



**TABLE OF CONTENTS**

BACKGROUND.....1

    Regulatory Background.....1

    Factual Background.....4

    Procedural Background.....5

ARGUMENT.....6

I.    This Court lacks jurisdiction over Plaintiffs’ claims.....6

    A.    Congress has vested exclusive jurisdiction over these claims in the courts of  
        appeals.....7

        1.    Plaintiffs are challenging the IFR. ....8

        2.    Plaintiffs cannot evade an exclusive jurisdiction statute by artful  
            pleading.....10

        3.    Plaintiffs’ authority purportedly limiting § 877’s scope is utterly  
            unpersuasive.....14

    B.    Plaintiffs do not meet the requirements for so-called *Leedom v. Kyne*  
        jurisdiction. ....16

    C.    To the extent plaintiffs are challenging some action other than the IFR, they  
        lack standing and any such challenge is not ripe for judicial review. ....18

        1.    Plaintiffs have not alleged an adequate injury to support standing. ....19

        2.    Plaintiffs’ claims are not ripe. ....20

II.    In any event, the Court should exercise its discretion to dismiss Plaintiffs’ claims for  
        equitable relief.....23

CONCLUSION.....27

**TABLE OF AUTHORITIES**

**CASES**

*Abbott Laboratories v. Gardner*,  
387 U.S. 136 (1967) ..... 17, 21

*Arbaugh v. Y&H Corp.*,  
546 U.S. 500 (2006) ..... 15-16

*Askeew v. Hargrave*,  
401 U.S. 476 (1971) ..... 26

*Attias v. CareFirst, Inc.*,  
969 F.3d 412 (D.C. Cir. 2020) ..... 6

*Babbitt v. Farm Workers*,  
442 U.S. 289 (1979) ..... 20

*Bd. of Governors of Fed. Reserve Sys. v. MCorp Fin., Inc.*,  
502 U.S. 32 (1991) ..... 17

*Bold All. v. FERC*,  
2018 WL 4681004 (D.D.C. Sept. 28, 2018) ..... 6

*Brillhart v. Excess, Ins. Co. of America*,  
316 U.S. 491 (1942) ..... 23

*Califano v. Sanders*,  
430 U.S. 99 (1977) ..... 14

*California Save Our Streams Council, Inc. v. Yeutter*,  
887 F.2d 908 (9th Cir. 1989) ..... 10

*Ciba-Geigy Corp. v. EPA*,  
801 F.2d 430 (D.C. Cir. 1986) ..... 22

*City of Los Angeles v. Lyons*,  
461 U.S. 95 (1983) ..... 19

*City of Rochester v. Bond*,  
603 F.2d 927 (D.C. Cir. 1979) ..... 11

*City of Tacoma v. Taxpayers of Tacoma*,  
357 U.S. 320 (1958) ..... 6

*Clapper v. Amnesty Int’l USA*,  
568 U.S. 398 (2013).....20

*Connors v. Amax Coal Co.*,  
858 F.2d 1226 (7th Cir. 1988).....10

*DCH Reg’l Med. Ctr. v. Azar*,  
925 F.3d 503 (D.C. Cir. 2019) .....17

\**Doe v. DEA*,  
484 F.3d 561 (D.C. Cir. 2007) .....*passim*

*DOJ v. FLRA*,  
981 F.2d 1339 (D.C. Cir. 1993) .....17

*Eccles v. Peoples Bank of Lakewood Vill., Cal.*,  
333 U.S. 426 (1948).....26

*FCC v. ITT World Commc’ns, Inc.*,  
466 U.S. 463 (1984)..... 10, 14

*Friends of the Earth, Inc. v Laidlaw Emt’l Servs. (TOC), Inc.*,  
528 U.S. 167 (2000).....19

*Gen. Fin. Corp. v. FTC*,  
700 F.2d 366 (7th Cir. 1983).....10

*Gov’t Emps. Ins. Co. v. Rivas*,  
573 F. Supp. 2d 12 (D.D.C. 2008) .....25

*Greenwood v. FAA*,  
28 F.3d 971 (9th Cir. 1994).....10

*Griffith v. FLRA*,  
852 F.2d 487 (D.C. Cir. 1988) .....17

*Hanes Corp. v. Millard*,  
531 F.2d 585 (D.C. Cir. 1976) .....24

*Heller, Ehrman, White & MacAuliffe v. Babbitt*,  
992 F.2d 360 (D.C. Cir. 1993) .....10

*Hi-Tech Pharm., Inc. v. Hahn*,  
2020 WL 3498588 (D.D.C. June 29, 2020).....22

*John Doe, Inc. v. Gonzalez*,  
 2006 WL 1805685 (D.D.C. June 29, 2006),  
*aff'd, Doe*, 484 F.3d 561 ..... 11, 15, 25, 26

*Khadr v. United States*,  
 529 F.3d 1112 (D.C. Cir. 2008) ..... 6

*Kokkonen v. Guardian Life Ins. Co. of Am.*,  
 511 U.S. 375 (1994) ..... 6

*Leedom v. Kyne*,  
 358 U.S. 184 (1958) ..... 16, 17

*Louie v. Dickson*,  
 964 F.3d 50 (D.C. Cir. 2020) ..... 19

*Lujan v. Defs. of Wildlife*,  
 504 U.S. 555 (1992) ..... 19

*Marchiano v. Nat’l Ass’n of Sec. Dealers, Inc.*,  
 134 F. Supp. 2d 90 (D.D.C. 2001) ..... 12

*McGinn, Smith & Co. v. Fin. Indus. Reg. Auth.*,  
 786 F. Supp. 2d 139 (D.D.C. 2011) ..... 13

*MedImmune, Inc. v. Genentech, Inc.*,  
 549 U.S. 118 (2007) ..... 20, 24

*Menominee Indian Tribe of Wisconsin v. DEA*,  
 190 F. Supp. 3d 843 (E.D. Wis. 2016) ..... 16

*Monson v. DEA*,  
 589 F.3d 952 (8th Cir. 2009) ..... 14, 15

*Morgan Drexen, Inc. v. CFPB*,  
 979 F. Supp. 2d 104 (D.D.C. 2013), *aff’d*, 785 F.3d 684 (D.C. Cir. 2015) ..... 23, 24, 25, 26

*Myers v. Bethlehem Shipbuilding Corp.*,  
 303 U.S. 41 (1938) ..... 14

*N.H. Hemp Council v. Marshall*,  
 203 F.3d 1 (1st Cir. 2000) ..... 15, 22

*Nader v. EPA*,  
 859 F.2d 747 (9th Cir. 1988) ..... 14

*Nat’l Park Hosp. Ass’n v. Dep’t of Interior*,  
538 U.S. 803 (2003) .....21

*New Mexico v. Regan*,  
745 F.2d 1318 (10th Cir. 1984)..... 10-11

*North v. Smarsh, Inc.*,  
160 F. Supp. 3d 63 (D.D.C. 2015) ..... 12, 13

*Novelty Distributors, Inc. v. Leonhart*,  
562 F. Supp. 2d 20 (D.D.C. 2008) .....16

*Novelty, Inc. v. Tandy*,  
2006 WL 2375485 (S.D. Ind. Aug. 15, 2006) ..... 14-15

*Nyunt v. Chairman, Broad. Bd. of Governors*,  
589 F.3d 445 (D.C. Cir. 2009) .....17

*Oregon v. Ashcroft*,  
368 F.3d 1118 (9th Cir. 2004).....7

*Oregon v. Ashcroft*,  
192 F. Supp. 2d 1077 (D. Or. 2002) .....27

*PDK Labs., Inc. v. DEA*,  
362 F.3d 786 (D.C. Cir. 2004) .....16

*PDK Labs Inc. v. Reno*,  
134 F. Supp. 2d 24 (D.D.C. 2001) .....14

*Public Affairs Assocs., Inc. v. Rickover*,  
369 U.S. 111 (1962) .....26

*Pub. Serv. Comm’n of Utah v. Wycoff Co., Inc.*,  
344 U.S. 237 (1952) .....10, 14, 26

*Quackenbush v. Allstate Ins. Co.*,  
517 U.S. 706 (1996) .....23

*Rann v. Chao*,  
154 F. Supp. 2d 61 (D.D.C. 2001) ..... 6

*Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm’n*,  
324 F.3d 726 (D.C. Cir. 2003) .....21

*Sec. Title Guarantee Corp. of Baltimore v. 915 Decatur St NW, LLC*,  
427 F. Supp. 3d 1 (D.D.C. 2019), as amended (Mar. 23, 2020) .....20

*Sharp Corp. v. Hisense USA Corp.*,  
292 F. Supp. 3d 157 (D.D.C. 2017) .....23

*Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*,  
549 U.S. 422 (2007) .....23

