

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
SHERMAN DIVISION

WALMART INC.,

*Plaintiff,*

v.

U.S. DEPARTMENT OF JUSTICE, ATTORNEY  
GENERAL WILLIAM P. BARR, U.S. DRUG  
ENFORCEMENT ADMINISTRATION, and  
ACTING ADMINISTRATOR TIMOTHY J.  
SHEA,

*Defendants.*

No. 4:20-cv-00817

**DEFENDANTS' MOTION TO DISMISS FOR LACK OF JURISDICTION**

**DEFENDANTS' MOTION TO DISMISS**

For the reasons set forth in the accompanying memorandum of law, Defendants respectfully move the Court to dismiss this action in its entirety for lack of jurisdiction, *see* Federal Rule of Civil Procedure 12(b)(1).

Dated: December 4, 2020

Respectfully submitted,

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**TABLE OF CONTENTS**

INTRODUCTION..... 1

STATEMENT OF THE ISSUES ..... 2

BACKGROUND..... 2

    A. The Government’s Enforcement Authority ..... 2

    B. Litigation Related to the Opioid Crisis ..... 4

    C. Walmart’s Preemptive Lawsuit..... 6

STANDARD OF REVIEW ..... 7

ARGUMENT..... 7

    I. This Court Lacks Subject-Matter Jurisdiction. .... 9

        A. Congress has provided no waiver of sovereign immunity for this  
            challenge. .... 9

        B. Walmart has not pleaded any cause of action to support jurisdiction. .... 14

        C. Walmart seeks an advisory opinion..... 16

CONCLUSION..... 21

**TABLE OF AUTHORITIES**

**Cases**

*Abbott Labs. v. Gardner*,  
387 U.S. 136 (1967) .....15

*Ariz. Christian Sch. Tuition Org. v. Winn*,  
563 U.S. 125 (2011) .....17

*Bennett v. Spear*,  
520 U.S. 154 (1997) .....11

*Better Mkts., Inc. v. DOJ*,  
83 F. Supp. 3d 250 (D.D.C. 2015).....8

*Califano v. Sanders*,  
430 U.S. 99 (1977) .....15

*California v. San Pablo & Tulare R.R. Co.*,  
149 U.S. 308 (1893) .....17

*Coffman v. Breeze Corp.*,  
323 U.S. 316 (1945) .....21

*DaimlerChrysler Corp. v. Cuno*,  
547 U.S. 332 (2006) .....17

*Dow Chem. v. EPA*,  
832 F.2d 319 (5th Cir. 1987) .....12

*Ewing v. Mytinger & Casselberry*,  
339 U.S. 594 (1950) .....8

*Exxon Mobil Corp. v. Allapattah Servs., Inc.*,  
545 U.S. 546 (2005) .....7

*FTC v. Standard Oil Co. of Cal.*,  
449 U.S. 232 (1980) ..... 11, 12

*Gaar v. Quirk*,  
86 F.3d 451 (5th Cir. 1996) ..... 14, 16

*Georgia v. City of Chattanooga*,  
264 U.S. 472 (1924) .....12

*Greater N.Y. Hosp. Ass’n v. United States*,  
 No. 98 Civ. 2741 (RLC), 1999 WL 1021561 (S.D.N.Y. Nov. 9, 1999) .....13

*Hawaii v. Gordon*,  
 373 U.S. 57 (1963) .....9

*Heckler v. Chaney*,  
 470 U.S. 821 (1985) .....8, 11, 13, 14

*Hollingsworth v. Perry*,  
 570 U.S. 693 (2013) .....17

*In re Nat’l Prescription Opiate Litig.*,  
 No. 1:17-MD-2804, 2019 WL 4686815 (N.D. Ohio Sept. 26, 2019)..... 4, 5

*In re Nat’l Prescription Opiate Litig.*,  
 No. 1:17-MD-2804, 2019 WL 3917575, (N.D. Ohio Aug. 19, 2019).....6

*In re Nat’l Prescription Opiate Litig.*,  
 No. 18-OP-45032, 2020 WL 4550400 (N.D. Ohio Aug. 6, 2020), *clarified on denial of reconsideration*,  
 2020 WL 5642173 (N.D. Ohio. Sept. 22, 2020)..... 5, 6

*Johnson v. United States*,  
 502 F. App’x 412 (5th Cir. 2012).....10

*Jones v. Alexander*,  
 609 F.2d 778 (5th Cir. 1980) .....15

*Kokkonen v. Guardian Life Ins. Co. of Am.*,  
 511 U.S. 375 (1994) .....7

*Lawson v. Callahan*,  
 111 F.3d 403 (5th Cir. 1997) .....14

*Lowe v. Ingalls Shipbuilding*,  
 723 F.2d 1173 (5th Cir. 1984) .....14

*Lujan v. Defs. of Wildlife*,  
 504 U.S. 555 (1992) .....7

*Marye v. Parsons*,  
 114 U.S. 325 (1885) .....17

*McMahon v. United States*,  
 342 U.S. 25 (1951) .....10

*MedImmune, Inc. v. Genentech, Inc.*,  
549 U.S. 118 (2007) .....17

*N.J. Hosp. Ass’n v. United States*,  
23 F. Supp. 2d 497 (D.N.J. 1998)..... 13, 18

*Nat’l Rifle Ass’n of Am. v. Magaw*,  
132 F.3d 272 (6th Cir. 1997) .....15

*Norris v. Hearst Tr.*,  
500 F.3d 454 (5th Cir. 2007) .....4

*Norton v. S. Utah Wilderness All.*,  
542 U.S. 55 (2004) ..... 20, 21

*Ohio Hosp. Ass’n v. Shalala*,  
978 F. Supp. 735 (N.D. Ohio 1997) .....18

*Parke, Davis & Co. v. Califano*,  
564 F.2d 1200 (6th Cir. 1977) .....13

*Perales v. Casillas*,  
903 F.2d 1043 (5th Cir. 1990) .....14

*Perez v. Mortg. Bankers Ass’n*,  
575 U.S. 92 (2015) .....20

*Physician Hosps. of Am. v. Sebelius*,  
691 F.3d 649 (5th Cir. 2012) .....7

*Pub. Serv. Comm’n of Utah v. Wycoff Co.*,  
344 U.S. 237 (1952) .....18

*Public Citizen, Inc. v. EPA*,  
343 F.3d 449 (5th Cir. 2003) .....14

*Quicken Loans Inc. v. United States*,  
152 F. Supp. 3d 938 (E.D. Mich. 2015).....13

*Raines v. Byrd*,  
521 U.S. 811 (1997) .....17

*Schilling v. Rogers*,  
363 U.S. 666 (1960) .....15

*Severe Records, LLC v. Rich*,  
658 F.3d 571 (6th Cir. 2011) .....15

*Sherwin-Williams Co. v. Holmes Cty.*,  
343 F.3d 383 (5th Cir. 2003) .....16

*Shoshone-Bannock Tribes v. Reno*,  
56 F.3d 1476 (D.C. Cir. 1995)..... 8, 13

*Skelly Oil Co. v. Phillips Petroleum Co.*,  
339 U.S. 667 (1950) .....15

*St. Tammany Par., ex rel. Davis v. FEMA*,  
556 F.3d 307 (5th Cir. 2009) .....10

