

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 19, 2022

Decided June 10, 2022

No. 20-1376

HEMP INDUSTRIES ASSOCIATION AND RE BOTANICALS, INC.,
PETITIONERS

v.

DRUG ENFORCEMENT ADMINISTRATION AND ANNE MILGRAM,
ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENTS

On Petition for Review of a Final Rule
of the Drug Enforcement Administration

Shane Pennington argued the cause for petitioners. With him on the briefs were *Matthew C. Zorn*, *Shawn Hauser*, and *David C. Kramer*.

Sarah Carroll, Attorney, U.S. Department of Justice, argued the cause for respondents. With her on the brief were *Brian M. Boynton*, Acting Assistant Attorney General, and *Mark B. Stern*, Attorney.

Before: HENDERSON and ROGERS, *Circuit Judges*, and SILBERMAN, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* SILBERMAN.

SILBERMAN, *Senior Circuit Judge*: Petitioners bring a rather weak case. They seek review of an interim final rule issued by the Drug Enforcement Administration. But Petitioners¹ are wholly unable to show their injury in fact and therefore lack standing.

I.

Members of the Hemp Industries Association manufacture various products using the cannabis plant as raw material. That plant, however, also produces marijuana and its psychoactive component tetrahydrocannabinol (“THC”). Those drugs are subject to stringent regulation under the Controlled Substances Act.² Marijuana is defined by statute to include all parts of a cannabis plant, its seeds, its resin, and any derivatives from those components. 21 U.S.C. § 802(16). Exempt from the definition of marijuana are mature stalks, fiber or other derivative of the stalks (except for resin), oil or cake made from the seeds, and sterilized seed. *Id.* THC is also subject to regulation through a separate statutory provision. 21 U.S.C. § 812 (Schedule I) (c)(17).

In 2018, Congress modified the marijuana and THC provisions through the Farm Bill, apparently relaxing regulation of the cannabis plant. Congress introduced the

¹ Petitioners are the Hemp Industries Association and one of its members, RE Botanicals, Inc.

² Marijuana and THC are on Schedule I, the list of drugs for which the manufacture or trafficking are subject to the harshest penalties. 21 U.S.C. § 802(16); 21 U.S.C. § 812 (Schedule I) (c)(17). There are four more schedules (II–V)—with descending harshness in associated penalties.

statutory concept of “hemp” which it also exempted from the definition of marijuana. 21 U.S.C. § 802(16)(B). Hemp in turn is defined as any part—including parts not previously exempt—of the cannabis plant with a delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.³ As a corollary, Congress also redefined THC to exempt THC found “in hemp.” 21 U.S.C. § 812 (Schedule I) (c)(17); *see also* Agriculture Improvement Act of 2018, § 12619(b).

The DEA has broad authority to promulgate regulations implementing the Controlled Substances Act. Shortly after the passage of the Farm Bill, the DEA accordingly issued an interim final rule implementing the statute. The regulation modified the existing regulatory definition of THC to make clear that it does not include, “any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639o.” 85 Fed. Reg. 51,639, 51,640 (codified at 21 C.F.R. § 1308.11(d)(31)). It also—consistent with the changed statutory definition of marijuana—modified the prior regulatory definition of marijuana extract limiting it to a substance “containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis.” *Id.* (codified at 21 C.F.R. § 1308.11(d)(58)). Then, it addressed an entirely different drug, Epidiolex. It removed Epidiolex from Schedule V regulation and accompanying import-export controls since it had less than 0.1% THC.

II.

Perhaps most mystifying is Petitioners’ claim that removing Epidiolex from Schedule V conflicts with United

³ Agriculture Improvement Act of 2018, Pub. L. No. 115-334, §10113, 132 Stat. 4490, 4908 (2018) (codified at 7 U.S.C. § 1639o).

States treaty obligations (regulation of Epidiolex was abandoned because its THC concentration is only 0.1%, far less than the 0.3% threshold devised by the Farm Bill). But Petitioners provide no evidence that they produce Epidiolex or that Epidiolex is a competitor to Petitioners. So we cannot even imagine how Petitioners could be injured by the DEA's relaxation of regulation of a non-marijuana drug. Their argument raised for the first time in a reply brief (and therefore subject to forfeiture, *Sierra Club v. EPA*, 292 F.3d 895, 900–01 (D.C. Cir. 2002)) is that in their view the DEA had not sufficiently explained why it removed Epidiolex from regulation and the DEA's reasoning for that action might affect them in some other context. This contention is frankly ridiculous. Petitioners cannot challenge the reasoning of a case that does not directly affect them—it is far too speculative to be an injury in fact. See *Clapper v. Amnesty International USA, et al.*, 569 U.S. 398, 401 (2013).

* * *

The core of Petitioners' challenge to the regulation is not much better. Petitioners explicitly do not quarrel with the Farm Bill itself but only the implementing regulation. Although Petitioners' opening brief suggests that the language of the implementing regulation is different from the language of the statute, they never explain the significance in their view of the textual difference nor why the textual difference causes them injury. There is simply the claim that the regulation increases DEA authority over what the statute contemplates.⁴ It is not

⁴ In a parallel challenge that Petitioners bring in the district court, Petitioners seem to indicate that their concern is that, during the processing of hemp, the THC concentration of intermediate hemp material and waste hemp material would rise above 0.3% and no longer be exempt as hemp. *Hemp Industries Association v. DEA*, 21-5111 (D.C. Cir. 2022) (slip op., at 7–10). But, Petitioners, perhaps

until the reply brief that Petitioners claim that the statute's language "in hemp" has a different meaning than the regulation's language "within the definition of hemp" and that this difference could hypothetically injure them. *Compare* 21 U.S.C. § 812 (Schedule I) (c)(17), *with* 21 C.F.R. § 1308.11(d)(31). Be that as it may, even if the argument was legitimately presented in the opening brief, it is not worth exploring the language differences because the government reiterated at oral argument that the DEA did not intend any difference between the regulatory language and the statute. *See also* 85 Fed. Reg. at 51,640 ("This interim final rule merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations."). Therefore, Petitioners' primary argument is simply pushing on an open door because there is no dispute with the government. In other words, jurisdiction is absent—over the major issue—not just because Petitioners lack injury, but also because we do not even have before us a case or controversy. *Flast v. Cohen*, 392 U.S. 83, 95 (1968); *see also Weissman v. Nat'l R.R. Passenger Corp.*, 21 F.4th 854, 862 (D.C. Cir. 2021) (Silberman, J., concurring).

* * *

Accordingly, we dismiss the petition.

in an attempt to preserve their characterization of that suit as not challenging the interim final rule, did not raise that before us in this petition.