*Spokeo, Inc. v. Robins*,  
136 S. Ct. 1540 (2016).....19

*Steel Co. v. Citizens for a Better Env't*,  
523 U.S. 83 (1998) .....16

*Susan B. Anthony List v. Driehaus*,  
573 U.S. 149 (2014) .....20

*Swish Mktg., Inc. v. FTC*,  
669 F. Supp. 2d 72 (D.D.C.2009) .....23, 24, 26

*Telecommunications Research and Action Center v. FCC*,  
750 F.2d 70 (D.C. Cir. 1984) .....12, 13, 19

*Thunder Basin Coal Co. v. Reich*,  
510 U.S. 200 (1994) ..... 10, 11

*Ticor Title Ins. Co. v. FDA*,  
814 F.2d 731 (D.C. Cir. 1987) .....16

*Toilet Goods Association v. Gardner*,  
387 U.S. 158 (1967) ..... 21, 22

*Ukiab Adventist Hosp. v. FTC*,  
981 F.2d 543 (D.C. Cir. 1992) ..... 10, 13

*United States v. Fausto*,  
484 U.S. 439 (1988) .....6

*Whitmore v. Arkansas*,  
495 U.S. 149 (1990) .....20

*Wilton v. Seven Falls*,  
515 U.S. 277 (1995) .....24

*Winter v. Nat. Res. Def. Council*,  
555 U.S. 7 (2008) .....23

*Woodrow v. FERC*,  
2020 WL 2198050 (D.D.C. May 6, 2020) .....6

**STATUTES**

7 U.S.C. § 1639*o* ..... 3, 18

21 U.S.C. § 802 ..... 3, 18

21 U.S.C. § 811(a) ..... 2

21 U.S.C. § 812 ..... 2, 3

21 U.S.C. § 822 ..... 2

21 U.S.C. § 823 ..... 2

21 U.S.C. § 824(d) ..... 16

21 U.S.C. § 877 ..... *passim*

28 U.S.C. § 1331 ..... 6, 7

28 U.S.C. § 1631 ..... 27

28 U.S.C. § 2201(a) ..... 23

Act of Aug. 2, 1937,  
75 Cong. Ch. 553, 50 Stat. 551 ..... 1

Controlled Substances Act of 1970 (CSA),  
Pub. L. No. 91-513, 84 Stat. 1236, 1242, codified as amended at 21 U.S.C. §§ 801 *et seq.* ..... 1, 2, 3

**ADMINISTRATIVE AND EXECUTIVE MATERIALS**

21 C.F.R. § 1308.11(d)(31)(ii) ..... 4

21 C.F.R. § 1308.11(d)(58) ..... 4

28 C.F.R. § 0.100(b) ..... 2, 7

85 Fed. Reg. 51,639 ..... 3

85 Fed. Reg. 51,641 ..... 3, 4, 5

85 Fed. Reg. 51,641–42 ..... 4

**OTHER AUTHORITIES**

10B Wright, Miller & Kane, *Federal Practice and Procedure* § 2759 (4th ed.) ..... 26



10B Wright, Miller & Kane, *Federal Practice and Procedure* § 2763 (4th ed.) .....26

Comment of Hemp Industries Ass’n on DEA Interim Final Rule (Sept. 18, 2020)  
[https://downloads.regulations.gov/DEA-2020-0023-2389/attachment\\_1.pdf](https://downloads.regulations.gov/DEA-2020-0023-2389/attachment_1.pdf) .....5

Comment of RE Botanicals on DEA Interim Final Rule (Oct. 19, 2020)  
<https://www.regulations.gov/contentStreamer?documentId=DEA-2020-0023-3090&attachmentNumber=1&contentType=pdf> .....5

In sum and substance, this action challenges an interim final rule that the Drug Enforcement Administration (DEA) has issued regarding hemp. Plaintiffs evidently disagree with the DEA over the proper interpretation of two statutes that relate to the cultivation and processing of the plant *Cannabis sativa L.*, the Controlled Substances Act (CSA) and the Agriculture Improvement Act of 2018 (AIA). Jurisdiction over this dispute, by statutory mandate, lies exclusively in the courts of appeals. 21 U.S.C. § 877. Notwithstanding that Plaintiffs have filed a petition for review of that rule in the D.C. Circuit, Plaintiffs ask this court to ignore the applicable statute and opine on their disagreements with DEA. For many independent reasons, the Court should decline their invitation.

First, § 877 vests exclusive jurisdiction to review DEA's decisions regarding the CSA in the courts of appeals. *See* 21 U.S.C. § 877. That jurisdictional provision precludes district courts from exercising jurisdiction over challenges to any final determination under the CSA, and also over challenges that might affect the circuit courts' future jurisdiction over those determinations. Nor is there any other basis for jurisdiction. Second, to the extent that Plaintiffs seek to evade their obligation to seek review in the courts of appeal by contending they are not challenging a final determination, they lack a sufficiently imminent injury, and adjudication of any controversy that *might* develop relating to the interplay between the CSA and AIA is not yet fit for judicial review. Third, even if Plaintiffs could clear both the jurisdictional bars, the circumstances of this case overwhelmingly counsel the Court to exercise its discretion to decline jurisdiction. The Court should dismiss Plaintiffs' claims and this dispute should be heard, if at all, in the proper forum.

## **BACKGROUND**

### *Regulatory Background*

Congress has long regulated both the plant *Cannabis sativa L.* and related psychoactive substances, tetrahydrocannabinols (THC). In 1937, Congress enacted the Marihuana Tax Act, which imposed broad registration requirements and high taxes on much cannabis-related activity. *See* 50 Stat. 551, 551–53. In 1970, Congress repealed the Marihuana Tax Act and enacted the Controlled Substances Act (CSA). *See* 84 Stat. 1242 *ff.*, codified at 21 U.S.C. §§ 801 *et seq.* (as

amended). Under the CSA, with limited exceptions, anyone who “manufactures,” “distributes,” or “dispenses” any controlled substance (or who proposes to do so) must be registered by the Attorney General. CSA § 302; *see* 21 U.S.C. § 822.

The CSA establishes five “schedules” of controlled substances. Substances are scheduled according to their particular characteristics; the schedule on which a substance is placed determines the scope of regulation and restrictions governing that substance. *See* CSA § 202, 84 Stat. 1247–48; 21 U.S.C. § 812. Substances on “Schedule I” are those that have been determined to have a “high potential for abuse,” “no currently accepted medical use in treatment in the United States,” and “a lack of accepted safety for use of the drug or other substance under medical supervision.” CSA § 202(b)(1), *see* 21 U.S.C. § 812(b)(1). Such substances are subject to the most restrictive controls. The Attorney General<sup>1</sup> shall register an applicant to manufacture or distribute Schedule I drugs—which, again, have been determined to have no legitimate medical or safe use—only if he determines doing so to be in “the public interest,” taking into account the need to maintain “effective controls against diversion” of the substances “into other than legitimate medical, scientific, research, or industrial channels,” among other factors. CSA § 303(a)(1), (b)(1); 21 U.S.C. § 823(a)(1), (b)(1).

Congress classified “marihuana” as a Schedule I drug in 1970. *See* CSA § 202(c) Schedule I (c)(10); 21 U.S.C. § 812(c) Schedule I (c)(10). Congress also separately added tetrahydrocannabinols (THC) to Schedule I. *See* CSA § 202(c) Schedule I (c)(17); 21 U.S.C. § 812(c) Schedule I (c)(17). Broadly speaking, tetrahydrocannabinols include the psychoactive chemical components that are naturally found in or derived from the cannabis plant, and their synthetic equivalents. Congress subsequently assigned to the Attorney General authority to add substances to, to remove them from, and to transfer them among the five schedules. *See* 21 U.S.C. § 811(a). Today, both marijuana and THC remain on Schedule I and are, at the federal level, among the most closely regulated controlled substances in the United States.

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<sup>1</sup> The Attorney General has delegated his authority to the DEA Administrator. 28 C.F.R. § 0.100(b).

As enacted in 1970, the CSA carried forward the earlier statutory definition of “marihuana” from the Marihuana Tax Act. CSA § 102(15), 84 Stat. 1244. Although that definition excluded certain parts of the cannabis plant from regulation, the plant itself could not, as a practical matter, be cultivated in the United States. More recently, Congress has adopted a different regulatory framework for *Cannabis sativa* L. plants and its derivatives that have lower concentrations of a specific variant of THC, delta-9 THC, which is the principal psychoactive component in the cannabis plant. Thus, the AIA, among many other things, defined “hemp”:

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.

7 U.S.C. § 1639*o*. The AIA also amended the CSA in two relevant ways. First, the AIA changed the definition for “marihuana” so that the “term ‘marihuana’ does not include hemp, as defined in [the AIA].” *See* 21 U.S.C. § 802(16)(B). Second, the AIA amended Schedule I of the CSA so that it included “Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined in under [the AIA]).” *See* 21 U.S.C. § 812(c)(17). Together with other recently enacted statutes, these amendments allow, under specified conditions, for the cultivation and processing of the cannabis plant without registering under the CSA.