*Steel Co. v. Citizens for a Better Env't*,  
523 U.S. 83 (1998) ..... 7, 17

*Time, Inc. v. Manning*,  
366 F.2d 690 (5th Cir. 1966) .....9

*Travis v. Pennyrite Rural Elec. Co-op.*,  
399 F.2d 726 (6th Cir. 1968) .....12

*United Pub. Workers of Am. (C.I.O.) v. Mitchell*,  
330 U.S. 75 (1947) .....18

*United States v. Armstrong*,  
517 U.S. 456 (1996) ..... 8, 13

*United States v. Mitchell*,  
463 U.S. 206 (1983) .....9

*United States v. Nordic Vill, Inc.*,  
503 U.S. 30 (1992) .....10

*United States v. Sherwood*,  
312 U.S. 584 (1941) .....9

*United States v. West Virginia*,  
295 U.S. 463 (1935) .....19

*Voluntary Purchasing Groups, Inc. v. Reilly*,  
889 F.2d 1380 (5th Cir. 1989) .....10

*Walmart Stores, Inc. v. Tex. Alc. Bev. Comm'n*,  
No. 1:15-CV-134-RP, 2017 WL 9481257 (W.D. Tex. May 22, 2017) .....15

*Warth v. Seldin*,  
422 U.S. 490 (1975) .....17

*Wayte v. United States*,  
470 U.S. 598 (1985) ..... 8, 13

*Webster v. Doe*,  
486 U.S. 592 (1988) .....11

**Statutes**

5 U.S.C. § 701 ..... 4, 10

5 U.S.C. § 701(a)(2)..... 11, 13

5 U.S.C. § 702 .....11

5 U.S.C. § 703 .....12

5 U.S.C. § 704 ..... 10, 12

5 U.S.C. § 706 .....10

5 U.S.C. § 551(13) .....11

21 U.S.C. § 801 .....2

21 U.S.C. § 811 .....2

21 U.S.C. § 821 ..... 2, 3

21 U.S.C. § 822 .....3

21 U.S.C. § 823 .....3

21 U.S.C. § 824(a)(4).....4

21 U.S.C. § 832 .....3

21 U.S.C. § 842 .....4

21 U.S.C. § 843 .....4

21 U.S.C. § 871 .....2

21 U.S.C. § 871(a) .....3

21 U.S.C. § 871(b) .....3

21 U.S.C. § 875 .....4

21 U.S.C. § 876.....4  
 21 U.S.C. § 880.....4  
 21 U.S.C. § 882(a) .....4  
 28 U.S.C. § 1331.....10  
 28 U.S.C. § 2201.....6, 10, 14, 17

**Rules**

Fed. R. Civ. P. 12(b)(1)..... 7

**Regulations**

21 C.F.R. § 1301.11.....3  
 21 C.F.R. § 1301.36.....4  
 21 C.F.R. § 1301.71(a) .....3  
 21 C.F.R. § 1301.74(b).....3  
 21 C.F.R. § 1306.04(a) ..... 3, 4  
 21 C.F.R. § 1306.06..... 3, 4  
 21 C.F.R. §§ 1300-1321 .....3  
 21 C.F.R. §§ 1301.31-46.....4  
 21 C.F.R. §§ 1316.41-68.....4  
 28 C.F.R. § 0.100(b).....3

**Executive Materials**

Exec. Order No. 11727, 38 Fed. Reg. 18,357 (July 10, 1973) .....2

**Constitution**

U.S. Const. art. II, § 3..... 8, 13

**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT**

**INTRODUCTION**

Walmart's complaint, devoid of any basis for subject-matter jurisdiction or even a cause of action, seeks improper pre-enforcement review of a hypothetical civil-enforcement action. Facing the prospect of uncertain potential liability for its conduct amidst a nationwide epidemic of opioid-related addiction and death, and having lost key legal arguments in multi-district litigation brought by state and local entities, Walmart now urges this Court to proclaim it innocent of violations of the Controlled Substances Act. In so doing, Walmart not only seeks collaterally to attack orders issued by another federal court, but also invites this Court to pioneer a dramatic expansion of judicial review of prosecutorial activity. Notwithstanding Walmart's attempt to frame its challenge as presenting ripe disputes on pure questions of law, Walmart's grievance boils down to dissatisfaction with the government's exercise of investigatory and prosecutorial discretion in relation to Walmart's opioid dispensing and distribution practices. If the Court could entertain this case, then any would-be defendant faced with a government investigation that it dislikes could raise a pre-filing challenge to the government's anticipated suit. That is not the law. Walmart's proper recourse is to mount its defense in the government's enforcement suit, should one be filed, not to spawn a public-relations stunt under the guise of preemptive litigation in Walmart's preferred forum and on Walmart's preferred timeline.

Walmart has not established a legal right preemptively to determine whether DOJ's alleged legal interpretations pass muster. First, Walmart has wholly ignored the requirement that it provide an "unequivocally expressed" waiver of sovereign immunity to sue the federal government. Second, it has failed to plead any cause of action underlying its declaratory-judgment claim, as it must, since that statute is procedural only and does not provide a cause of action. Third, in urging this Court to opine

on its legal culpability in a hypothetical suit untethered from any factual context, Walmart asks this Court to issue an advisory opinion. The parties' allegedly divergent views about the scope of a pharmacies' or pharmacists' duties under the CSA, and Walmart's request for abstract declarations on the same, does not demonstrate the existence of an actual controversy. It appears, at best, to be an end-run around unfavorable rulings made by the United States District Court for the Northern District of Ohio in ongoing multidistrict opioid litigation, orders that Walmart already has moved unsuccessfully to reconsider. Accordingly, this Court has no basis to opine on hypothetical fact patterns that *could* arise in some future enforcement proceeding and, given the potential consequences for other pending federal litigation, should not indulge Walmart's efforts to relitigate issues it already has lost.

Any of these grounds is reason to grant DOJ's motion to dismiss in its entirety.

### **STATEMENT OF THE ISSUES**

1. Can Walmart sue the federal government without identifying any waiver of sovereign immunity?
2. Can Walmart obtain a declaratory judgment without identifying any cause of action on which to base its suit?
3. Does Walmart's suit purportedly seeking to resolve "disputes of law" between the parties ask this Court to issue an unlawful advisory opinion?

