United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 19, 2022 Decided June 10, 2022

No. 21-5111

HEMP INDUSTRIES ASSOCIATION AND RE BOTANICALS, INC., APPELLANTS

v.

DRUG ENFORCEMENT ADMINISTRATION AND ANNE MILGRAM, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:20-cv-02921)

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

Sarah Carroll, Attorney, U.S. Department of Justice, argued the cause for appellees. 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 *Circuit Judge* HENDERSON.

KAREN LECRAFT HENDERSON, *Circuit Judge*: This appeal centers on recent statutory and regulatory changes to the legal status of hemp—a non-psychoactive variant of the *Cannabis sativa L.* (cannabis) plant that is related to but distinct from marijuana, the more well-known psychoactive variant. In August 2020, the United States Drug Enforcement Administration (DEA) issued a rule meant to conform its existing regulations to recent congressional amendments to the Controlled Substances Act (CSA or Act), 21 U.S.C. § 801 *et seq*., in its treatment of hemp. Shortly thereafter, the Hemp Industries Association (Hemp Association), a trade association of the hemp industry, and RE Botanicals, Inc. (RE Botanicals), a manufacturer and seller of consumer products derived from hemp, (collectively, the Plaintiffs) filed suit against the DEA, seeking declaratory and injunctive relief preventing the agency from enforcing the CSA against two necessary byproducts of the hemp-extract production process. The district court dismissed for lack of subject matter jurisdiction, concluding that the Plaintiffs' suit impermissibly challenged the DEA rule by failing to use the statutory review provision for rules promulgated under the CSA. *See generally Hemp Indus. Ass'n v. DEA*, 539 F. Supp. 3d 120 (D.D.C. 2021). As detailed *infra*, we affirm.

I. Background

At the motion-to-dismiss stage, we "assume the truth of all material factual allegations in the complaint and 'construe the complaint liberally, granting plaintiff[s] the benefit of all inferences that can be derived from the facts alleged.'" *Am. Nat'l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (quoting *Thomas v. Principi,* 394 F.3d 970, 972 (D.C. Cir. 2005)).

A.

In 1970, the Congress passed the Controlled Substances Act,[1] "a comprehensive statute designed to rationalize federal control of dangerous drugs." *Nat'l Org. for Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 737 (D.C. Cir. 1977). Under the CSA, each "controlled substance," *see* 21 U.S.C. § 802(6) (defining the term), is placed on one of five "schedules"—designated as Schedules I through V—of descending regulatory severity based on the risks and benefits associated with the substance. *See id.* § 812(a)–(b) (establishing and defining each schedule). The controls imposed on the manufacture, acquisition and distribution of substances listed under the CSA and the penalties for violations of those controls vary according to the schedule in which a substance is listed. *See id.* §§ 821–32 (controls), 841–65 (offenses and penalties); *see also Gonzales v. Raich*, 545 U.S. 1, 13–14 (2005). For example, Schedule I substances—which have "a high potential for abuse," "no currently accepted medical use in treatment" and "a lack of accepted safety for use . . . under medical supervision"—are subject to the most stringent controls and penalties. *See id.* §§ 812(b)(1)(A)–(C), 841. The Attorney General has delegated his authority under the CSA, including his rulemaking and scheduling authority, to the DEA. *See* 28 C.F.R. § 0.100(b); *see also* 21 U.S.C. § 871(a) (permitting delegation). The court of appeals has exclusive jurisdiction of "[a]ll final determinations, findings, and conclusions" issued by the DEA pursuant to the CSA. 21 U.S.C. § 877; *see John Doe, Inc. v. DEA*, 484 F.3d 561, 568 (D.C. Cir. 2007).

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[1] The Controlled Substances Act comprises Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242.

The CSA lists marijuana as a Schedule I substance. *See* 21 U.S.C. § 812(c) (Schedule I (c)(10)). Before 2018, the statutory definition of marijuana excluded hemp from its purview by carving out the non-psychoactive parts of the cannabis plant:

> The term "marihuana"[2] means 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. *Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination*.

Id. § 802(16) (emphasis added) (2012). The Congress also listed tetrahydrocannabinols (THC), the key psychoactive compound found in the cannabis plant, as a Schedule I controlled substance, *see* 21 U.S.C. § 812(c) (Schedule I (c)(17)), but it did not define the term, leaving the definition up to the DEA, *see* 21 C.F.R. § 1308.11(d)(31).

After what one can fairly characterize as a series of longstanding disputes among the hemp industry, the DEA, States and the Congress regarding the DEA's authority to regulate hemp, *see* Am. Compl. ¶¶ 40–61; *see also Monson v. DEA*, 589 F.3d 952, 957 (8th Cir. 2009); *United States v.*

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[2] The Controlled Substances Act and implementing regulations often use the "marihuana" spelling. Other than direct references to or quotations of either, we use "marijuana."