On August 21, 2020, the DEA published an interim final rule (IFR) that conformed DEA’s regulations to these new statutory definitions. *Implementation of the Agriculture Improvement Act of 2018*, 85 Fed. Reg. 51,639 (Aug. 21, 2020). The IFR first clarified that “marihuana” now excludes cannabis and cannabis derivatives that “contain[] 0.3% or less of [delta-9 THC] on a dry weight basis,” but that “any such material that contains greater than 0.3% of [delta-9 THC] on a dry weight basis remains controlled in schedule I.” 85 Fed. Reg. 51,641. Thus, “[c]annabis-derived products that exceed the 0.3% [delta-9 THC] limit do not meet the statutory definition of ‘hemp’ and are schedule I substances,” even if they are “derived from a hemp plant.” *Id.*

The IFR also made two related amendments to the CFR. The regulatory provisions for THC now exclude “any material, compound, mixture, or preparation that falls within the definition of hemp set forth in [the AIA].” 85 Fed. Reg. 51,641; *see* 21 C.F.R. § 1308.11(d)(31)(ii). Second, the definition of “marihuana extract” now reads “an extract containing one or more cannabinoids that has been derived from any plant of the genus *Cannabis*, containing greater than 0.3% [THC] on a dry weight basis, other than the separated resin (whether crude or purified) obtained from the plant.” 85 Fed. Reg. 51,641–42, *see* 21 C.F.R. § 1308.11(d)(58).

#### *Factual Background*

Plaintiffs are a company involved in the manufacture and distribution of cannabis products and a trade association representing over 1,000 businesses involved in the cannabis industry. First Am. Compl. (FAC) ¶¶ 11–12, ECF No. 26. According to Plaintiffs’ First Amended Complaint, they and the businesses they represent process cannabis plants meeting the statutory definition for hemp into products—“hemp extracts”—that are then sold to the public. *See* FAC ¶¶ 11–12, 29–39, 102. Their manufacturing process generates two substances that “naturally (and unavoidably) exceed” 0.3% delta-9 THC concentration. FAC ¶ 37. The first, “intermediate hemp materials” (IHM) results from the evaporation of an extraction solvent from “an oil comprised of the extracted cannabinoids and any extraction solvent used.” FAC ¶ 34. IHM “contains concentrated levels of cannabinoids.” FAC ¶ 35. According to Plaintiffs, “special equipment refines [IHM] even further” to create “extracts and isolates” whose delta-9 THC concentrations are “at or below 0.3%.” FAC ¶ 38.

The second substance these businesses produce that exceeds 0.3% delta-9 THC are called “waste hemp materials” (WHM). The processing of IHM into “isolates of specific cannabinoids,” produces (in addition to those isolates) WHM, which, like IHM, “contains concentrated levels of cannabinoids.” FAC ¶ 36. Plaintiffs allege that WHM “is not added to, or used as an ingredient in,

any consumer product,” but Plaintiffs do not otherwise indicate what these businesses ultimately do with the WHM. *Id.*

The IFR, as noted above, indicated that “[c]annabis-derived products that exceed the 0.3% [delta-9 THC] limit do not meet the statutory definition of ‘hemp’ and are schedule I substances,” even if they are “derived from a hemp plant.” 85 Fed. Reg. 51,641. Although Plaintiffs allege that IHM and WHM are both substances derived from hemp plants whose delta-9 THC content “naturally (and unavoidably) exceed” 0.3%, FAC ¶ 37, the IFR did not specifically address those two substances. Plaintiffs further allege that DEA officials have subsequently indicated that IHM and WHM are, in Plaintiffs’ words, “legitimate targets for DEA enforcement under the CSA.” FAC ¶ 84; *see also id.* ¶¶ 85–87.

Both Plaintiffs have submitted comments on the IFR. *See* Comment of Hemp Industries Ass’n on DEA Interim Final Rule (Sept. 18, 2020), [https://downloads.regulations.gov/DEA-2020-0023-2389/attachment\\_1.pdf](https://downloads.regulations.gov/DEA-2020-0023-2389/attachment_1.pdf); Comment of RE Botanicals on DEA Interim Final Rule (Oct. 19, 2020), <https://www.regulations.gov/contentStreamer?documentId=DEA-2020-0023-3090&attachmentNumber=1&contentType=pdf>.

#### *Procedural Background*

Shortly after DEA promulgated the IFR, Plaintiffs filed a petition for review of the IFR in the D.C. Circuit. *See Hemp Indus. Ass’n, et al. v. DEA, et al.*, No. 20-1376 (D.C. Circuit, filed Sept. 18, 2020). Less than a month later, Plaintiffs filed this action, which, broadly speaking, challenges DEA’s interpretation of the CSA and AIA set out in the IFR. *See* Compl., ECF 1; FAC, ECF 26. And soon after that, Plaintiffs moved to hold the D.C. Circuit case in abeyance until “an appealable decision is reached” in these district court proceedings. Petitioners’ Unopposed Motion to Hold Petition for Review in Abeyance, *Hemp Indus. Ass’n*, No. 20-1376 (D.C. Cir. Oct. 20, 2020). The reason for that motion was straightforward: in these district court proceedings, Plaintiffs “seek declaratory relief that involves interpretation of the same hemp-related amendments that the IFR

purports to implement,” and these proceedings therefore “may affect the outcome of” the D.C. Circuit case. *Id.* at 3. Defendants moved to dismiss Plaintiffs’ Complaint, *see* ECF No. 26; Plaintiffs responded by filing an amended complaint, ECF No. 29, and the Court dismissed Defendants’ motion as moot, *see* Minute Order of January 21, 2021. (Plaintiffs also had earlier filed a motion for expedited discovery, Pls.’ Disc. Mot., ECF No. 21, which the Court denied, ECF No. 24.)

## ARGUMENT

### I. This Court lacks jurisdiction over Plaintiffs’ claims.

Federal courts are courts of limited jurisdiction; there is a presumption *against* jurisdiction, such that Plaintiffs bear the burden of demonstrating jurisdiction by a preponderance of the evidence. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008). A Rule 12(b)(1) motion should be granted if the complaint fails to allege facts sufficient to establish subject matter jurisdiction or if evidence external to the complaint refutes the jurisdictional facts alleged. *See Woodrow v. FERC*, 2020 WL 2198050, at \*4 (D.D.C. May 6, 2020). Courts are “not required . . . to accept inferences unsupported by the facts or legal conclusions that are cast as factual allegations.” *Rann v. Chao*, 154 F. Supp. 2d 61, 64 (D.D.C. 2001). For the Court to properly exercise jurisdiction, it must have both constitutional jurisdiction consistent with Article III as well as statutory jurisdiction. *See Attias v. CareFirst, Inc.*, 969 F.3d 412, 416 (D.C. Cir. 2020). And “[w]hen Congress provides for exclusive review in a court of appeals, that specific grant of jurisdiction displaces the general federal question statute, 28 U.S.C. § 1331.” *Bold All. v. FERC*, 2018 WL 4681004, at \*4 (D.D.C. Sept. 28, 2018); *see also United States v. Fausto*, 484 U.S. 439, 448–49 (1988) (providing that where a specific statute both provides subject matter jurisdiction and sets out the conditions under which substantive relief may be available, resort should not be made to the general federal question statute). This rule extends to “all issues inhering in the controversy.” *City of Tacoma v. Taxpayers of Tacoma*, 357 U.S. 320, 336 (1958).

Here, a specific statutory provision provides for judicial review of DEA applications of the CSA only in the courts of appeals. *See* 21 U.S.C. § 877. That provision therefore supersedes any jurisdiction that might be found under the more general grant of federal question jurisdiction in 28 U.S.C. § 1331. Such is the case when, as here, a plaintiff challenges agency action that falls within the statutory grant of exclusive jurisdiction. It is also the case when, as Plaintiffs erroneously claim to do, a plaintiff challenges not-yet-taken agency action the adjudication of which by the district court will affect the exclusive jurisdiction of the courts of appeals. Plaintiffs can point to no other valid source of the district court's statutory jurisdiction. But even if the district court did have statutory jurisdiction, it would lack Article III jurisdiction because any claim not challenging the IFR itself does not present an imminent injury and is not ripe for judicial review.