### **BACKGROUND**

#### **A. The Government's Enforcement Authority**

Congress established in the Controlled Substances Act ("CSA" or "the Act") a comprehensive framework for the manufacture, importation, distribution, and dispensing of controlled substances, including those with "useful and legitimate medical purpose[s]," *see* 21 U.S.C. §§ 801 *et seq.*, and vested authority to enforce the Act in the Attorney General, *id.* §§ 811, 821, 871. President Nixon established the Drug Enforcement Administration ("DEA") as a subagency within the Department of Justice in

1973, *see* Executive Order No. 11727, 38 Fed. Reg. 18,357, 18,357-58 (July 10, 1973), and the Attorney General delegated his authority to regulate under the Act to the DEA Administrator. 21 U.S.C. § 871(a); 28 C.F.R. § 0.100(b). The CSA authorizes DEA (pursuant to its delegated authority) to “promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances,” 21 U.S.C. § 821, and to enforce the Act’s provisions and the rules issued thereunder. *Id.* § 871(b). The DEA has relied on this broad authority to issue regulations under the CSA. 21 C.F.R. §§ 1300-1321.

One primary objective of the CSA and its implementing regulations is to prevent diversion and abuse of controlled substances. To achieve that goal, the CSA regulates all participants in the controlled-substance supply chain, including, as relevant here, pharmacies that dispense controlled substances to patients and distributors that deliver controlled substances to pharmacies. All such participants must register with the DEA. *See* 21 U.S.C. §§ 822-23; 21 C.F.R. § 1301.11. In addition, pharmacies must, among other things, ensure that they fill only prescriptions issued for a legitimate medical purpose by a prescriber acting in the usual course of professional medical practice, *see* 21 C.F.R. § 1306.04(a); *see also id.* § 1306.06 (requiring pharmacists to act in “the usual course of [their] professional practice”). And distributors and dispensers must, among other things, “provide effective controls and procedures to guard against theft and diversion of controlled substances,” 21 C.F.R. § 1301.71(a), and “design and operate a system to disclose to the registrant suspicious orders of controlled substances” that enables the distributor to “inform the [DEA] of suspicious orders when discovered by the registrant ... includ[ing] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency,” *id.* § 1301.74(b); 21 U.S.C. § 832. In effect, registrants must maintain a closed system of distribution. 21 U.S.C. §§ 822-23; 21 C.F.R. § 1301.11.

Regulations issued by DEA also impose requirements on pharmacists and pharmacies, *e.g.*, that a pharmacist may fill a prescription only if it is “issued for a legitimate medical purpose by an

individual practitioner acting in the usual course of his professional practice,” *id.* § 1306.04(a), and must fill the prescription in the usual course of pharmacy practice, *id.* § 1306.06.

The CSA imposes a range of administrative, civil, and criminal penalties for violations of these requirements, including loss of registration and civil monetary penalties. *See, e.g.*, 21 U.S.C. §§ 842((a), (c), 843(f), 882(a). Registrants, including distributors and retail pharmacies, who fail in these or other duties may have their registration revoked, *inter alia*, upon a finding by DEA that the registrant’s continued registration is “inconsistent with the public interest.” 21 U.S.C. § 824(a)(4); 21 C.F.R. § 1301.36. And the DEA employs broad investigatory and adjudicatory powers to carry out its regulatory and law-enforcement missions, including: the ability to issue subpoenas; to conduct inspections; and to carry out administrative hearings resulting in binding decisions that may suspend, revoke, or otherwise restrict registrations, subject to judicial review under the Administrative Procedure Act (“APA”), 5 U.S.C. § 701 *et seq.* *See* 21 U.S.C. §§ 875-76, 880; 21 C.F.R. §§ 1301.31-46, 1316.41-68.

## **B. Litigation Related to the Opioid Crisis**

The United States remains in the throes of “one of the greatest tragedies of our time,” a “historic” epidemic of rampant opioid abuse fueling a “staggering” “human toll” and a consequent “extreme” “economic burden on government at all levels.” *In re Nat’l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4686815, at \*1 (N.D. Ohio Sept. 26, 2019).<sup>1</sup> Several years ago, as litigation proliferated seeking to hold drug manufacturers, distributors, retail pharmacies, and others liable for the flood of illegal prescription drugs on American streets, the Judicial Panel on Multidistrict Litigation created the Opioid MDL to consolidate discovery and bellwether trials before the U.S. District Court

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<sup>1</sup> This Court can properly consider developments in the United States District Court for the Northern District of Ohio in evaluating this motion to dismiss because “it is clearly proper in deciding a 12(b)[(1)] motion to take judicial notice of matters of public record.” *Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007).

for the Northern District of Ohio. *Id.* That litigation now encompasses thousands of lawsuits, filed primarily by state and local governmental entities, against dozens of defendants. *Id.* Although the United States is neither plaintiff nor defendant in the MDL, it has filed a statement of interest and, through the DEA and other federal agencies, is participating in and producing discovery in the MDL. *See, e.g.*, ECF Nos. 161, 165, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804 (N.D. Ohio).

Walmart, a multinational corporation with more than 5,000 retail stores across the United States (many of which include pharmacies), *see* Compl. ¶¶ 65-66, ECF No. 1, is among the pharmacy defendants in the Opioid MDL. In addition to its retail dispensing of addictive narcotics, Walmart self-distributed opioids to its stores from 2002 through early 2018. *Id.* ¶ 94.

In the Opioid MDL Walmart joined other pharmacy defendants, including several of the nation's largest chain drug stores, in moving to dismiss claims filed by state and local governments on the ground that “the CSA, as a matter of law, does not impose any obligation on a pharmacy-registrant, itself, to identify or investigate dubious prescriptions prior to filling them.” *In re Nat'l Prescription Opiate Litig.*, No. 18-OP-45032, 2020 WL 4550400, at \*6 (N.D. Ohio Aug. 6, 2020), *clarified on denial of reconsideration*, 2020 WL 5642173 (N.D. Ohio. Sept. 22, 2020). The pharmacies have lost on this and other related theories of legal non-liability, which the MDL court described as “troubling” and “a frightening abdication of responsibility.” *Id.* at \*6-7. That court was emphatic in rejecting the pharmacies' interpretation of the CSA:

In sum, the Court concludes that Pharmacy Defendants have failed to meet their burden of demonstrating there is no corporate-level obligation to design and implement systems, policies, or procedures to identify red flag prescriptions. And the Pharmacy Defendants' ultimate argument—that they cannot be liable to Plaintiffs because only their pharmacist-employees are responsible for preventing diversion of opioids via illegitimate prescriptions—is premised upon a tortured reading of the CSA and its regulations. Because Defendants' reading of the CSA is antithetical to its very purpose, the Court rejects Defendants' positions.

*Id.* at \*13. The MDL court also rejected the MDL defendants' arguments about distribution. *See* 2019 WL 3917575, at \*9 (“[T]he Court concludes that the CSA statutory and regulatory duties to maintain

effective controls against diversion includes a duty not to ship suspicious orders”). The MDL litigation remains ongoing.