Mallory, 372 F. Supp. 3d 377, 382–83, 384–85 (S.D. W. Va. 2019), the Congress significantly altered the CSA regulation of hemp as part of the Agricultural Improvement Act of 2018, Pub. L. No. 115–334, 132 Stat. 4490 (2018 Farm Bill). Relevant here, the 2018 Farm Bill included a new definition of "hemp":

> "[H]emp" means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

7 U.S.C. § 1639*o*(1).[3] It also amended the CSA in two key respects. First, it clarified that "[t]he term 'marihuana' does not include . . . hemp, as defined in section 1639*o* of Title 7." 21 U.S.C. § 802(16)(B)(i). Second, it removed "[THC] in hemp (as defined under section 1639*o* of Title 7)" from the statutory listing of THC. *Id.* § 812(c) (Schedule I (c)(17)). The 2018 Farm Bill granted the Secretary of the United States Department of Agriculture (USDA)—subject to exceptions not pertinent here—"sole authority to promulgate Federal regulations and guidelines that relate to the production of hemp," 7 U.S.C. § 1639r(b); *see also id.* § 1639*o*(3), and

[3] The Congress first differentiated hemp from marijuana based on delta-9 THC concentration in the Agricultural Act of 2014, Pub. L. No. 113-79, 128 Stat. 649, which authorized the cultivation of "industrial hemp," defined according to the same 0.3 per cent delta-9 THC concentration threshold as the 2018 Farm Bill's definition of "hemp," for agricultural and academic purposes pursuant to a state pilot program. *See* 7 U.S.C. § 5940.

directed the USDA Secretary to administer and implement hemp production plans,[4] *see id.* §§ 1639q, 1639p.

In August 2020, the DEA published an interim final rule intended to "conform[] [its] regulations" to the 2018 Farm Bill's amendments to the CSA. *See* Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639, 51,639 (Aug. 21, 2020) (Interim Final Rule or IFR). The IFR noted that to be deemed marijuana under the CSA, "cannabis and cannabis-derived material must both fall within the pre-[2018 Farm Bill] CSA definition of marihuana"—the definition that excluded particular parts of the cannabis plant—"and contain more than 0.3 percent [delta-9]-THC on a dry weight basis." *Id.* at 51,640–41. The rule accordingly limited the agency's definition of THC, a Schedule I controlled substance, to exclude "any material, compound, mixture, or preparation that falls within the [2018 Farm Bill's] definition of hemp set forth in 7 U.S.C. § 1639*o*." *Id.* at 51,641; *see also* 21 C.F.R. § 1308.11(d)(31)(ii). Of note here, the DEA specifically addressed products derived from the hemp plant, stating that "the definition of hemp does not automatically exempt any product derived from a hemp plant, regardless of the [delta-9]-THC content of the derivative" and "[i]n order to meet the definition of 'hemp,' and thus qualify for the exemption from schedule I, the derivative must not exceed the 0.3% [delta-9]-THC limit." 85 Fed. Reg. at 51,641. The agency also declared that "entities no longer require a DEA registration

[4] The USDA has since issued a rule for the regulation of hemp production. *See* Establishment of a Domestic Hemp Production Program, 86 Fed. Reg. 5,596 (Jan. 19, 2021). Notably, its rule "do[es] not cover hemp or its products beyond production," noting that "DEA has issued regulations covering some of these products or 'in-process materials.'" *Id.* at 5,649.

or import and export permits to handle hemp extract that does not exceed the statutory 0.3% THC limit." *Id.* at 51,644.

B.

As an agricultural commodity, hemp has a wide variety of uses, including in the production of textiles, fabrics and paper. Hemp seeds are used in beverages and foods. Hemp extracts are used in a wide range of products like soaps, shampoo, lotions, bath gels and cosmetics. Hemp extracts can be particularly lucrative; according to the Plaintiffs, "[t]he U.S. wholesale market for hemp extracts currently stands at $2 billion" and "the wholesale market for products containing extracts exceeds $5 billion." Am. Compl. ¶ 29.

This appeal focuses on the hemp-extract production process. As the Plaintiffs see it, the process produces intermediate and waste byproducts that exceed the 0.3 per cent delta-9 THC concentration threshold, thereby raising understandable confusion regarding DEA regulation even after the 2018 Farm Bill. To briefly summarize the production process: After hemp plants are determined to be below the 0.3 per cent delta-9 THC threshold and cultivated, the milling process separates the hemp flowers, which are high in THC, from the remainder of the plant, which is comparatively low in THC. The milled hemp flower material is then mixed with an extraction solvent meant to extract the cannabinoids—compounds including THC and cannabidiol (CBD) found in the cannabis plant. The hemp flower material is discarded, leaving behind an oil comprised of the extracted cannabinoids and the extraction solvent. The oil is subjected to evaporation in order to isolate what the Plaintiffs call "intermediate hemp material" (IHM), which, at this point, contains highly concentrated levels of cannabinoids like THC. The Plaintiffs assert that "IHM itself is not added to, or used as an ingredient

in, any consumer product; rather, IHM is refined into extracts or isolates containing not more than 0.3% [delta-9] THC." *Id.* at ¶ 35. If the processor creates cannabinoid isolates, the evaporation process generates a waste output the Plaintiffs call "waste hemp material" (WHM), which they similarly assert "is not added to, or used as an ingredient in, any consumer product." *Id.* at ¶ 36. Because both IHM and WHM are produced after stripping or evaporating away parts of the hemp plant that are low in THC, the two byproducts have high THC concentrations. "As a result, IHM and WHM naturally (and unavoidably) exceed 0.3% [delta-9] THC," notwithstanding the "harvested hemp plant contains 0.3% or less [delta-9] THC." *Id.* at ¶ 39.

