had petitioned for review of DEA's earlier failure to reschedule marijuana. We dismissed their petition for lack of standing. *Gettman v. DEA,* 290 F.3d 430 (D.C.Cir.2002).

2 The petitioners' reply brief, while providing a more detailed standing argument and including (improperly) a supplemental affidavit, was nonetheless deficient. With their post-argument opportunity to supplement, the petitioners have now been allowed three chances to establish standing.

3 We have found "good cause" if, for example, a petitioner had a reasonable belief its standing was self-evident, *see Am. Library Ass'n,* 401 F.3d at 492 or if supplemental declarations submitted with a reply brief made standing "patently obvious," *see Communities Against Runway Expansion,* 355 F.3d at 685.

4 Oregon's policy—not that of the VA or of DEA—is the direct cause of Krawitz's annual $140.00 injury because, if Oregon eliminated the physician documentation requirement, Krawitz's injury would be immediately redressed. By contrast, if we ordered DEA to reschedule marijuana, the VA *might* rescind VHA Directive 2011–004 and Krawitz's VA physician *might* complete the Oregon documentation for Krawitz. *See Memorandum Regarding State Medical Marijuana Registration Forms* from Department of Veterans Affairs General Counsel to Under Secretary of Health at 5 (May 21, 2008) (cited by VHA Directive 2011–004) (stating, prior to promulgation of VHA Directive 2011–004, "[a]t present, the language of 38 C.F.R. § 17.38(c)(3) does not require the completion of [medical marijuana] forms by VHA physicians [because t]his regulatory provision eliminates non-FDA approved drugs from the basic care provided to veterans"); *see also* VHA Directive 2011–004, *supra.*

5 ASA and similar organizations have had great *political* success in recent years. *See, e.g.,* Louise Radnofsky, *Voters Weigh Social Issues,* Wall St. J., Nov. 7, 2012 (seventeen states and District of Columbia have legalized the medicinal use of marijuana; Washington and Colorado have legalized marijuana for recreational use).

6 The ASA Members' standing argument is reminiscent of the nursery rhyme "For Want of a Nail:"

> For want of a nail, the shoe was lost,
> For want of the shoe, the horse was lost,
> For want of the horse, the rider was lost,
> For want of the rider, the battle was lost,
> For want of the battle, the kingdom was lost,
> And all for the want of a horse-shoe nail!

Stuart Minor Benjamin, *Proactive Legislation and the First Amendment,* 99 MICH. L.REV. 281, 329 n. 168 (2000) (quoting Mother Goose's Nursery Rhymes 191 (Walter Jerrold ed., Alfred A. Knopf Inc.1993) (1903)). While a lost nail may lead to a lost kingdom, establishing Article III standing requires more than a good imagination.

7 *But see* James M. Cole, Deputy Attorney General, U.S. Dep't of Justice, *Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use* (June 29, 2011), *available at* http:// www.azdhs.gov/ medicalmarijuana/documents/resources/ guidance_regarding_ medical_marijuana.pdf (Ogden Memorandum was not intended to shield from prosecution "planned facilities" with "revenue projections of millions of dollars" and that "[p]ersons who are in the business of cultivating, selling or distributing marijuana ... are in violation of the Controlled Substances Act, regardless of state law").

8 In addition, intervenor Carl Olsen lacks standing. He concedes that his injury can be redressed only if marijuana is removed from all CSA schedules, a remedy the petitioners do not seek. Furthermore, Olsen makes distinct arguments from those of the petitioners—for example, he invokes "federalism"—and thus he cannot supply the requisite standing. *See Ill. Bell Tel. Co. v. FCC,* 911 F.2d 776, 786 (D.C.Cir.1990).

9 While my dissent begins with the observation that some of my colleagues are more forgiving than others in allowing exceptions to the *Sierra Club* rule, codified in Rule 28(a)(7), it is now apparent the majority would have the exceptions swallow the Rule. Ignoring our longstanding precedent that arguments may not be made for the first time in a reply brief, *see, e.g., Porter v. Shah,* 606 F.3d 809, 814 n. 3 (D.C.Cir.2010), during oral argument, *see, e.g., United States v. Southerland,* 486 F.3d 1355, 1360 (D.C.Cir.2007), or during rebuttal oral argument, *see, e.g., Coal. of Battery Recyclers Ass'n v. EPA,* 604 F.3d 613, 623 (D.C.Cir.2010)—they would revise Rule 28(a)(7) to create a "reasonable belief/effort" mega-exception permitting any party to assert an entirely new standing theory not only in a reply brief or during oral argument but even after oral argument.

The elephant in the room is that we do not allow "a party to assert an entirely new injury (and thus, an entirely new theory of standing) in its reply brief," *Coal. for Responsible Regulation,* 684 F.3d at 147, much less in a supplemental brief. As already noted, in his supplemental affidavit Krawitz raises a new injury and, thus, a new theory of standing. Yet in response to this undisputed fact, my colleagues do not attempt to claim Krawitz's theory of standing is *not* new. Instead, they skirt the issue by noting that DEA did not so argue in its supplemental brief. First and foremost, whether a party has established standing is for the court—not the parties—to decide. *See, e.g., Animal Legal Defense Fund, Inc. v. Espy,* 29 F.3d 720, 723 n. 2 (D.C.Cir.1994) ("Standing ... is a jurisdictional issue which cannot be waived or conceded."); *cf. Am.*

Library Ass'n, 401 F.3d at 495 ("[W]hether standing is self-evident must be judged from the perspective of the court[.]"). And the majority's statement that Rule 28(a)(7) (let alone *Sierra Club*) "ha[s] no relevance" absent an objection, *see* Maj. Op. 444, is wholly unsupported. In any event, DEA *did* protest that Krawitz raised a new standing theory. While DEA did not cite *Sierra Club* or Rule 28(a)(7), it maintained that Krawitz "states, for the first time, that he participates in the 'Oregon Medical Marijuana Program;' " and now "claims not that he is denied VA pain treatment in Oregon but that the VA prohibits its physicians from completing a state program form." Resp't Supp. Br. 1.

The majority's new exception declares that "[i]f the parties reasonably, but mistakenly, believed that the initial filings before the court had sufficiently demonstrated standing, the court may—as it did here—request supplemental affidavits and briefing." Maj. Op. 443 (citing *Pub. Citizen, Inc.,* 489 F.3d at 1296–97; *Am. Library Ass'n,* 401 F.3d at 492, 496); *see also* Maj. Op. 444 (suggesting we should allow supplemental briefing if parties make a "reasonable effort" to satisfy Rule 28(a)(7)). But *Public Citizen* and *American Library Association* establish no such exception to our Rule. *See, e.g., Am. Library Ass'n,* 401 F.3d at 492 (establishing exception if the petitioners "reasonably [but mistakenly] believed their standing [was] self-evident"). Moreover, I do not see how the majority's new exception would not apply in virtually every case—presumably parties do not make "unreasonable" standing arguments or fail to use reasonable efforts to establish their standing.