### C. WALMART’S PREEMPTIVE LAWSUIT

Walmart now sues DOJ, DEA, and the heads of each agency, “seek[ing] a judicial declaration to resolve” what it characterizes as “a dispute . . . about the obligations of pharmacists and pharmacies under the Controlled Substances Act.” Compl. at 1. Although Walmart is a Delaware corporation with its principal place of business in Arkansas, *id.* ¶ 26, and each of the federal Defendants (collectively, “DOJ”) is based in the Washington, D.C. area, Walmart filed suit in the Eastern District of Texas solely because the local U.S. Attorney’s Office initiated (but no longer is leading) an investigation into the company’s activities. *Id.* ¶¶ 25, 108-13.

According to the complaint, DOJ began investigating Walmart for potential CSA violations in late 2016.<sup>2</sup> Compl. ¶ 108. Walmart casts the local U.S. Attorney’s Office as heavy-handed and admits to having “elevated” the matter to DOJ leadership, prompting the creation of a civil Working Group of attorneys based both in D.C. and in USAOs across the country. *Id.* ¶¶ 108-13. According to Walmart, DOJ has expended “resources and taxpayer funds to this investigation . . . out of all proportion to any evidence of wrongdoing” and now, “on information and belief, [] intend[s] to pursue a civil enforcement action against Walmart based on a number of positions . . . that are wrong as a matter of federal law.” *Id.* ¶¶ 113, 115.

Walmart’s complaint contains no cause of action. Instead, it pleads a claim for relief under the Declaratory Judgment Act, 28 U.S.C. § 2201, on the ground that the company “faces the risk of a civil enforcement action under the CSA.” Compl. ¶ 163. This Court should head off that as-yet unfiled civil suit, Walmart insists, because it allegedly “is based on legal theories that have no basis in statute

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<sup>2</sup> Allegations in the complaint are presumed true solely for purposes of this motion.

or regulation,” *id.* ¶ 18, and “[t]he CSA and its duly promulgated regulations do not set forth the legal standards upon which Defendants purport to base their civil enforcement action against Walmart.” *Id.* ¶ 164. In order to “clarify and settle the parties’ legal obligations,” Walmart asks the Court to proclaim the outer bounds of liability for pharmacies and pharmacists under the CSA and to instruct DOJ to “follow their own regulations and [] not base any enforceable legal positions on the alleged violation of agency guidance rather than obligations found in a statute or duly promulgated rule or regulation.” *Id.* ¶ 175, Prayer for Relief.

### **STANDARD OF REVIEW**

Defendants move to dismiss this action for lack of subject-matter jurisdiction. *See* Fed. R. Civ. P. 12(b)(1). As the Supreme Court has said “many times,” “[t]he district courts of the United States ... are ‘courts of limited jurisdiction. They possess only that power authorized by Constitution and statute.’” *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 552 (2005) (*quoting Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994)). Accordingly, this Court has a duty to ensure that it is acting within the scope of its jurisdictional authority, *see Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94-95 (1998), and “the plaintiff[] carr[ies] the burden of establishing that statutory subject-matter jurisdiction exists.” *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 652 (5th Cir. 2012); *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

### **ARGUMENT**

For myriad reasons, Walmart’s proposal that this Court preemptively review the government’s enforcement efforts through the mechanism of their first-filed suit is baseless.

Fundamentally, enforcement is an obligation for the government to undertake, and is subject to its discretion. Here, Walmart seeks to arrogate to itself the power to litigate, in the abstract, the disputes it imagines a suit against it might present. This approach is backward. “The harm to property and business can [] be incalculable by the mere institution of proceedings. Yet it has never been held

that the hand of government must be stayed until the courts have an opportunity to determine whether the government is justified in instituting suit in the courts.” *Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 599 (1950). “Choosing whether and how to enforce a statute is the quintessential type of action committed to an agency’s absolute discretion” and “[s]uch decisions are presumptively unreviewable.” *Better Mkts., Inc. v. DOJ*, 83 F. Supp. 3d 250, 256 (D.D.C. 2015) (citing *Heckler v. Chaney*, 470 U.S. 821, 831 (1985)). Agencies “have this latitude because they are designated by statute as the President’s delegates to help him discharge his constitutional responsibility to ‘take Care that the Laws be faithfully executed.’” *United States v. Armstrong*, 517 U.S. 456, 464 (1996) (quoting U.S. Const. art. II, § 3).

At bottom, the question of how the matters Walmart seeks to litigate make their way to the courts implicate the exercise of prosecutorial discretion. “[C]ourts [are] properly hesitant to examine the decision whether to prosecute” because “the decision to prosecute is particularly ill-suited to judicial review” and “not readily susceptible to the kind of analysis the courts are competent to undertake.” *Wayte v. United States*, 470 U.S. 598, 607-08 (1985). “The presumption of regularity supports [agencies’] prosecutorial decisions and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties.” *Armstrong*, 517 U.S. at 464 (quotation and alteration omitted); *see also Shoshone-Bannock Tribes v. Reno*, 56 F.3d 1476, 1480 (D.C. Cir. 1995) (“In both civil and criminal cases, courts have long acknowledged that the Attorney General’s authority to control the course of the federal government’s litigation is presumptively immune from judicial review.”).

Walmart’s suit turns prosecutorial discretion on its head by challenging the legal basis of a potential government enforcement suit through a separate preemptive lawsuit, rather than simply raising its defenses in any potential enforcement suit itself (if one is filed). Moreover, Walmart has attempted to upset traditional legal processes by arrogating to itself procedural choices that should, absent unusual circumstances, be accorded the party bearing the burden of proof—such as selecting

the forum for adjudication and initially framing the issues for the Court and the public. “Plaintiff’s privilege to choose, or not to be ousted from, his chosen forum is highly esteemed.” *Time, Inc. v. Manning*, 366 F.2d 690, 698 (5th Cir. 1966) (internal citation omitted). Indeed, with this action Walmart invites this Court to hand over this discretion to Walmart itself, through pre-enforcement litigation.

Walmart’s effort is both substantively and procedurally improper, for numerous reasons set forth below. Most fundamentally, Walmart has failed to identify any arguable basis for subject-matter jurisdiction. Walmart identifies no waiver of sovereign immunity, nor any cause of action. Instead, Walmart attempts to invoke the Declaratory Judgment Act to entreat this Court into issuing an advisory opinion on abstract legal questions (many of which have been decided against Walmart in other litigation). The Court should decline Walmart’s baseless invitation to do so.

**I. This Court Lacks Subject-Matter Jurisdiction.**

**A. Congress has provided no waiver of sovereign immunity for this challenge.**

Walmart’s complaint makes no attempt to identify a waiver of sovereign immunity; none exists, so this action must be dismissed.