*A. Congress has vested exclusive jurisdiction over these claims in the courts of appeals.*

Congress has provided that all “final determinations, findings, and conclusions” of the Attorney General related to drug control “shall be final and conclusive,” “*except that* any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia” or other appropriate geographic court of appeals. 21 U.S.C. § 877. As the D.C. Circuit has explained, that provision “vests exclusive jurisdiction in the courts of appeals” over final determinations applying the CSA made by the DEA (to whom the Attorney General has delegated his authority, 28 C.F.R. § 0.100(b)). *Doe v. DEA*, 484 F.3d 561, 568 (D.C. Cir. 2007); *see also Oregon v. Ashcroft*, 368 F.3d 1118, 1120 & n.1 (9th Cir. 2004) (holding courts of appeals had exclusive jurisdiction over a complaint seeking (among other relief) a declaration that a specific state law “is permitted by Section 903 of the CSA and is not preempted in any way by federal law,” *see* Compl. at 8, *Oregon v. Ashcroft*, No. 01-1647 (Jan. 22, 2002), 2002 WL 33119405). This is why “as a matter of practice,” challenges to DEA’s interpretation of the CSA are almost always “filed directly in the court of appeals.” *Doe*, 484 F.3d at 568. Indeed, Plaintiffs in this



case followed that practice: before initiating this action, they first filed a petition for review in the D.C. Circuit. *See Hemp Indus. Ass'n*, No. 20-1376 (D.C. Cir., filed Sept. 18, 2020).

1. *Plaintiffs are challenging the IFR.*

There can be no real doubt that this is a challenge to a “final decision” concerning the application of the CSA: Plaintiffs are challenging DEA’s August 21, 2020 Interim Final Rule. Plaintiffs’ complaint is that they believe the IFR—as reiterated in subsequent statements made by DEA officials—misinterprets how the AIA and CSA interact, and that their own interpretation is the correct one. To be sure, Plaintiffs have attempted to obscure this truth somewhat in their amended pleading. *Compare* Compl. ¶¶ 79–84 (focusing on the interpretation in the IFR itself), *with* FAC ¶¶ 82–87 (identifying additional DEA statements made outside the IFR); *compare also* Compl. ¶ 114 (seeking “an injunction enjoining the IFR and enjoining DEA from promulgating rules that relate to the production of hemp”), *with* FAC ¶ 110 (seeking “preliminary and permanent injunctive relief enjoining DEA from enforcing the CSA as to IHM and WHM”).

But the fact remains: Plaintiffs seek through this lawsuit to nullify DEA’s interpretation of the CSA set out in the IFR. Plaintiffs allege that the “necessary implication” of the IFR’s explanatory text is that CSA “registration requirements **do** continue to apply to entities handling **any** hemp extract that exceeds the 0.3% Δ9-THC limit, including IHM and WHM.” FAC ¶ 83 (emphasis in original). They contend that such an interpretation is contrary to the law. *See* FAC ¶¶ 90, 99–100. And as relief, they seek a declaration that “possession and manufacture of IHM and WHM during the hemp production process does not require registration under the CSA,” *id.* ¶ 105, and an injunction “enjoining DEA from enforcing the CSA as to IHM and WHM.”

It is therefore difficult to comprehend Plaintiffs’ contention that they “do not challenge the IFR” in this case. Pls.’ Reply ISO Mot. for Expedited Disc. (Pls.’ Disc. Reply) at 3, ECF No. 23. That assertion was literally impossible to reconcile with their now-abandoned claim seeking “an injunction enjoining the IFR.” Compl. ¶ 114. But neither can it be squared with their amended

claims seeking a *broader* injunction enjoining CSA enforcement as to IHM and WHM, FAC ¶ 110, and a declaration that—contrary to the DEA view Plaintiffs themselves allege is set out in the IFR, *id.* ¶¶ 83, 101—the AIA definition of hemp “includes IHM and WHM” or that those materials are otherwise not subject to the CSA, *id.* ¶ 105. And Plaintiffs’ own insistence that obtaining the declaratory and injunctive relief they seek in these proceedings will “obviate the need to challenge the IFR,” Pls.’ Disc. Mot. at 3, makes clear that they seek the same functional relief from this Court that they do in the D.C. Circuit: invalidation of and relief from the IFR.

That Plaintiffs have now expanded their complaint to include additional indications of the IFR’s meaning does not change this reality. *See* FAC ¶¶ 84–86, 101. These newly added statements were made subsequent to the IFR to explain the IFR’s scope, and are consistent with what Plaintiffs call the “necessary implication” of the IFR itself. The IFR was published in August 2020. Plaintiffs allege that a DEA spokesperson’s statement made two months later “could reasonably be understood to mean” that substances like IHM and WHM “would not be exempted from the CSA and would be classified and controlled as Schedule I substances.” *Id.* ¶ 86. And Plaintiffs allege that, two months after that, the Chief of DEA’s Office of Intergovernmental Affairs “explained that . . . DEA retains discretion to enforce the CSA as to IHM and WHM.” *Id.* ¶ 84. And in January 2021—five months after the IFR—the Department of Agriculture “confirmed that DEA intends to regulate ‘in-process materials’” such as IHM and WHM. *Id.* ¶ 104. None of these statements creates DEA policy; each reflects the policy that Plaintiffs allege is *already set out* in the IFR.

Plaintiffs cannot deny that a direct challenge to the IFR must proceed in the court of appeals. 21 U.S.C. § 877. That subsequent public statements reflect a policy set out in a final regulation is not some hidden exception to that exclusive jurisdiction—such a rule would make a mockery of Congressional intent and strongly deter public officials from discussing their agency’s official policy. In any event, it is the IFR, not later statements repeating its contents, that are the source of any injury Plaintiffs might claim. Their claimed injury is alleged harm to their and their

members' businesses and operations. FAC ¶¶ 91–94. The cause of this injury? DEA's allegedly "unlawful assertion of regulatory authority" over IHM and WHM. *Id.* ¶ 95. And it is the IFR, in Plaintiffs' own telling, that "constitute[s] DEA's most direct claim that IHM and WHM are illegal." *Id.* ¶ 84. That DEA officials and other government agencies have allegedly recognized this assertion of authority in subsequent statements cannot change the nature of the claim.

2. *Plaintiffs cannot evade an exclusive jurisdiction statute by artful pleading.*

More broadly, Plaintiffs "may not, by creatively framing their complaint, circumvent a congressional grant of exclusive jurisdiction." *Heller, Ehrman, White & MacAuliffe v. Babbitt*, 992 F.2d 360, 363 (D.C. Cir. 1993). As originally filed, Plaintiffs' Complaint scarcely tried to do so, and their more recent attempts to re-frame their claims fare no better. "Litigants may not evade these provisions [for exclusive court of appeals review] by requesting the District Court to enjoin action that is the outcome of the agency's order." *FCC v. ITT World Commc'ns, Inc.*, 466 U.S. 463, 468 (1984); *see also Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207 (1994) (holding that statute providing for exclusive judicial review in the courts of appeals after administrative process precluded a pre-enforcement challenge in district court); *Greenwood v. FAA*, 28 F.3d 971, 975 (9th Cir. 1994) (similar); *Connors v. Amax Coal Co.*, 858 F.2d 1226, 1231 (7th Cir. 1988) (similar); *Gen. Fin. Corp. v. FTC*, 700 F.2d 366, 368 (7th Cir. 1983) ("You may not bypass the specific method that Congress has provided for reviewing adverse agency action simply by suing the agency in federal district court under 1331 or 1337; the specific statutory method, if adequate, is exclusive."). The same is true for an action seeking declaratory relief "the practical effect" of which is "an assault on an important ingredient of" the final action committed to another court's exclusive jurisdiction. *California Save Our Streams Council, Inc. v. Yeutter*, 887 F.2d 908, 912 (9th Cir. 1989); *see Pub. Serv. Comm'n of Utah v. WycOFF Co., Inc.*, 344 U.S. 237, 246 (1952). Nor does it matter if, as Plaintiffs insist, their claims "are grounded in DEA's lack of *authority* to act" to regulate IHM and WHM in the first place, Pls.' Disc. Reply at 3; *see also, e.g., FAC* ¶ 62. *See Ukiab Adventist Hosp. v. FTC*, 981 F.2d 543, 550–51 (D.C. Cir. 1992). *Cf. New*

*Mexico v. Regan*, 745 F.2d 1318, 1322 (10th Cir. 1984) (holding that “the Claims Court’s exclusive jurisdiction may not be avoided by framing a complaint in the district court as one seeking injunctive, declaratory, or mandatory relief when, in reality, the thrust of the suit is one seeking money from the United States” for which the Court of Claims has exclusive jurisdiction). It thus does not matter for this Court’s jurisdictional analysis whether Plaintiffs are challenging a completed final determination embodied in the IFR (as they are) or instead or in addition are challenging a hypothetical final determination that may take place in the future, *e.g.*, FAC ¶ 90 (referencing possibility of future liability); *id.* ¶ 110 (seeking injunction against future enforcement).