C.

In September 2020, the Plaintiffs petitioned for review of the IFR. *See Hemp Indus. Ass'n v. DEA*, No. 20-1376 (D.C. Cir.). While the petition levies a series of challenges against the IFR, it does not make any explicit reference to the status of IHM, WHM or any particular byproduct of the hemp-extract production process under the CSA. *See generally* Pet. for Review, *Hemp Indus. Ass'n v. DEA*, No. 20-1376 (D.C. Cir.).

Less than one month later, the Plaintiffs filed suit in district court. They initially sought a declaration that IHM and WHM are no longer subject to the CSA after the enactment of the 2018 Farm Bill regardless of their THC concentration, *see* Compl. ¶¶ 85–102, a related declaration that the DEA lacks authority to regulate "any aspect of hemp production, including the production of IHM and WHM[,]" after the 2018 Farm Bill, *see id.* at ¶¶ 103–110, and "an injunction enjoining the IFR and enjoining DEA from promulgating rules that relate to the production of hemp," *id.* at ¶ 111–14. While the Plaintiffs' suit was pending in the district court, they requested this Court to

hold their September 2020 petition for review in abeyance *pendente lite*, which we granted. *See* Order, *Hemp Indus. Ass'n v. DEA*, No. 20-1376 (D.C. Cir. Oct. 21, 2021).[5]

The DEA moved to dismiss the Plaintiffs' initial complaint for lack of subject matter jurisdiction on a variety of grounds, including that 21 U.S.C. § 877 divested the district court of jurisdiction and that the Plaintiffs lacked standing; the Plaintiffs then amended their complaint. The amended complaint sought a judicial declaration that either the definition of "hemp" set forth in 7 U.S.C. § 1639*o* encompasses IHM and WHM or that the 2018 Farm Bill otherwise immunizes the possession and manufacture of IHM and WHM so that "the possession and manufacture of IHM and WHM during the hemp production process does not require registration under the CSA," Am. Compl. ¶ 105, as well as an injunction "enjoining DEA from enforcing the CSA as to IHM and WHM," *see id.* at ¶ 110. The Plaintiffs alleged that the DEA "publicized its view" that it possessed authority to regulate hemp byproducts like IHM and WHM "in multiple forums, including in the explanatory text of its August 2020 interim final rule . . . and through the public statements of [DEA] staff and representatives." *Id.* at ¶ 3. The amended complaint dropped the Plaintiffs' original request to enjoin the IFR but it repeatedly references and challenges the DEA's conclusions contained therein. *See, e.g.*, *id.* at ¶ 82 ("In defiance of Congress's delegation of exclusive authority to regulate hemp production to USDA, DEA promulgated its own interim final rule . . . ."); *id.* at 84 (describing IFR as "DEA's most direct

[5] The abeyance was lifted once the district court dismissed the Plaintiffs' suit. Oral argument on the petition was held on the same day as the instant appeal and the petition is today dismissed. *See Hemp Indus. Ass'n v. DEA*, No. 20-1376, slip op. at 5 (D.C. Cir. June 10, 2020).

claim that IHM and WHM are illegal"); *id.* at ¶ 101 (quoting IFR in describing instant suit against DEA).

The district court granted the DEA's motion to dismiss for lack of subject matter jurisdiction, concluding that the Plaintiffs erroneously sought review of the IFR in district court, instead of this Court, in contravention of 21 U.S.C. § 877. *See Hemp Indus. Ass'n*, 539 F. Supp. 3d at 123. The district court acknowledged that the Plaintiffs' amended complaint did not "seek a declaration that the IFR itself is invalid or an injunction directly enjoining its application" but it also recognized that the "Amended Complaint specifically identifies the IFR as embodying what [Plaintiffs] contend is an incorrect interpretation of the relevant statutes and an unlawful assertion [of] regulatory authority." *Id.* at 129–30. Further, it held, that the Plaintiffs effectively "seek an injunction enjoining DEA from asserting that regulatory authority and a judicial declaration that their own, contrary interpretation is the correct one, and that they should be exempt from its application." *Id.* at 129 (second and third alterations in original) (internal quotation marks and citation omitted); *see also id.* ("For relief, [the Plaintiffs] seek a declaration that—contrary to the IFR—'the definition of hemp as set forth in [the 2018 Farm Bill] includes IHM and WHM,' or that the [2018 Farm Bill] 'authorizes and/or immunizes the possession and manufacture of IHM and WHM' such that the substances need not be registered under the CSA." (quoting Am. Compl. ¶ 105)). The Plaintiffs timely appealed and we have appellate jurisdiction pursuant to 28 U.S.C. § 1291.

II. Analysis

In reviewing a district court's dismissal of a complaint for lack of subject matter jurisdiction, we review the district court's legal determinations de novo. *See Am. Nat'l Ins.*, 642

F.3d at 1139; *Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1202–03 (D.C. Cir. 2019). As explained *infra*, we, like the district court, conclude that the Plaintiffs' amended complaint impermissibly seeks review of the same issues addressed in the IFR—the authorization (or lack thereof) of the manufacture and possession of IHM and WHM—outside the review scheme set forth in 21 U.S.C. § 877. In addition, to the extent the Plaintiffs seek a declaration that the IFR does not address either authorization or liability regarding IHM and WHM, they have failed to plead a plausible injury-in-fact related to enforcement against their manufacture or possession of IHM and WHM.