1. Walmart’s claim against DOJ, DEA, and the agencies’ heads in their official capacities is a suit against the United States. Yet “[i]t is axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction.” *United States v. Mitchell*, 463 U.S. 206, 212 (1983); *see also Hawaii v. Gordon*, 373 U.S. 57, 58 (1963) (per curiam) (explaining that declaratory relief was unavailable absent sovereign-immunity waiver because “The general rule is that relief sought nominally against an officer is in fact against the sovereign if the decree would operate against the latter.”). The party suing the government has the burden of showing that the government has consented to suit, *United States v. Sherwood*, 312 U.S. 584, 586 (1941), and in response to a motion to dismiss under Rule 12(b)(1), the “Plaintiff bears the burden of showing Congress’s unequivocal waiver of sovereign immunity.” *St. Tammany Par., ex rel. Davis v. FEMA*, 556 F.3d 307, 315 (5th Cir.

2009); *see also United States v. Nordic Vill, Inc.*, 503 U.S. 30, 33-34 (1992) (explaining that waiver of sovereign immunity, “to be effective, must be ‘unequivocally expressed,’” and “construed strictly in favor of the sovereign”) (second phrase quoting *McMahon v. United States*, 342 U.S. 25, 27 (1951)).

Walmart avers subject-matter jurisdiction under just two sources—the federal-question statute, 28 U.S.C. § 1331, and the Declaratory Judgment Act, 28 U.S.C. § 2201. *See* Compl. ¶ 24. But neither of these statutes provides any waiver of sovereign immunity. *See Voluntary Purchasing Groups, Inc. v. Reilly*, 889 F.2d 1380, 1385 (5th Cir. 1989) (“[I]t is well settled that section 1331 implies no general waiver of sovereign immunity, and, therefore, cannot alone be relied upon as the basis of jurisdiction in this case.”) (internal citation and alterations omitted); *Johnson v. United States*, 502 F. App’x 412, 416-17, 419 (5th Cir. 2012) (affirming dismissal of Declaratory Judgment Act claim on sovereign-immunity ground). Indeed, Walmart’s complaint fails to make even a passing reference to sovereign immunity. Because the company has not carried its burden to demonstrate an unequivocally expressed waiver, this suit must be dismissed on this ground alone.

2. To be sure, Walmart made the distinct choice *not* to ground its suit on the waiver of sovereign immunity provided by the APA, 5 U.S.C. §§ 701 *et seq.*, (*i.e.*, the typical framework for challenging federal agency action). The only reference to that statute in the company’s complaint is a vague, conditional reference to DEA’s licensing-revocation adjudications—proceedings to which Walmart makes no claim to have been subjected.<sup>3</sup> Should Walmart launch a belated effort to salvage its complaint by invoking the APA, however, that effort would be futile.

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<sup>3</sup> *See* Compl. ¶ 134 (“Even if Defendants were entitled to effectively amend the relevant regulations through adjudicatory proceedings, they would nevertheless be obligated to explain their change in position in a manner detailed enough for a reviewing court to examine under 5 U.S.C. § 706 ... To the extent that DEA’s revocation decisions modify the parties’ obligations under the CSA’s implementing regulations, they are arbitrary and capricious.”).

As amended in 1976, the APA waives sovereign immunity as to suits seeking nonmonetary relief against legal wrongs for which governmental agencies are accountable. *See id.* § 702. But that waiver may not be invoked unless a party establishes that the challenged government action fits within the APA’s waiver: Judicial review is available only to challenge a “final agency action for which there is no other adequate remedy in a court,” *id.* § 704, and which is not “committed to agency discretion by law,” *id.* §§ 551(13), 701(a)(2), 702. *See also Webster v. Doe*, 486 U.S. 592, 599 (1988); *Heckler*, 470 U.S. at 828. Walmart’s claim fails at each step in the analysis.

*First*, Walmart does not challenge any agency action—much less a final one. On the contrary, its complaint repeatedly avers that the government *intends* to file suit, sets forth the purported legal theories the company *believes* DOJ will pursue, and asks the Court to declare them invalid.<sup>4</sup> But a “final agency action” must impose an obligation, deny a legal right, or fix some relationship pursuant to the consummation of an administrative process. *Bennett v. Spear*, 520 U.S. 154, 156 (1997). When some aspect of an enforcement proceeding is challenged, the decision must have binding legal force and practical effects on the challenger beyond simply imposing on the party the burden of responding to charges made against it. *See FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 241-42 (1980) (holding that filing of complaint is not final agency action under § 704 because “the issuance of the complaint ... has no legal force” and “itself is a determination only that adjudicatory proceedings will commence”). If the actual filing of an enforcement action (whether before an agency body or a federal court) fails

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<sup>4</sup> *See, e.g.*, Compl. ¶ 57 (“On information and belief, DOJ intends to sue Walmart for filling prescriptions when there were what DEA calls ‘red flags’”); ¶ 115 (“And now, on information and belief, Defendants intend to pursue a civil enforcement action against Walmart based on a number of positions ... that are wrong as a matter of federal law.”); ¶ 117 (“On information and belief, DOJ intends to seek massive liability based on the prescriptions Walmart’s pharmacists filled for doctors whose prescriptions should supposedly have been rejected across the board.”); ¶ 119 (“On information and belief, Defendants intend, in a civil complaint against Walmart, to attempt to retroactively transform general duties demanding case-by-case exercise of professional judgment by pharmacists into mechanical and categorical rules—not found in any statute or regulation ...”).

to constitute final agency action, then *a fortiori* so too does an alleged resolve to take such action at some later date. *See id.* at 243 (“Judicial review of the averments in the [agency’s] complaints should not be a means of turning prosecutor into defendant before adjudication concludes.”); *Dow Chem. v. EPA*, 832 F.2d 319, 325 (5th Cir. 1987) (“We conclude, however, that the allegations made in an enforcement suit [in district court] do not impose the *kind* of legal obligations with which [the] finality doctrine is concerned.”).

*Second*, Walmart obviously has an adequate remedy in court—defending itself against DOJ’s enforcement action if one eventually is filed. *See* 5 U.S.C. § 704. The Federal Rules of Civil Procedure provide Walmart the opportunity to engage in discovery and defend itself fully against the government’s enforcement action in federal district court. And it is firmly established that a party’s ability to assert its claim as a defense in another proceeding constitutes an adequate remedy at law. *See Georgia v. City of Chattanooga*, 264 U.S. 472, 483-84 (1924); *see also Travis v. Pennyrite Rural Elec. Co-op.*, 399 F.2d 726, 729 (6th Cir. 1968) (“An injunction against threatened legal action will not issue if the party will have an adequate opportunity to fully present his defenses and objections in the legal action he seeks to enjoin.”). Indeed, the APA expressly contemplates that any review of the agency’s enforcement decision will be had in the enforcement action itself. *See* 5 U.S.C. § 703 (“Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.”). Yet Walmart’s suit is far from novel: Courts routinely dismiss actions seeking judicial review of pending or planned enforcement actions by federal entities on the ground that defending the legality of one’s actions in the enforcement proceeding constitutes an adequate remedy in court.<sup>5</sup> This Court should do the same.