Sound policy supports these rules. See *City of Rochester v. Bond*, 603 F.2d 927, 936 (D.C. Cir. 1979) (identifying benefits of “coherence and economy” by avoiding “duplication and inconsistency”). Allowing Plaintiffs to bring what is, unavoidably in substance, a challenge to the DEA’s IFR in district court, either on some alternative theory or by artful pleading, would “encourage[] forum shopping and encourage[] dissatisfied claimants to ‘jump the gun’ by going directly to district court to develop their cases instead of exhausting their administrative remedies before the agency.” *Doe*, 484 F.3d at 570. It would lead to “duplicative” review and accompanying delays. *Id.*; see also *John Doe, Inc. v. Gonzalez*, 2006 WL 1805685, at \*21 (D.D.C. June 29, 2006) (noting similar reasons for exclusive court of appeals review, even when there is not a “final determination”), *aff’d*, *Doe*, 484 F.3d 561. This is no less true for a pre-enforcement challenge to later enforcement of the CSA. *Thunder Basin*, 510 U.S. at 207. Indeed, essentially any challenge to a final decision regarding application of the CSA could be reframed as a challenge to the agency’s authority to act in the first place, or as a declaration that the activity affected by the final action is lawful, or as an injunction against enforcing the CSA. Take the facts of *Doe* as an example: There, the plaintiff sought to import what it contended was a Schedule III controlled substance; DEA denied an application for registration to do so on the grounds that the substance at issue was in fact a Schedule I controlled substance. 484 F.3d at 564. The plaintiff argued that DEA was wrong to

conclude that the substance at issue was not a Schedule III substance, and that DEA’s denial of the application was therefore erroneous. *See id.* at 571. The D.C. Circuit held that such a claim could proceed only in one of the courts of appeals. *Id.* at 568–70. The plaintiff in *Doe* could not simply have reframed its claim as one seeking declaratory relief that the substance was a Schedule III substance, and then proceeded in district court. Nor could it have done so by framing its complaint as a claim that DEA was not authorized to enforce the CSA should the plaintiff choose to import the substance anyway. So too, here.

Unsurprisingly, decades of precedent confirm this common-sense result. In *Telecommunications Research and Action Center v. FCC (TRAC)*, 750 F.2d 70 (D.C. Cir. 1984), the D.C. Circuit squarely held that “where a statute commits review of agency action to the Court of Appeals,”—as § 877 does— “any suit seeking relief that might affect the Circuit Court’s future jurisdiction”—such as this one—“is subject to the *exclusive* review of the Court of Appeals.” *Id.* at 75 (emphasis in original). This litigation readily satisfies both aspects of the *TRAC* analysis, which establishes a two-pronged test: “(1) the relevant statute ‘commits review to the Court of Appeals’; and (2) ‘the action seeks relief that might affect the circuit court’s future jurisdiction.’” *North v. Smarsh, Inc.*, 160 F. Supp. 3d 63, 83 (D.D.C. 2015) (quoting *Marchiano v. Nat’l Ass’n of Sec. Dealers, Inc.*, 134 F. Supp. 2d 90, 93 (D.D.C. 2001)). In *North*, for example, the district court held that, consistent with *TRAC*, the Exchange Act precluded a party from enjoining disciplinary actions brought under that law. *See id.* at 83–84. The disciplinary actions at issue “originate[d] from the authority delegated by the Exchange Act” and an injunction “would prevent . . . a final disciplinary order,” without which “there would be no review by the Court of Appeals.” *Id.* at 83 (quoting *Marchiano*, 134 F. Supp. 2d at 93).

Just so here: First, there can be no question that § 877 commits review to the courts of appeals for issues concerning application of the CSA. *See Doe*, 484 F.3d at 568. The actions Plaintiffs seek to enjoin—enforcement of the CSA against them—would “originate from the

authority delegated by” the CSA. *North*, 160 F. Supp. 3d at 83. And Plaintiffs themselves assert that the relief they seek in this court may “obviate the need to challenge the IFR” in the Court of Appeals. Pls.’ Disc. Mot. at 3. An injunction preventing DEA from enforcing the CSA as to specific substances (as Plaintiffs seek, *see* FAC ¶ 110) would prevent the Administrator from ever making a final decision under the CSA such that there “would be no review by the Court of Appeals.” *North*, 160 F. Supp. 3d at 83; *see also Ukiab Adventist Hosp. v. FTC*, 981 F.2d 543, 549 (D.C. Cir. 1992) (court of appeals had exclusive jurisdiction because “if the District Court enjoins the FTC proceeding against [the plaintiff] as requested, ‘the statutory obligation of a Court of Appeals to review [the FTC’s order] on the merits may be defeated’” (quoting *TRAC*, 750 F.2d at 76)). Moreover, Plaintiffs’ contentions, which focus on the scope of DEA’s authority to regulate under the CSA and on the meaning of terms within the CSA, as amended by the AIA, “almost certainly implicate[] issues that would be addressed by the Court of Appeals upon final review” of a final action under the CSA. *North*, 160 F. Supp. 3d at 84 (quoting *McGinn, Smith & Co. v. Fin. Indus. Reg. Auth.*, 786 F. Supp. 2d 139, 146 (D.D.C. 2011)). That this is so in this case is evident from reviewing Plaintiffs’ Petition for Review filed in the D.C. Circuit, where they contend that the IFR must be set aside because DEA “lacks statutory authority to promulgate the IFR” and because the IFR “is not in accordance with” the AIA—precisely the same arguments Plaintiffs make in these proceedings. *See* Pet’n for Review at 5, *Hemp Industries Ass’n*, No. 20-1376 (D.C. Cir. Sept. 18, 2020). And the D.C. Circuit has expressly rejected Plaintiffs’ suggestion that there is an “agency jurisdiction” exception to the otherwise exclusive conferral of jurisdiction on the courts of appeals. *Ukiab*, 981 F.2d at 550–51.

In enacting § 877, Congress evinced a clear intent to resolve challenges related to the CSA in the courts of appeals. This statutory review scheme necessarily means that regulated entities may not obtain judicial resolution of their contentions as quickly as they desire. But that is a consequence of Congress’s choice that such determinations be made first by the agency with

relevant expertise, whose “final determinations, findings, and conclusions . . . shall be final and conclusive,” subject to review—after they are made—by the courts of appeals. Plaintiffs cannot evade that intent through artful pleading or otherwise.<sup>2</sup> *Cf. Califano v. Sanders*, 430 U.S. 99, 108 (1977) (“Congress’ determination so to limit judicial review to the original decision denying benefits is a policy choice obviously designed to forestall repetitive or belated litigation of stale eligibility claims. Our duty, of course, is to respect that choice.”). As the Supreme Court itself held long ago, “the declaratory judgment procedure will not be used to pre-empt and prejudge issues that are committed for initial decision to an administrative body or special tribunal any more than it will be used as a substitute for statutory methods of review.” *Pub. Serv. Comm’n of Utah v. Wycoff Co., Inc.*, 344 U.S. 237, 246 (1952); *see also Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 48 (1938). The same is true for injunctive relief. *See FCC v. ITT World Commc’ns, Inc.*, 466 U.S. 463, 468 (1984). This Court lacks jurisdiction and should dismiss Plaintiffs’ claims.

3. *Plaintiffs’ authority purportedly limiting § 877’s scope is utterly unpersuasive.*

In their attempt to obtain discovery prior to review of this motion, Plaintiffs pointed to various cases that they contended undermine this mountain of authority. This contention is wrong.

Start with the Eighth Circuit’s decision in *Monson v. DEA*, 589 F.3d 952 (8th Cir. 2009). As Defendants have already noted, that out-of-circuit decision is in clear tension with the D.C. Circuit’s binding decision in *Doe*. *See* Defs.’ Disc. Opp’n at 7. After all, the Eighth Circuit relied on district court decisions that *Doe* explicitly rejected. *Compare Monson*, 589 F.3d at 960 (citing, among others, *PDK Labs Inc. v. Reno*, 134 F. Supp. 2d, 24, 29 (D.D.C. 2001) and *Novelty, Inc. v. Tandy*, 2006 WL

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<sup>2</sup> Plaintiffs’ theory would subvert Congress’s intent in another way: by allowing a party to evade the thirty-day time limit to challenge a final action. *See* 21 U.S.C. § 877. This action, for instance, was filed outside that time period. Plaintiffs of course have a timely challenge to the IFR pending in the D.C. Circuit. But Plaintiffs’ contention is that they may come to district court to invalidate, by injunction or declaratory judgment, a final decision under the CSA. Such a scheme would require DEA to defend “regulations long established that parties failed to contest at the time of their promulgation,” which is contrary to Congress’s clear intent in “prescrib[ing] a fixed deadline for appeals from regulations.” *Nader v. EPA*, 859 F.2d 747, 753 (9th Cir. 1988).