A.

"Within constitutional bounds, Congress decides what cases the federal courts have jurisdiction to consider." *Am. Fed'n of Gov't Emps., AFL-CIO v. Trump*, 929 F.3d 748, 754 (D.C. Cir. 2019) (quoting *Bowles v. Russell*, 551 U.S. 205, 212 (2007)). The district court possesses jurisdiction of questions of federal law by statute, *see* 28 U.S.C. § 1331, but the Congress may circumscribe this authority "by establishing an alternative statutory scheme for administrative and judicial review." *Am. Fed'n of Gov't Emps.*, 929 F.3d at 754. "If a special statutory review scheme exists, . . . 'it is ordinarily supposed that Congress intended that procedure to be the exclusive means of obtaining judicial review in those cases to which it applies.'" *Jarkesy v. SEC*, 803 F.3d 9, 15 (D.C. Cir. 2015) (quoting *City of Rochester v. Bond,* 603 F.2d 927, 931 (D.C. Cir. 1979)); *see also Telecomms. Rsch. & Action Ctr. v. FCC*, 750 F.2d 70, 77 (D.C. Cir. 1984) ("[A] statute which vests jurisdiction in a particular court cuts off original jurisdiction in other courts in all cases covered by that statute.").

The CSA provides that the DEA's "final determinations, findings, and conclusions" under the CSA "shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision" of the DEA "may obtain review of the decision" in the court of appeals. 21 U.S.C. § 877. This Court has previously concluded that section 877 "vests exclusive jurisdiction in the courts of appeals over '[a]ll final determinations, findings, and conclusions' of the DEA applying the CSA." *John Doe, Inc.*, 484 F.3d at 568 (alteration in original) (quoting 21 U.S.C. § 877). Thus, claims falling within the ambit of section 877—those challenging a final decision of the DEA under the CSA—are considered by the courts of appeals, not the district courts. The question here is whether the Plaintiffs' claims challenge a final decision of the DEA—namely the IFR.[6] If so, section 877 deprives the district court of subject matter jurisdiction. *See Jarkesy*, 803 F.3d at 15.

The Plaintiffs' principal argument on appeal is that their amended complaint does not seek to challenge or invalidate the IFR but instead seeks a declaratory judgment that the manufacture and possession of hemp byproducts is authorized by the 2018 Farm Bill or otherwise immune from the CSA's registration and enforcement provisions, whether or not it is deemed a controlled substance by the DEA per its IFR. *See* Appellants' Br. 30–31; *see also* Am. Compl. ¶ 105. The Plaintiffs attempt to draw a meaningful distinction between what the IFR purportedly does—that is, it conforms DEA's regulations to the 2018 Farm Bill's classification decision

[6] The district court concluded that the IFR is a "final decision" under 21 U.S.C. § 877, *see Hemp Indus. Ass'n*, 539 F. Supp. 3d at 128, and the Plaintiffs do not argue otherwise. Further, the fact that a rule is characterized as an "interim" rule is of no consequence. *See Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012) (reviewing and vacating interim final rule).

regarding hemp and hemp-based substances—and the relief the Plaintiffs seek—immunization from registration requirements for IHM and WHM, regardless of the classification decision. *See* Appellants' Br. 31–32. In the Plaintiffs' view, the IFR "adopts no position on the question of whether the 2018 Farm Bill authorizes the manufacture and possession of intermediate and waste hemp material," which they contend is the crux of their challenge, and that silence allows their suit to proceed notwithstanding 21 U.S.C. § 877. *Id.* at 35.

The classification/liability distinction drawn by the Plaintiffs has some superficial appeal. Granted, the CSA is intended to be a "comprehensive regime" to control the "legitimate and illegitimate traffic in controlled substances," *Raich*, 545 U.S. at 12, but its individual Parts serve distinct purposes in achieving those ends: Part B defines a controlled substance, *see* 21 U.S.C. §§ 811–14, Part C provides regulatory requirements (e.g., registering, labeling and packaging, and recordkeeping) for those substances, *see id.* §§ 821–32, and Parts D and E provide enforcement mechanisms and penalties to enforce the controls placed on controlled substances, *see id.* §§ 841–65 (Part D), 871–90 (Part E).

The problem for the Plaintiffs is that the IFR addresses *both* classification (whether IHM and WHM are controlled) *and* authorization (what controls or immunities do or do not apply to IHM and WHM)—a conclusion that even the Plaintiffs cannot help but reach—meaning that the classification/authorization distinction drawn by the Plaintiffs does not help them evade 21 U.S.C. § 877. *See Hemp Indus. Ass'n*, 539 F. Supp. 3d at 128–30.