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<sup>5</sup> *See, e.g., Quicken Loans Inc. v. United States*, 152 F. Supp. 3d 938, 950 (E.D. Mich. 2015) (dismissal warranted because “no cognizable legal harm will result, unless and until the enforcement action results in a judgment... And the enforcement action will adequately provide Quicken with the

*Third*, the decision whether to bring an enforcement proceeding is the paradigmatic example of presumptively unreviewable action committed to agency discretion by law. *See* 5 U.S.C. § 701(a)(2). The Attorney General and his designates enjoy “broad discretion” to enforce the nation’s laws, *Wayte*, 470 U.S. at 607, and that discretion includes the responsibility to institute proceedings to prevent and restrain violations of the CSA. “They have this latitude because they are designated by statute as the President’s delegate to help him discharge his constitutional responsibility to ‘take Care that the Laws be faithfully executed.’” *Armstrong*, 517 U.S. at 464 (quoting U.S. Const. art. II, § 3). The Supreme Court unequivocally has held that exercises of prosecutorial discretion are presumptively unreviewable, *Heckler*, 470 U.S. at 832, and “courts have long acknowledged that the Attorney General’s authority to control the course of the federal government’s litigation is presumptively immune from judicial review.” *Shoshone-Bannock Tribes*, 56 F.3d at 1480-81. Walmart may not use the Declaratory Judgment Act to pierce the insulated realm of prosecutorial discretion, for multiple reasons including that the declaration it seeks would directly bind DOJ’s hand in any enforcement proceeding it might pursue. *See* Compl., Prayer for Relief. Because Walmart’s claim is entirely concerned with a potential exercise of discretion committed to the agency, it cannot seek review under the APA.<sup>6</sup>

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opportunity to defend against any effort to impose such a legal consequence”); *N.J. Hosp. Ass’n v. United States*, 23 F. Supp. 2d 497, 501 (D.N.J. 1998) (refusing APA review because “plaintiff’s members do have an adequate remedy in a court—the ability to raise a defense to an [] action by the DOJ”); *Greater N.Y. Hosp. Ass’n v. United States*, No. 98 Civ. 2741 (RLC), 1999 WL 1021561, at \*8 (S.D.N.Y. Nov. 9, 1999) (refusing APA review where plaintiffs had “adequate legal remedies available to them other than APA claims” by presenting defenses to, and winning, suit by DOJ); *Parke, Davis & Co. v. Califano*, 564 F.2d 1200, 1206 (6th Cir. 1977) (admonishing district court for abusing its discretion by enjoining agency “where pending enforcement actions provided an opportunity for a full hearing before a court”).

<sup>6</sup> The phrase “prosecutorial discretion,” as used in *Heckler* and its progeny, fully encompasses agency civil enforcement (as distinct from criminal prosecution). *Heckler* itself concerned the Food and Drug Administration’s discretion to enforce a drug-usage law. 470 U.S. at 823. And it frequently is applied to deny review of other agencies’ civil-enforcement decisions. *E.g.*, *Public Citizen, Inc. v. EPA*, 343 F.3d

At bottom, Walmart’s allegations reflect nothing more than its disagreement with DOJ’s and DEA’s purported interpretations of the CSA. That fails even to present a justiciable case or controversy, *see infra* § II.C, much less a reviewable challenge to final agency action with no adequate remedy in court, as is required to rely upon the APA’s waiver of sovereign immunity. Walmart’s complaints about “the cloud of indeterminacy” it faces as a result of the government’s “threats,” Compl. ¶ 120—complaints any company under government investigation could make—do not suffice to vest this Court with jurisdiction in the absence of a cognizable claim.

**B. Walmart has not pleaded any cause of action to support jurisdiction.**

Walmart’s complaint contains no cause of action whatsoever and seeks only declaratory relief, *see* Compl., Prayer for Relief, premised on the Declaratory Judgment Act, 28 U.S.C. § 2201, as the sole basis for this Court’s jurisdiction (other than the federal-question statute). Compl., ¶ 24. But the Declaratory Judgment Act does not create a substantive cause of action that would permit Walmart to obtain an at-will advisory opinion from this Court. Instead, it is a procedural, enabling statute that does not itself confer jurisdiction. *See Lawson v. Callahan*, 111 F.3d 403, 405 (5th Cir. 1997) (“[I]t is well settled that this section does not confer subject matter jurisdiction on a federal court where none otherwise exists.”); *see also Gaar v. Quirk*, 86 F.3d 451, 453 (5th Cir. 1996) (“A petition for a declaratory judgment concerning federal law is not sufficient to create federal jurisdiction; ‘hence the relevant cause of action must arise under some other federal law.’”) (citing *Lowe v. Ingalls Shipbuilding*, 723 F.2d 1173, 1179 (5th Cir. 1984)); *Jones v. Alexander*, 609 F.2d 778, 781 (5th Cir. 1980) (“The Declaratory Judgment Act is not an independent ground for jurisdiction; it permits the award of declaratory relief only when other bases for jurisdiction are present.”) (citing *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671 (1950)). Rather, to maintain a declaratory-judgment action, a plaintiff must point to a

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449, 464-65 (5th Cir. 2003) (Clean Air Act enforcement); *Perales v. Casillas*, 903 F.2d 1043, 1047-51 (5th Cir. 1990) (immigration-benefit decisions).

cause of action arising under some other law. *See Schilling v. Rogers*, 363 U.S. 666, 667, 677 (1960); *see also Severe Records, LLC v. Rich*, 658 F.3d 571, 580 (6th Cir. 2011) (court must determine “whether, absent the availability of declaratory relief, the instant case could nonetheless have been brought in federal court.”).

Walmart cannot identify a proper cause of action, given that the CSA—the only federal law remotely implicated by its complaint—contains no private right of action on which to ground this suit. In other words, Walmart could not possibly bring this suit under the CSA itself, and cannot excuse the absence of a cause of action by purporting to sue directly under the Declaratory Judgment Act instead.<sup>7</sup>

That facial pre-enforcement challenges to supposedly invalid *statutes or regulations* sometimes are justiciable does not compel a different result. For instance, in *Abbott Labs. v. Gardner*, the court upheld the availability of a pre-enforcement challenge to certain drug rules. *See* 387 U.S. 136 (1967) (abrogated by *Califano v. Sanders*, 430 U.S. 99 (1977)). But that suit challenged duly promulgated regulations—*i.e.*, final agency action—under the APA. *Id.* at 152-54. Likewise, pre-enforcement review sometimes is available where the constitutionality of a federal statute is challenged. *See Nat’l Rifle Ass’n of Am. v. Magaw*, 132 F.3d 272, 279 (6th Cir. 1997) (explaining “pre-enforcement review is usually granted under the Declaratory Judgment Act when a statute ‘imposes costly, self-executing compliance burdens or if it chills protected First Amendment activity.’”) (citation omitted). Finally, the Declaratory Judgment Act often is used to preempt a common-law or statutory claim between private parties—such as, *inter alia*, contract, insurance, or trademark disputes. *E.g.*, *Gaar*, 86 F.3d at 453-54. But each