2375485, at \*7 (S.D. Ind. Aug. 15, 2006)), *with Doe*, 484 F.3d at 569 (rejecting the reasoning of *PDK Labs* and *Novelty, Inc.*). And as this case illustrates, the same reasons that both this District Court and the D.C. Circuit gave as supporting exclusive court of appeals jurisdiction in *Doe* apply with equal force to an action seeking a judicial declaration that a plaintiff's proposed action is lawful: such a "loophole" would subvert "the basic intent behind Congress' enactment of Section 877," would "allow selective forum shopping," and would "ultimately delay[]" resolution of "important determinations regarding critical issues vital to the public" by adding an additional layer of judicial review. *John Doe, Inc.*, 2006 WL 1805685, at \* 21; *see also Doe*, 484 F.3d at 570. Simply put, *Monson* was wrong on the law, is not binding in this circuit, and should not be followed.

But even on its own terms, *Monson* does not support jurisdiction here. As the Eighth Circuit noted, in that case "there was no final decision of the DEA to be reviewed." *Monson*, 589 F.3d at 961. Plaintiffs may contend, as they already have, that they do not challenge the IFR or any other final decision. *See* Pls.' Disc. Reply at 3. *But see supra* section I.A.1 (demonstrating that contention to be false). But they cannot deny that here, unlike in *Monson*, there is in fact a "final decision of the DEA to be reviewed"—the IFR that Plaintiffs allege "has serious, immediate, and irreparable consequences" that justify their claims. FAC ¶ 90. Given *Monson's* out-of-circuit provenance, its contradiction by the D.C. Circuit in *Doe*, and its distinct factual context, it is a thin reed indeed to rely on to support Plaintiffs' claim of district court jurisdiction.

The First Circuit's decision in *N.H. Hemp Council v. Marshall*, 203 F.3d 1 (1st Cir. 2000), offers even weaker support. True, the court there reviewed a district court decision regarding application of the CSA. *Id.* at 4 (the district court had itself dismissed on jurisdictional grounds for lack of standing). But the First Circuit did not reach a holding on, or even advert to, the jurisdictional issue presented by § 877. Rather, the court evidently assumed, without analysis, that the district court had jurisdiction and that its own exercise of appellate jurisdiction was therefore proper. Such "drive-by jurisdictional rulings" are given "no precedential effect." *Arbaugh v. Y&H*



*Corp.*, 546 U.S. 500, 511 (2006) (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 91 (1998)). Indeed, in *Doe* itself, the D.C. Circuit expressly noted that it, too, had previously and inadvertently exercised appellate jurisdiction over district court decisions related to application of the CSA. 484 F.3d at 569 n.5 (citing *PDK Labs., Inc. v. DEA*, 362 F.3d 786, 792 (D.C. Cir. 2004)). But, the D.C. Circuit explained, its “lack of comment cannot be construed as sanctioning the district court’s earlier assertion of jurisdiction” because “it is well settled that cases in which jurisdiction is assumed *sub silentio* are not binding authority for the proposition that jurisdiction exists.” *Id.* (quoting *Ticor Title Ins. Co. v. FDA*, 814 F.2d 731, 749 (D.C. Cir. 1987) (opinion of Williams, J.)). The First Circuit’s decision is of no moment to this Court’s analysis of § 877.

Plaintiffs have also cited to a district court decision from the Eastern District of Wisconsin, *Menominee Indian Tribe of Wisconsin v. DEA*, 190 F. Supp. 3d 843 (E.D. Wis. 2016). *See* Pls.’ Disc. Reply at 9. But that citation suffers the same infirmity: the district court did not address any issues regarding the exclusive jurisdiction afforded the court of appeals by § 877.

Plaintiffs did not identify any precedent from this district or circuit that would support jurisdiction. The D.C. Circuit in *Doe* expressly disapproved many examples Plaintiffs might cite. *See Doe*, 484 F.3d at 568–70. And Plaintiffs do not suggest that *Novelty Distributors, Inc. v. Leonhart*, 562 F. Supp. 2d 20, 28 (D.D.C. 2008), carries any weight here. There, the court relied on 21 U.S.C. § 824(d), which has no application to this case. *See* Defs.’ Disc. Opp’n at 7.

*B. Plaintiffs do not meet the requirements for so-called Leedom v. Kyne jurisdiction.*

Plaintiffs have also invoked *Leedom v. Kyne*, 358 U.S. 184 (1958), to support their claim to extra-statutory jurisdiction in the district court. *See* FAC ¶ 10; Pls.’ Disc. Reply at 8–9. That case does not support jurisdiction.

In *Kyne*, the Supreme Court held that the district court had jurisdiction to set aside what the defendant agency, the National Labor Relations Board, conceded was unlawful action. *Id.* at 187. This was so notwithstanding that the challenged action was not within the terms of the statutory

provisions for judicial review. *Id.* at 188–89. The Supreme Court reasoned that absent jurisdiction there would be “no other means” for a plaintiff to “protect and enforce that right” Congress had bestowed. *Id.* at 190. Given that circumstance, courts “cannot lightly infer that Congress does not intend judicial protection of rights it confers against agency action taken in excess of delegated powers.” *Id.*

In the six decades since *Kyne* was decided, both the Supreme Court and the D.C. Circuit have cautioned against over-reading *Kyne*. Thus, “*Kyne* stands for the familiar proposition that ‘only upon a showing of clear and convincing evidence of a contrary legislative intent should the courts restrict access to judicial review.’” *Bd. of Governors of Fed. Reserve Sys. v. MCorp Fin., Inc.*, 502 U.S. 32, 44 (1991) (quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (1967)); *see also DOJ v. FLRA*, 981 F.2d 1339, 1342 (D.C. Cir. 1993) (noting the doctrine has “very limited scope”). The D.C. Circuit recently elaborated the circumstances that allow for extra-statutory jurisdiction under this doctrine. *See DCH Reg’l Med. Ctr. v. Azar*, 925 F.3d 503, 508–10 (D.C. Cir. 2019). Three requirements must be met: “(i) the statutory preclusion of review is implied rather than express; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.” *Id.* at 509 (quoting *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009)).

Even assuming Plaintiffs’ claims satisfy the first requirement, they cannot meet either the second or third requirement to invoke the “Hail Mary pass” that is an assertion of *Kyne* jurisdiction. *Nyunt*, 589 F.3d at 449. As to the second, Plaintiffs may obtain judicial review of their statutory claims in a petition for review—either in their currently pending petition or in a future petition based on some future final determination by the DEA. As to the third, it “covers only ‘extreme’ agency error, not merely ‘[g]arden-variety errors of law or fact.’” *DCH Reg’l Med. Ctr.*, 925 F.3d at 509 (quoting *Griffith v. FLRA*, 852 F.2d 487, 493 (D.C. Cir. 1988)). That requirement is categorically unsatisfied on Plaintiffs’ own theory of the case: one where they do not challenge any agency action

*at all* (for, if they did, § 877 would plainly preclude jurisdiction in this Court). Agency action not yet taken can scarcely amount to “extreme agency error” warranting extra-statutory jurisdiction.

Of course, that is not Defendants’ view of Plaintiffs’ claims. As explained at length above, this action, properly understood, challenges the IFR. But even so, their claims do not remotely satisfy *Kyne*’s third requirement. Whatever may be said of DEA regulation of cannabis plant derivatives whose delta-9 THC content exceeds 0.3%, such regulation would not be “extreme agency error” that is “contrary to a specific prohibition that is clear and mandatory.” The statutory definition of regulated cannabis plants and derivatives includes “all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin,” 21 U.S.C. § 802(16)(a), except (as relevant here) “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*. These are complex statutory definitions; even assuming DEA were to make some error as to the precise legal border between “marihuana” and “hemp,” that error would not be “extreme” within the meaning of the *Kyne* requirements.

Because Plaintiffs plainly cannot satisfy either the second or the third requirement to invoke *Kyne* jurisdiction, they have not met their burden to establish jurisdiction.

*C. To the extent plaintiffs are challenging some action other than the IFR, they lack standing and any such challenge is not ripe for judicial review.*

Plaintiffs’ contention that they do not challenge the IFR in this action (and that it therefore falls outside § 877) is implausible and contradicted by their Amended Complaint. *See supra* section I.A.1. And as explained above, Plaintiffs’ attempt to recast their claims as something other than a challenge to the IFR changes nothing: Section 877 would still preclude district court jurisdiction because such a challenge nonetheless “might affect the Circuit Court’s future jurisdiction” over a

final determination concerning application of the CSA. *TRAC*, 750 F.2d at 75; *see supra* section I.A.2. But even if Plaintiffs could escape § 877’s jurisdictional frying pan, it would take them only into the fire of Article III. If Plaintiffs are challenging some other agency action not yet taken (as they inconsistently contend), the Court would lack jurisdiction for yet another reason: Plaintiffs have not identified a sufficiently imminent and non-speculative injury and any such claims are not ripe for judicial review.