Begin with the DEA's position on hemp and hemp-derived substances as articulated in the IFR. The DEA adopts the view, as the Plaintiffs relate in their amended complaint, that "the

definition of hemp [in the 2018 Farm Bill] does not automatically exempt [from Schedule I] any product derived from a hemp plant, regardless of the [delta-9]-THC content of the derivative" and that "a cannabis derivative, extract, or product that exceeds the 0.3% [delta-9]-THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less [delta-9]-THC on a dry weight basis." 85 Fed. Reg. at 51,641; *see* Am. Compl. ¶ 83 (quoting same). Because, as the Plaintiffs assert, both IHM and WHM, which are "derived from" the cannabis plant, generally exceed this 0.3 per cent threshold, *see* Am. Compl. ¶ 37 ("IHM and WHM naturally (and avoidably) exceed 0.3% [delta 9]-THC."), the DEA *could* reasonably view both byproducts as controlled substances. But the IFR also abjures regulation of cannabis-derived substances below the 0.3 per cent delta-9 THC concentration threshold: "[E]ntities no longer require a DEA registration or import and export permits to handle hemp extract that does not exceed the statutory 0.3% THC limit." 85 Fed. Reg. at 51,644; *see* Am. Compl. ¶ 83 (quoting same). These two provisions could lead to the not unreasonable interpretation that notwithstanding the 2018 Farm Bill, hemp-derived substances exceeding the 0.3 per cent threshold—a group that could include IHM and WHM—are still subject to registration requirements and import/export controls.

Indeed, the Plaintiffs allege that "the necessary implication" of the IFR's explanatory language is "that the CSA's registration requirements do continue to apply to entities handling any hemp extract that exceeds the 0.3% [delta-9]-THC limit, including IHM and WHM." Am. Compl. ¶ 83 (emphases omitted); *see also id.* at ¶ 3 (alleging the IFR "publicized" the DEA's "mistaken[]" view that it possesses "authority to impose criminal and/or civil liability against unregistered hemp processors who manufacture and/or process IHM and WHM"); *id.* at ¶ 84 (characterizing the IFR as

"DEA's most direct claim that IHM and WHM are illegal"); *id.* at ¶¶ 100–01 (quoting the IFR as evidence of DEA's position that the 2018 Farm Bill does not "authorize[] the manufacture of byproducts necessarily or unavoidably created during the production of hemp-based" substances). Thus, the Plaintiffs cannot avoid the conclusion that the IFR is as much about registration requirements and liability as it is about classification.

This brings us to the Plaintiffs' amended complaint and requested relief. They allege that the DEA's "asserti[on] [of] authority to regulate the hemp production process" constitutes "an affront to Congress's clear command that possession and manufacture of IHM and WHM be permitted." *Id.* at ¶ 90; *see also id.* at ¶¶ 99–101; *id.* at ¶ 83 ("The explanatory language accompanying the text of the IFR, however, confirms DEA's intent to regulate hemp production in defiance of Congress's express mandate in the 2018 Farm Bill."); *id.* at ¶ 88 (touting letters from senators and members of Congress asserting the IFR "rewrites the 2018 Farm Bill contrary to Congressional intent"). Accordingly, the Plaintiffs request "a judicial determination" that, contrary to the IFR, "the definition of 'hemp' as set forth in [7 U.S.C. § 1639*o*], includes IHM and WHM" or that the 2018 Farm Bill "authorizes and/or immunizes the possession and manufacture of IHM and WHM"—with the result of either declaration being that "the possession and manufacture of IHM and WHM during the hemp production process does not require registration under the CSA." *Id.* at ¶ 105. The Plaintiffs also request injunctive relief that, again contrary to the IFR, "enjoin[s] DEA from enforcing the CSA as to IHM and WHM." *Id.* at ¶ 110.

Taken together, the Plaintiffs' amended complaint, "[i]n substance," seeks review of the "same issue[]" the IFR purportedly addresses—whether CSA controls continue to

apply to the manufacture and possession of hemp-derived substances like IHM and WHM—and requests the district court "require the [DEA] to conduct future [action] on the terms that [the Plaintiffs] proposed." *FCC v. ITT World Commc'ns, Inc.*, 466 U.S. 463, 468 & n.5 (1984); *see also Hemp Indus. Ass'n*, 539 F. Supp. 3d at 131 (Plaintiffs "ask the Court to endorse their own desired statutory interpretation—which just so happens to be the complete opposite of the position they claim DEA adopted in a promulgated rule—and to enjoin the agency from acting any differently."). Both the Supreme Court and this Court have stressed, however, that "[l]itigants may not evade" an exclusive review provision like 21 U.S.C. § 877 "by requesting the District Court to enjoin action that is the outcome of the agency's order." *ITT World Commc'ns*, 466 U.S. at 468; *see also Heller, Ehrman, White & MacAuliffe v. Babbitt*, 992 F.2d 360, 361, 363–64 (D.C. Cir. 1993) ("[E]ager litigant[s]" may not "circumvent a congressional grant of exclusive jurisdiction . . . by simply converting the suit into one for injunctive relief."); *Daniels v. Union Pac. R.R. Co.*, 530 F.3d 936, 942–43 (D.C. Cir. 2008) (Litigants may not "circumvent[] review of the [agency's] regulations in this Court . . . by instead indirectly . . . seeking review of the regulations in district court.").