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<sup>7</sup> Walmart must be aware of these legal doctrines, for it successfully relied upon them to seek dismissal of a Declaratory Judgment Act counterclaim asserted against it in another federal court in this state. *See Walmart Stores, Inc. v. Tex. Alc. Bev. Comm’n*, No. 1:15-CV-134-RP, 2017 WL 9481257, at \*1-3 (W.D. Tex. May 22, 2017) (agreeing with Walmart that “the Declaratory Judgment Act does not authorize [the party] to obtain a general declaration” regarding the outcome of a legal dispute and that the Act “does not create a freestanding cause of action”).

of these scenarios is a far cry from the present suit, where Walmart seeks to block the exercise of unreviewable prosecutorial discretion by the executive-branch component charged with administration of the statute under which Walmart is regulated. Nowhere does Walmart claim that DEA's regulations themselves are unlawful. In other words, although the Declaratory Judgment Act (or APA) may sometimes be used to challenge the *facial validity* of a statute or regulation, precedent does not support its use to thwart government enforcement activities by seeking judicial review of a purported *interpretation* of a concededly valid regulation prior to that interpretation manifesting in an agency action—here, a potential civil enforcement action in which Walmart assuredly would present these same arguments. Any attempt by Walmart in opposing dismissal to rely on *Abbott Labs.* and its progeny, or other authority where a determination of statutory or regulatory validity was at stake, is misguided and should be rejected.<sup>8</sup>

### **C. Walmart seeks an advisory opinion.**

In addition to these jurisdictional flaws, Walmart cannot demonstrate either the “case or controversy” required to sustain federal jurisdiction or the “actual controversy” requisite under the Declaratory Judgment Act.

“Article III, § 2, of the [United States] Constitution extends the ‘judicial Power’ of the United States only to ‘Cases’ and ‘Controversies.’” *Steel Co.*, 523 U.S. at 102. “No principle is more fundamental to the judiciary’s proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.” *DaimlerChrysler Corp. v. Cuno*,

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<sup>8</sup> The Fifth Circuit has announced a seven-factor test to aid in the determination whether to dismiss or to exercise discretion by deciding a declaratory claim. *See, e.g., Sherwin-Williams Co. v. Holmes Cty.*, 343 F.3d 383, 387-88 (5th Cir. 2003). That analysis does not apply to Walmart’s claim because a court only has discretion potentially to decide a declaratory action if jurisdiction is proper. *Id.* Even if Walmart had identified a proper basis for jurisdiction and did not seek an advisory opinion, however, this suit still would fail the *Sherwin-Williams* test because, *inter alia*, “the plaintiff engaged in forum shopping in bringing the suit,” “the plaintiff filed suit in anticipation of a lawsuit filed by the defendant,” and “possible inequities in allowing the declaratory plaintiff to gain precedence in time or to change forums exist.” *Id.*

547 U.S. 332, 341 (2006) (citation omitted). “As used in the Constitution, those words do not include every sort of dispute, but only those ‘historically viewed as capable of resolution through the judicial process.’” *Hollingsworth v. Perry*, 570 U.S. 693, 700 (2013) (internal citation omitted). Thus Article III restricts the authority of federal courts to resolve only those disputes that involve the “determin[ation] [of] rights of persons or of property which are actually controverted in the particular case before it.” *California v. San Pablo & Tulare R.R. Co.*, 149 U.S. 308, 314 (1893); see also *Marye v. Parsons*, 114 U.S. 325, 330 (1885) (“There must be a litigation upon actual transactions between real parties, growing out of a controversy affecting legal or equitable rights as to person or property.”). “This is a ‘bedrock requirement.’” *Raines v. Byrd*, 521 U.S. 811, 818 (1997) (citation omitted).

Nor is it “enough that the party invoking the power of the court ha[s] a keen interest in the issue.” *Hollingsworth*, 570 U.S. at 700; *Warth v. Seldin*, 422 U.S. 490, 498 (1975). Indeed, to review such cases “would be inimical to the Constitution’s democratic character” and would weaken “the public’s confidence in an unelected but restrained Federal Judiciary.” *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 133 (2011).

Similarly, “[t]he Declaratory Judgment Act provides that, ‘in a case of actual controversy within its jurisdiction . . . any court of the United States may declare the rights and other legal relations of any interested party seeking such declaration.’” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007) (quoting 28 U.S.C. § 2201(a)). For purposes of a declaratory-judgment action, an “actual controversy” exists only where “there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Id.* at 127.

The Declaratory Judgment Act cannot be invoked to obtain an advisory opinion. *United Pub. Workers of Am. (C.I.O.) v. Mitchell*, 330 U.S. 75, 89 (1947). And—critically—it cannot be used preemptively “to hold in readiness for use should the [government] at any future time attempt to apply

any part of a complicated regulatory statute to” a plaintiff. *Pub. Serv. Comm’n of Utah v. Wycoff Co.*, 344 U.S. 237, 245 (1952). Persuasive authority from the Northern District of Ohio is instructive:

The true purpose of the requested declaration is for the [plaintiffs] to hold it in readiness for use should the Attorney General attempt at any future time to apply any part of the [] statute to them. This purpose exceeds any permissible discretionary use of the Federal Declaratory Judgment Act. The [plaintiffs’] assertion ... is properly tendered as a defense to a [] suit. It is not properly tendered as the basis for what would essentially be an advisory opinion in this case, to the effect that if the Attorney General ever brings a [] lawsuit ... then the suit must fail because the Attorney General cannot prove an element of the claim ....

*Ohio Hosp. Ass’n v. Shalala*, 978 F. Supp. 735, 740 (N.D. Ohio 1997) (internal alterations and citations omitted) (reversed in part on other grounds); *see also N.J. Hosp. Ass’n*, 23 F. Supp. 2d 503-04 (no case or controversy to issue declaration that plaintiffs could not be liable in potential suit by DOJ because, “when such an assertion would be a defense to a suit ... and no such suit has yet been filed” plaintiffs “ask[] this Court for an advisory opinion on the merits of some potential future litigation”).