1. *Plaintiffs have not alleged an adequate injury to support standing.*

Plaintiffs bear the burden to establish the “irreducible constitutional minimum of standing,” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)—that they have “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision,” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). Moreover, a plaintiff must “demonstrate standing separately for each form of relief sought.” *Friends of the Earth, Inc. v. Laidlaw Env’tl Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000) (citing *City of Los Angeles v. Lyons*, 461 U.S. 95, 109 (1983)); *see also Louie v. Dickson*, 964 F.3d 50, 54 (D.C. Cir. 2020) (same).

It is ordinarily straightforward for a regulated party to establish standing. *Lujan*, 504 U.S. at 561–62. But Plaintiffs’ convoluted attempt to escape § 877 puts them in a bind. They allege “serious, immediate, and irreparable consequences” arising from DEA’s “attempted usurpation” of regulatory authority over IHM and WHM embodied by the IFR. FAC ¶ 90; *see id.* ¶ 84. If Plaintiffs are challenging the IFR, then § 877 bars district court jurisdiction. And if instead Plaintiffs are challenging something other than the IFR, then their claimed injury (which they allege is caused by the IFR and related statements) is not caused by whatever other conduct they in fact challenge.

Charitably understood, then, Plaintiffs’ alternative contention must be that their injury will occur in the future and be caused by some possible future action, unrelated to the IFR, to enforce the CSA to interfere with their current business practices. If that is so, though, Plaintiffs run into the problem of imminence. The Supreme Court has “repeatedly reiterated that ‘threatened injury

must be *certainly impending* to constitute injury in fact,’ and that ‘[a]llegations of *possible* future injury’ are not sufficient.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). But Plaintiffs have not alleged such an injury: they have not alleged that DEA will take enforcement action against them, imminently or otherwise. To be sure, when constitutional rights are at stake it is often enough to show “an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)). But Plaintiffs do not allege any constitutional interest; indeed, Plaintiffs’ contention is that the conduct they seek to engage in is not “proscribed by statute” at all.

But even if a mere statutory right were sufficient to confer standing in those circumstances, Plaintiffs have not alleged, and cannot demonstrate, a “credible threat of prosecution” or enforcement. On the contorted view where Plaintiffs are not challenging the IFR, it is not clear on what basis they think DEA will regulate their proposed conduct. Put another way, Plaintiffs fail to show “an intention to engage in a course of conduct arguably affected with a [statutory] interest, but proscribed by [regulation], and there exists a credible threat of [enforcement] thereunder.” *Id.* If Plaintiffs do not challenge the IFR (or its future enforcement), then they have not adequately alleged an injury sufficiently imminent to confer standing. The Court therefore lacks jurisdiction over such a claim.

2. *Plaintiffs’ claims are not ripe.*

Ripeness is also a component of Article III jurisdictional analysis, often closely related to the question of Article III injury. *See Trump v. New York*, \_\_\_ U.S. \_\_\_ (Dec. 18, 2020), slip op. at 3–4; *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128 n.8 (2007). *Cf. Sec. Title Guarantee Corp. of Baltimore v. 915 Decatur St NW, LLC*, 427 F. Supp. 3d 1, 19 (D.D.C. 2019), *as amended* (Mar. 23, 2020) (recognizing that the Declaratory Judgment Act’s requirement of an “actual controversy” is

essentially a heightened ripeness inquiry). The doctrine prevents courts, “through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies,” and “protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Nat’l Park Hosp. Ass’n v. Dep’t of Interior*, 538 U.S. 803, 807–08 (2003) (quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148–49 (1967)). Determining whether administrative action is ripe for judicial review requires courts to evaluate (1) the fitness of the issues for judicial decision; and (2) the hardship to the parties of withholding court consideration. *Id.* at 808; see also *Abbott Laboratories*, 387 U.S. at 153.

These principles preclude adjudication of Plaintiffs’ claims here. To the extent Plaintiffs make any claim unrelated to the IFR, it is a preenforcement challenge to regulation of IHM and WHM, two byproducts of Plaintiffs’ manufacturing processes. Regulation of IHM and WHM raises numerous statutory, technical, and scientific issues. These issues cry out for the exercise of DEA’s relevant expertise. And if, as Plaintiffs now claim, they are not challenging the IFR (which does not specifically refer to either IHM or WHM), then they are not challenging any particular action by DEA—whether enforcement or rulemaking or something else—to regulate these two substances. Without such a concrete action to focus the judicial inquiry, it is premature for this Court to review Plaintiffs’ claims.

In doctrinal terms, the issues in this case, once separated from the IFR, are not yet “fit” for judicial review. Thus, as the Supreme Court explained in *Toilet Goods Association v. Gardner*, it is “wiser to require [a plaintiff] to exhaust this administrative process through which the factual basis . . . will certainly be aired and where more light may be thrown on the [agency’s] statutory and practical justifications” for any final determination. 387 U.S. 158, 166 (1967). “Judicial review will then be available, and a court at that juncture will be in a better position to deal with the question of statutory authority.” *Id.*; see also *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm’n*, 324 F.3d 726, 732–33 (D.C. Cir. 2003) (“Judicial review [prior to final agency action] improperly intrudes

into the agency's decisionmaking process. It also squanders judicial resources since the challenging party still enjoys an opportunity to convince the agency to change its mind." (quoting *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986)); *Hi-Tech Pharm., Inc. v. Hahn*, 2020 WL 3498588, at \*4 (D.D.C. June 29, 2020). Here, Plaintiffs need not even risk non-compliance, as did the challengers in *Toilet Goods Association*, to avail themselves of the prescribed administrative process that could culminate in an opportunity for judicial review of the DEA's statutory authority to regulate IHM and WHM. Rather, Plaintiffs (and their members) can seek registration under the CSA, or seek a final determination specifically with regard to IHM and WHM through the rulemaking process. Should Plaintiffs obtain registration or be told that they do not need to register, for example, the dispute may be moot. Conversely, should registration be denied, a court reviewing the denial of Plaintiffs' registration applications would be in a better position to address Plaintiffs' then-ripe challenge to DEA's concomitant determination that registration is required under the CSA. *See Toilet Goods Ass'n*, 387 U.S. at 166 (holding that challenge to FDA's statutory authority to regulate should be challenged after administrative process, even if that process assumed such authority).

The First Circuit's decision in *New Hampshire Hemp Council* is not to the contrary. As the First Circuit explained there, the DEA's "emphatic position equitably argues for review" because "that view having been expressed, there ought to be a way to resolve the legal correctness of its position without subjecting an honest businessman to criminal penalties." 203 F.3d at 5. To the extent Plaintiffs do not challenge the IFR, of course, no "emphatic position" on IHM or WHM has been expressed. And if DEA does in the future make some separate final determination, *via* review of registration applications, a rulemaking, or otherwise, and thereby sets out an "emphatic position" through the regulatory process—then Plaintiffs may, at that time, seek review of that determination in one of the courts of appeals, as § 877 requires. True, this may impose some delay on ultimate

resolution on Plaintiffs' contentions, but such is the consequence of the review scheme Congress has established.

**II. In any event, the Court should exercise its discretion to dismiss Plaintiffs' claims for equitable relief.**

A district court may decline to exercise jurisdiction over claims seeking equitable relief, including declaratory judgment actions, even though subject-matter jurisdiction is otherwise proper.<sup>3</sup> See 28 U.S.C. § 2201(a); *Brillhart v. Excess, Ins. Co. of America*, 316 U.S. 491, 494 (1942). Thus, “even when a suit otherwise satisfies subject matter jurisdictional prerequisites, the [Declaratory Judgment] Act gives courts discretion to determine ‘whether and when to entertain an action.’” *Morgan Drexen, Inc. v. CFPB*, 979 F. Supp. 2d 104, 116 (D.D.C. 2013), *aff'd*, 785 F.3d 684 (D.C. Cir. 2015) (quoting *Swish Mktg., Inc. v. FTC*, 669 F.Supp.2d 72, 76 (D.D.C.2009)). On the circumstances of this case, the Court should decline jurisdiction even if it determines jurisdiction exists, so that Plaintiffs' claims may be resolved in the pending action before the D.C. Circuit.<sup>4</sup>

There are no dispositive factors guiding the Court's discretion to decline jurisdiction over an action for declaratory judgment. The determination whether to exercise jurisdiction instead “is guided by the court's sense of ‘practicality and wise judicial administration,’ as well as numerous other factors.” *Sharp Corp. v. Hisense USA Corp.*, 292 F. Supp. 3d 157, 181 (D.D.C. 2017) (Boasberg,

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<sup>3</sup> Although Defendants here focus on the propriety of jurisdiction over the declaratory judgment claims, the same reasoning counsels against exercising jurisdiction over Plaintiffs' claim for injunctive relief. “[T]he authority of a federal court to abstain from exercising its jurisdiction extends to all cases in which the court has discretion to grant or deny relief.” *Quackenbush v. Allstate Ins. Co.*, 517 U.S. 706, 718 (1996). Moreover, because Plaintiffs must prevail on every aspect of their claim for injunctive relief, the Court can deny such relief without first resolving the merits of their claim. See *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 23–24 (2008). Injunctive relief in this case—even assuming Plaintiffs were to prevail on the merits and to demonstrate irreparable harm—would be contrary to the public interest because it would subvert Congress's evident intent to have the Attorney General, or his delegate, decide in the first instance issues concerning the application of the CSA, subject to judicial review in a court of appeals. See 21 U.S.C. § 877.