The Plaintiffs' remaining arguments are unavailing. They first fault the district court for not "accept[ing] [their] view of the case at the pleadings stage"—presumably their assertion that they do not directly attack the IFR. Appellants' Br. 30. A court is obliged to accept "as true all of the factual allegations contained in the complaint and draw[] all inferences in favor of the nonmoving party," *City of Harper Woods Emps.' Ret. Sys. v. Olver*, 589 F.3d 1292, 1298 (D.C. Cir. 2009); *see Browning v. Clinton*, 292 F.3d 235, 240 (D.C. Cir. 2002) (same), but there is no such requirement with respect to a litigant's "view" or "characterization" of the complaint. In fact, "constru[ing] [a]

complaint liberally in the plaintiff's favor" does not entail "accept[ing] inferences unsupported by facts or legal conclusions cast in the form of factual allegations." *Harper Woods*, 589 F.3d at 1298 (citing *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994)). Further, in the context of exclusive review statutes, we have cautioned against being lulled to sleep by "creative[] framing." *Heller, Ehrman, White & MacAuliffe*, 992 F.2d at 363; *Daniels*, 530 F.3d at 942–43; *accord ITT World Commc'ns*, 466 U.S. at 468. We therefore find no basis for the Plaintiffs' proposition that the district court was obligated to accept their "view" of the case.

The Plaintiffs also assert that their action is nothing more than a "mirror image" of a government action brought under 21 U.S.C. § 882. *See* Appellants' Br. 45–46 (quoting *Menominee Indian Tribe of Wis. v. DEA*, 190 F. Supp. 3d 843, 850 (E.D. Wis. 2016)). Section 882 grants "district courts of the United States . . . jurisdiction in proceedings" brought by the government "to enjoin violations of" the CSA. 21 U.S.C. § 882. But a narrow grant of jurisdiction in favor of the government simply underscores that the Congress "knew how to provide alternative forums for judicial review based on the nature of a[] [plaintiff's] claim," *Elgin v. Dep't of Treasury*, 567 U.S. 1, 13 (2012), and instead chose to require that litigants "proceed exclusively through" section 877 in making a challenge within its scope, *Jarkesy*, 803 F.3d at 15; *cf. id.* at 17 ("Congress, though, gave *the SEC* the option to pursue violations in district court. Congress did not thereby necessarily enable *respondents in administrative proceedings* to collaterally attack those proceedings in court." (emphases in original)).

The Plaintiffs finally spill much ink arguing that the district court erred in not applying *Thunder Basin* to determine whether 21 U.S.C. § 877 in fact divested it of jurisdiction. *See*

Appellants' Br. 43–58; *see generally Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994). But *Thunder Basin* is unilluminating here. The "ultimate question" *Thunder Basin* asks is "whether Congress intended exclusivity when it established the statutory scheme" at issue. *Jarkesy*, 803 F.3d at 12. Following the Supreme Court's lead, our Court employs a two-part framework: "Congress intended that a litigant proceed exclusively through a statutory scheme . . . when (i) such intent is fairly discernible in the statutory scheme, and (ii) the litigant's claims are of the type Congress intended to be reviewed within [the] statutory structure." *Am. Fed'n of Gov't Emps.*, 929 F.3d at 754 (internal quotation marks omitted) (quoting *Jarkesy*, 803 F.3d at 15); *accord Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 489–90 (2010); *Elgin*, 567 U.S. at 10, 15.

We have already answered the first part of the *Thunder Basin* framework with respect to the exclusivity of 21 U.S.C. § 877 by concluding that it "vests *exclusive* jurisdiction in the courts of appeals over '[a]ll final determinations, findings, and conclusions' of the DEA applying the CSA." *John Doe, Inc.*, 484 F.3d at 568 (emphasis added) (quoting 21 U.S.C. § 877). Thus, we can definitively "discern that Congress intended the statutory scheme to be exclusive with respect to claims within its scope." *Am. Fed'n of Gov't Emps.*, 929 F.3d at 755. The second step, whether a claim is "of the type Congress intended to be reviewed within [the] statutory structure," *id.* at 754 (quoting *Jarkesy*, 803 F.3d at 15), reduces to whether the Plaintiffs' claims challenge a final agency decision subject to section 877. *See Hemp Indus. Ass'n*, 539 F. Supp. 3d at 134. We have already affirmed that it does.

B.

Alternatively, the Plaintiffs strenuously argue on appeal that the IFR makes no "mention [of] the manufacture and possession of hemp byproducts." Appellants' Br. 35. But even if we accept this reframing of the Plaintiffs' position, *see supra* p. 14–15, there we fail to find any plausible basis to support the requisite injury-in-fact to support the Plaintiffs' claims.[7] We note that at the pleading stage, a complaint need only contain "sufficient factual matter, accepted as true, to state a claim [of standing] that is plausible on its face." *Kareem v. Haspel*, 986 F.3d 859, 866 (D.C. Cir. 2021) (internal quotation marks omitted and alteration in original) (quoting *Ashcroft v. Iqbal*, 566 U.S. 662, 678 (2009)).

In their amended complaint, the Plaintiffs invoked the district court's authority under the Declaratory Judgment Act, *see* Am. Compl. ¶ 8, which provides that "[i]n a case of actual controversy within its jurisdiction," a district court may "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought," 28 U.S.C. § 2201(a), and order "[f]urther necessary or proper relief based on [the] declaratory judgment or decree," *id.* § 2202. "[J]ust like suits for every other type of remedy, declaratory-judgment actions must satisfy Article III's case-or-controversy requirement." *California v. Texas*, 141 S. Ct. 2104, 2115 (2021) (citing *MedImmune, Inc. v. Genentech,*

[7] The district court did not reach the DEA's argument that the Plaintiffs lack standing, *see Hemp Indus. Ass'n*, 539 F. Supp. 3d at 135, but the DEA has raised the argument on appeal, *see* Appellee's Br. 32–33. And, of course, we operate under the "well established" background principle that courts have the "independent obligation to assure that standing exists." *Shea v. Kerry*, 796 F.3d 42, 49–50 (D.C. Cir. 2015) (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009)).

Inc., 549 U.S. 118, 126–27 (2007)). This includes, *inter alia*, demonstrating an injury-in-fact that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotation marks and citation omitted). In other words, a plaintiff cannot simply rest on some abstract desire to know his rights or status under a statute, *see, e.g.*, *Ashcroft v. Mattis*, 431 U.S. 171, 172 (1977); *Golden v. Zwickler*, 394 U.S. 103, 109 (1969), but rather needs to connect the requested declaration to some actual or imminent injury, *see Steffel v. Thompson*, 415 U.S. 452, 458–59 (1974).

The Plaintiffs' asserted injury is that the DEA's position on hemp byproducts like IHM and WHM presents them with "the immediate dilemma of choosing between ceasing to process, manufacture and/or store hemp; obtaining a Schedule I registration from DEA; or risking criminal and/or civil prosecution under the CSA by DEA for conducting such activities." Am. Compl. ¶ 102. Neither the Plaintiffs nor the DEA asserts that the agency is currently undertaking or has undertaken an enforcement action against the Plaintiffs' possession or manufacture of hemp byproducts, meaning that the Plaintiffs' challenge is therefore grounded in the alleged *threat* of enforcement. Although a plaintiff requesting pre-enforcement review "is not required 'to expose himself to liability before bringing suit to challenge the basis' for an enforcement action by the government," *Matthew A. Goldstein, PLLC v. U.S. Dep't of State*, 851 F.3d 1, 4 (D.C. Cir. 2017) (quoting *MedImmune*, 549 U.S. at 128–29); *see also Susan B. Anthony List v. Driehaus* (*SBA List*), 573 U.S. 149, 158 (2014) ("When an individual is subject to [] a threat, an actual arrest, prosecution, or other enforcement action is not a prerequisite to challenging the law."), he must nevertheless demonstrate that either the threatened enforcement injury is "certainly impending" or there is a "substantial risk" such injury will

occur, *see Attias v. Carefirst, Inc.*, 865 F.3d 620, 627 (D.C. Cir. 2017) (quoting *SBA List*, 573 U.S. at 158); *see also TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2210 (2021) ("[A] person exposed to a risk of future harm may pursue forward-looking, injunctive relief to prevent the harm from occurring, at least so long as the risk of harm is sufficiently imminent and substantial.").

Here, the Plaintiffs have failed to assert a sufficiently imminent or substantial risk of enforcement against their desired course of conduct: handling hemp byproducts, like IHM and WHM, that exceed the 0.3 per cent delta-9 THC concentration threshold set forth in the 2018 Farm Bill. *If* we accept the Plaintiffs' preferred interpretation, the IFR answers only the question whether hemp byproducts are "controlled in the schedules after the 2018 Farm Bill," not the separate question whether "the manufacture and possession of hemp byproducts during the hemp production process [is] authorized" or, conversely, prohibited absent DEA registration. Appellants' Br. 32; *see also id.* at 35 ("The [IFR] adopts no position on the question of whether the 2018 Farm Bill authorizes the manufacture and possession of intermediate and waste hemp material."). We would be hard-pressed to conclude that an agency rule that allegedly takes no position on the liability or immunity of a desired course of conduct can simultaneously proscribe or deny immunity for that same conduct. *Cf. Matthew A. Goldstein*, 851 F.3d at 5 (finding lack of credible threat of enforcement from plaintiff's allegations of "vague and general descriptions of legal activities that the firm intends to undertake, none of which the State Department views as" unlawful).

The Plaintiffs also point to several statements by DEA officials that purportedly highlight the view "that IHM and WHM are illegal," Am. Compl. ¶ 84, and have caused the

Plaintiffs and their members to live in fear of DEA action, *see id.* at ¶ 93; *see also* Decl. of Rick Trojan III (Trojan Decl.) ¶ 4, *reprinted in* Appendix (App.) 098–99. For example, the Plaintiffs cite a statement from Chief of the DEA Office of Intergovernmental Affairs Sean Mitchell:

> When asked about DEA's position regarding elevated levels of [delta-9]-THC during "CBD extraction," Mr. Mitchell responded that DEA retains discretion to enforce the CSA as to hemp byproducts such as IHM and WHM, adding "*you'll never hear DEA say that we're not going to enforce any federal law . . . .*"

Am. Compl. ¶ 84 (emphasis added). They also point to Mitchell's statement that allegedly "equated hemp processors with pharmaceutical companies that 'take[]non-controlled raw materials' but are nevertheless 'required to be [] registered with DEA as a controlled substance manufacturer' because they 'produce[] or manufacture[] controlled substances . . .' 'during th[e] manufacturing of that not controlled end product.'" *Id.* at ¶ 85 (alterations in original). But even if we accept these statements as true—as well as the Plaintiffs' legal contention that the 2018 Farm Bill leaves the DEA no enforcement discretion with respect to IHM and WHM—they fail to evince any credible or imminent threat that the DEA will use its enforcement discretion against the Plaintiffs or any of the Hemp Association's members. Mitchell's statements are akin to a statement of intent to "prosecut[e] all violators of the statute under normal prosecutorial standards" that, absent allegations of "prior threats" or "characteristics indicating an especially high probability of enforcement," do not constitute a threat of enforcement. *Seegars v. Gonzales*, 396 F.3d 1248, 1255 (D.C. Cir. 2005) (internal quotation marks and citation omitted); *see also Aeronautical Radio, Inc. v. FCC*, 983 F.2d

275, 284 (D.C. Cir. 1993) (finding "no indication in the record . . . that the [agency] is likely to attempt to [enforce the challenged interpretation against the petitioner]" and concluding that the petitioner's "alleged injury is therefore merely conjectural" (internal quotation marks omitted)).