<sup>4</sup> The Court may dismiss Plaintiffs' claims on this ground even without first resolving the mandatory jurisdictional issues, as discretionary jurisdiction is, like statutory and Article III jurisdiction, a “non-merits threshold” issue. See *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422 (2007).



J.) (quoting *Wilton v. Seven Falls*, 515 U.S. 277, 282 (1995); see also *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 136 (2007) (courts should consider a range of “equitable, prudential, and policy arguments”). Among the factors that courts in this circuit consider are:

[1] whether it would finally settle the controversy between the parties; [2] whether other remedies are available or other proceedings pending; [3] the convenience of the parties; [4] the equity of the conduct of the declaratory judgment plaintiff; [5] prevention of ‘procedural fencing’; [6] the state of the record; [7] the degree of adverseness between the parties; and [8] the public importance of the question to be decided.

*Morgan Drexen, Inc.*, 979 F. Supp. 2d at 116 (quoting *Hanes Corp. v. Millard*, 531 F.2d 585, 591 n.4 (D.C. Cir. 1976)). Consideration of these factors strongly supports declining jurisdiction.

First and most obviously, there are “other proceedings pending” in which Plaintiffs can raise all the same arguments they might raise in these proceedings. See *id.* at 117 (pending proceedings where same arguments may be raised counseled against jurisdiction). And even to the extent any relief Plaintiffs might obtain in those particular pending proceedings might differ from that available here, “other remedies are available” to Plaintiffs through the mechanisms for judicial review that Congress has established. More broadly, and as set forth at length above, the statutory scheme Congress enacted evinces a clear preference for initial judicial resolution of the issues in this case by a court of appeals. Even if the statutory scheme did allow for jurisdiction over a suit like this (and it does not), the identity of the parties and the close relation of the issues to the earlier-filed litigation in the D.C. Circuit still counsels against this Court’s exercising jurisdiction.

Second, this action may not “finally settle the controversy between the parties.” To be sure, an injunction entirely preventing DEA from regulating the products at issue might do so. See FAC ¶ 110. But in assessing this factor, “[t]he Court cannot assume . . . that it will resolve the merits of [Plaintiffs’] complaint in [their] favor.” *Swish Mktg.*, 669 F. Supp. 2d at 77. And should the Court resolve these claims in Defendants’ favor, then Plaintiffs’ pending petition for review would still need to be adjudicated, as Plaintiffs raise arguments there (pertaining to APA procedures) not available to them in these proceedings. By contrast, every issue Plaintiffs might raise here may be

raised and resolved in either the pending or future proceedings challenging a final determination. *See Morgan Drexen, Inc.*, 979 F. Supp. 2d at 117 (declining jurisdiction when declaratory judgment action would resolve only some issues whereas other pending proceedings could resolve all issues). Avoiding piecemeal litigation “weighs in favor of dismissal.” *Id.* (quoting *Gov’t Emps. Ins. Co. v. Rivas*, 573 F. Supp. 2d 12, 15 (D.D.C. 2008)).

Third, the litigation in both this and the pending proceedings will proceed in the District of Columbia. Plaintiffs evidently are content to endure the inconvenience of litigating in two forums. But it is more convenient for Defendants to litigate these issues only in the Court of Appeals—where litigation will have to occur regardless if Defendants were to prevail in these proceedings, and where any appeal from these proceedings would be heard in any event. This factor, too, weighs against discretionary jurisdiction.

Fourth, Defendant cannot say why Plaintiffs prefer to begin this litigation in the district court with eventual appeal to the same court of appeals where their petition for review is held in abeyance. But that decision reflects some degree of “procedural fencing”—more commonly called forum shopping. *See John Doe, Inc.*, 2006 WL 1805685, at \*21 (noting the value to a plaintiff of picking a forum when seeking a preliminary injunction). Plaintiffs might have made all the arguments they raise here in the D.C. Circuit, but have chosen to press them here instead. This factor therefore weighs, albeit weakly, against discretionary jurisdiction. Certainly this is unlike the more-common circumstance where a putative defendant seeks to preempt a plaintiff’s choice of forum; here, Plaintiffs themselves have chosen both forums. Thus, while Defendants maintain that these issues should be litigated only in a court of appeals, Defendants do not believe that Plaintiffs have acted inequitably in seeking relief in the district court. That factor is therefore neutral.

Fifth: As to the state of the record, there is none. In the D.C. Circuit, the IFR will be reviewed on an administrative record. But as Plaintiffs maintain that they do not challenge the IFR, but rather challenge some future, hypothetical regulatory or enforcement action, there is no

administrative record to review. And to the extent Plaintiffs' claims relate to particular conduct they or their members have taken (or will take), the Court will be deprived of the factual record that would be available to a court of appeals in any future enforcement action. *Cf. Public Affairs Assocs., Inc. v. Rickover*, 369 U.S. 111, 112 (1962) (per curiam) (vacating declaratory judgment which decided "matters of serious public concern" upon "woefully lacking" record).

The "public importance of the question to be decided" also weighs against exercising discretionary jurisdiction.<sup>5</sup> Courts "particularly are reluctant to resolve important questions of public law in a declaratory action." 10B Wright, Miller & Kane, *Federal Practice and Procedure* § 2759 (4th ed.); *see id.* § 2763. Whether and how DEA regulates substances containing relatively high amounts of delta-9 THC is just such an important question. *See John Doe, Inc.*, 2006 WL 1805685, at \* 21. And that is a question that should be resolved, in the first instance, by the agency with relevant expertise, subject to the statutory scheme for judicial review.

In sum, *none* of the frequently considered factors supports the discretionary exercise of jurisdiction over Plaintiffs' claims for equitable relief; most weigh against discretionary jurisdiction—the first two especially heavily against—and some are, at best, neutral. The Court should accordingly decline to exercise jurisdiction over these claims.

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<sup>5</sup> Some judicial decisions—no doubt abetted by confused litigants—consider the public importance of the issues to weigh *in favor of* declaratory relief, rather than *against* it. *E.g. Morgan Drexen, Inc.*, 979 F. Supp. 2d at 119 n.6; *Swish Mktg.*, 669 F. Supp. 2d at 80. That understanding is incorrect: The Supreme Court has repeatedly indicated that issues of public importance should *not* be decided in a declaratory judgment posture. *See, e.g., Eccles v. Peoples Bank of Lakewood Vill., Cal.*, 333 U.S. 426, 431 (1948) ("Especially where governmental action is involved, courts should not intervene unless the need for equitable relief is clear, not remote or speculative."); *Pub. Serv. Comm'n of Utah v. Wycoff Co.*, 344 U.S. 237, 243 (1952) (similar); *Public Affairs Assocs., Inc. v. Rickover*, 369 U.S. 111, 112 (1962) (per curiam); *Askew v. Hargrave*, 401 U.S. 476 (1971).

But even if that were not the case, the reason for favoring resolution of such issues in a declaratory judgment would be to obtain quicker judicial resolution of an important question. That interest is not served in circumstances like this—where declining jurisdiction will allow the issues to be addressed *immediately* by the same court that would, eventually, hear any appeal from this Court's initial resolution of the same issues.

## CONCLUSION

The courts of appeals have exclusive jurisdiction over any of Plaintiffs' claims related to the IFR or any other final decision. If Plaintiffs are challenging only a hypothetical regulation or policy concerning manufacturing byproducts from *Cannabis sativa L.*, then they also cannot establish Article III jurisdiction. The Court should therefore dismiss Plaintiffs' First Amended Complaint for lack of jurisdiction.<sup>6</sup> If the Court concludes that it does have jurisdiction, it should nonetheless dismiss Plaintiffs' claims in exercise of its discretion not to award equitable relief.

Dated: January 26, 2021

Respectfully submitted,

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<sup>6</sup> It might ordinarily be appropriate to transfer jurisdiction to the appropriate court of appeals, rather than to dismiss. *See* 28 U.S.C. § 1631; *see Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1086–87 (D. Or. 2002). Because Plaintiffs already have a petition pending in the D.C. Circuit, transfer is unnecessary; because Plaintiffs initiated this action outside the statutory time limits, *see* 21 U.S.C. § 877, transfer is unwarranted.