The Plaintiffs also cite a statement from "DEA spokesman Michael Miller" that the 2018 Farm Bill "'exempted any product from a *Cannabis sativa L.* plant with a delta-9 THC content of less than 0.3% by dry weight basis.'" Am. Compl. ¶ 86. This is nothing more than a restatement of law that cannot plausibly constitute a threat of enforcement. *Compare* 7 U.S.C. § 1639*o*(1) ("The term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."), *with* 21 U.S.C. § 802(16)(B)(i) ("The term 'marihuana' does not include . . . hemp, as defined in section 1639*o* of Title 7.").

The Plaintiffs also point to three additional sources for their alleged threat of enforcement, none of which provides a plausible basis for a threat of enforcement against the possession and/or manufacture of IHM and WHM. First, the Plaintiffs point to letters from a handful of Senators and members of Congress objecting to the DEA's stance and asserting that the IFR "criminalizes the intermediate steps of hemp processing, which is wholly inconsistent with . . . the 2018 Farm Bill." Letter from Senators Ron Wyden and Jeffrey A. Merkley to Acting DEA Administrator Timothy J. Shea (Oct. 22, 2020), *reprinted in* App. 093; *see also* Letter from Members of Congress to Acting DEA Administrator Timothy J. Shea (Oct. 20, 2020), *reprinted in* App. 095–97. But these letters involve the DEA's assertion of authority under the IFR

and, if anything, largely support our overarching conclusion that the source of the Plaintiffs' aggrievement is the IFR.

Second, the Plaintiffs point to instances of alleged DEA overreach in the marijuana and hemp industries predating the 2018 Farm Bill. *See* Am. Compl. ¶¶ 40–61; Appellants' Reply Br. 24–25. "'[P]ast wrongs' may serve as 'evidence bearing on whether there is a real and immediate threat of repeated injury,'" *N.B. ex rel. Peacock v. District of Columbia*, 682 F.3d 77, 84 (D.C. Cir. 2012) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983)), but a plaintiff seeking prospective declaratory and injunctive relief may not rest on past injuries alone, *see Dearth v. Holder*, 641 F.3d 499, 502 (D.C. Cir. 2011); *Arpaio v. Obama*, 797 F.3d 11, 19 (D.C. Cir. 2015). Further, the pre-2018 Farm Bill conduct cited by the Plaintiffs involves the agency's treatment of THC naturally occurring in the cannabis plant, *see* Am. Compl. ¶¶ 44–49, and hemp pilot programs administered by states for academic and research purposes, *see id.* at ¶¶ 50–59, meaning it has nothing to do with IHM, WHM or any other byproduct of the hemp-extract production process and no "bearing on whether there is a real and immediate threat of repeated injury" to the Plaintiffs' production of hemp extracts after the 2018 Farm Bill. *N.B. ex rel. Peacock*, 682 F.3d at 84 (quoting *Lyons*, 461 U.S. at 102).

Third, and finally, the Plaintiffs assert that the DEA's statements and history of enforcement conduct have caused hemp manufacturers to curtail their operations and reduced their access to financial services. *See* Am. Compl. ¶¶ 91–95; *see also* Trojan Decl. at ¶¶ 4–7. But we have previously held that "broad-based market effects stemming from regulatory uncertainty are quintessentially conjectural, and it is difficult to imagine a[n] [agency] action that would not confer standing under this theory." *New England Power Generators Ass'n, Inc. v. FERC*, 707 F.3d 364, 369 (D.C. Cir.

2013) (rejecting petitioner's argument that "chilling effect" on petitioner's ability to attract capital investments conferred standing) (citing *Shell Oil Co. v. FERC*, 47 F.3d 1186, 1202 (D.C. Cir. 1995)); *cf. Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 418 (2013) ("[A]llegations of subjective chill are not an adequate substitute for a claim of specific present objective harm or a threat of specific harm." (internal quotation marks omitted) (quoting *Laird v. Tatum*, 408 U.S. 1, 13–14 (1972))).

In sum, if we were to view the IFR as agnostic regarding the manufacture and/or possession of IHM and WHM, the Plaintiffs fail to plausibly allege an enforcement action that is "certainly impending" nor a "substantial risk" that such action will occur, thereby failing to assert a sufficient injury-in-fact to survive dismissal. *See Attias*, 865 F.3d at 627 (quoting *SBA List*, 573 U.S. at 158). This accords with our overarching conclusion that the IFR is the target of the Plaintiffs' challenge.

For the foregoing reasons, the district court's judgment is affirmed.

So ordered.