Walmart asks this Court to issue a quintessential advisory opinion regarding the proper interpretation of the CSA and its implementing regulations, and answer general questions of what a pharmacy may do—unmoored from any concrete dispute between the parties or factual basis in which to apply the regulatory framework—based solely on Walmart’s own speculation as to what the federal government may be planning. *See, e.g.*, Compl. ¶ 168 (encouraging the Court to opine that “Defendants’ interpretation is unsupported by the relevant text”); ¶ 169 (“The CSA reaches, at most, individual pharmacists and registrant pharmacy locations—not a corporate headquarters operating a nationwide chain of pharmacies with individual registrations.”); ¶ 171 (“[T]he CSA does not provide a cause of action *for Defendants* to pursue penalties for the purported failure to submit suspicious order reports.”) (emphasis added). These unattributed assertions as to DOJ’s alleged legal theories in as-yet-unfiled litigation fail to set forth any actual, concrete controversy between the parties.<sup>9</sup>

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<sup>9</sup> Put differently, and as stated above, *see supra* § I.a.2, Walmart cannot identify a final agency action that it validly could challenge under the APA, because no action has yet been taken. Without such a

The vague declarations Walmart seeks further demonstrate the nebulous nature of their claim: No rights could be finally determined by a ruling that pharmacists need not “second-guess a registered and licensed doctor’s decision,” or that pharmacists are not required “to refuse to fill entire categories of prescriptions without regard to individual facts and circumstances.” Compl., Prayer for Relief. Nor would it be appropriate for a court to instruct an agency, in the abstract, to “follow [its] own regulations” or direct it *in advance* on what grounds to “base [] enforceable legal positions” in a forthcoming complaint. *Id.* Contending that a suit seeks help “resolving [] disputes of law,” Compl. ¶ 23, does not make it so. Walmart cannot enlist this Court’s aid in “clarifying its legal rights and duties under the CSA and its implementing regulations,” *id.*, absent a concrete and justiciable dispute between the parties. In reality Walmart merely has alleged a difference of opinions between the parties, which cannot by itself serve as the basis for a justiciable action. *See, e.g., United States v. West Virginia*, 295 U.S. 463, 473 (1935) (no actual controversy where complaint “states a difference of opinion between the officials of two governments”). Unless and until DOJ brings the civil action Walmart fears, no such dispute exists—and even then, Walmart must present its defenses in response to claims DOJ actually has asserted, not straw-man arguments it thinks DOJ will present.<sup>10</sup>

Walmart’s insistence that it and its pharmacists have urgent need to clarify legal obligations due to “a dramatic change in agency policy” does not alter the analysis. *See, e.g.,* Compl. ¶¶ 151-54 (challenging DEA’s alleged position on distribution policies); *id.* ¶¶ 155-61 (disagreeing with DEA’s purported views on suspicious order policies); *id.* Prayer for Relief (urging this Court to admonish DOJ and DEA to “follow their own regulations and [] not base any enforceable legal positions on the

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basis to proceed under the APA, Walmart resorts to the Declaratory Judgment Act to invite this Court to issue an advisory opinion, prior to any final agency action that would give rise to a basis to litigate.

<sup>10</sup> Walmart also seeks improperly to relitigate, in what it perhaps believes is a more-friendly forum, the questions of law already resolved against it in the MDL. *See supra* Background § B. There is no basis for this Court to issue its own view, untethered from an actual dispute between the parties.

alleged violation of agency guidance”). Walmart does not plead the basis on which it purports to have ascertained DOJ’s and DEA’s legal positions in unfiled litigation; unless and until any civil enforcement action is brought, the government’s legal theories necessarily are indeterminate. But even accepting *all* of Walmart’s assertions as to DEA’s positions—and even if DOJ were planning to file suit based on “non-existent” obligations, Compl. at 45, Walmart’s only recourse would *still* be to raise its objections as defenses arguing for dismissal of that civil-enforcement action. *See Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 96 (2015) (confirming that only “legislative rules” “issued through the notice-and-comment process ... have the force and effect of law”).<sup>11</sup>

By instead seeking a sweeping declaration as to the legal bases on which DEA may ground future enforcement actions (and arguing for the exclusion of agency guidance in any such efforts), Walmart is effectively mounting an improper programmatic challenge to agency operations. This lawsuit is not an appropriate vehicle to resolve Walmart’s programmatic attack on the enforcement scheme under which DEA operates, or on the use of guidance generally.<sup>12</sup> Walmart “cannot seek *wholesale* improvement of this program by court decree, rather than in the offices of the Department or the halls of Congress, where programmatic improvements are normally made.” *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004) (citation omitted). Because “[t]he prospect of pervasive oversight by federal courts” over the enforcement program of DOJ and DEA “is not contemplated by the

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<sup>11</sup> Presuming that DOJ will file a groundless claim in another federal court also flouts the presumption of regularity. *See supra* § I.

<sup>12</sup> In so insisting, Walmart speculates the hypothetical civil suit will be largely grounded in informal guidance in violation of DOJ policy. DOJ recognizes, of course, the impropriety of bringing an enforcement action based on guidance documents—it is part of the Department of Justice Manual—and needs no reminder of its policy. But Walmart should not be heard to criticize a hypothetical complaint’s reliance on guidance documents when its own complaint relies on statements in those same documents. *See, e.g.*, Compl. ¶¶ 13, 127.

APA,” *i.e.*, the proper vehicle for challenging agency action, *id.* at 67, the Court should decline Walmart’s invitation to instruct DEA in its exercise of enforcement discretion.<sup>13</sup>

This Court should decline Walmart’s invitation to improperly expand Article III beyond its jurisdictional limits. “The declaratory judgment procedure is available in the federal courts only in cases involving an actual case or controversy ... and it may not be made the medium for securing an advisory opinion in a controversy which has not arisen.” *Coffman v. Breeze Corp.*, 323 U.S. 316, 324 (1945).

### **CONCLUSION**

For the reasons set forth herein, the Court should dismiss this action.

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<sup>13</sup> The *amicus curiae* brief supporting Walmart’s summary-judgment motion filed by the U.S. Chamber of Commerce and a consortium of related business trade associations also urges this Court to engage in improper, programmatic review of DEA’s enforcement efforts writ large. *Amici* provide this Court with a veritable administrative-law treatise, complain that “federal agencies have increasingly avoided notice and comment procedures under the [APA],” and claim an “interest in seeing that agencies respect administrative law principles, stop unlawfully enforcing non-binding guidance, and operate consistently with due process and the rule of law.” *See* Br. Amicus Curiae of U.S. Chamber of Commerce, et al. at 2, ECF No. 40. Indeed, another *amicus* filed by the National Association of Chain Drug Stores, which is represented by the same law firm and counsel that represents another defendant in the MDL, also has interests in doing an end-run around prior MDL rulings. *See* Br. Amicus Curiae of Nat’l Assoc. of Chain Drug Stores, ECF No. 39.

This Declaratory Judgment Act suit is an inappropriate vehicle to secure an opinion on the general enforceability of agency guidance or the requirements of due process. Indeed, *amicus*’s filing exemplifies the risk that a determination on the merits of Walmart’s suit will mire this Court in a programmatic review of agency operations, with the goal of eliciting an advisory opinion regarding grievances that should be addressed to the halls of Congress or raised in APA challenges to specific final agency actions. *See* ECF 40 at 4 (urging the Court “to stop the otherwise inexorable trend toward regulation by post-hoc enforcement”); 13 (bemoaning the need for courts to “rein in agencies’ enforcement of subregulatory guidance”).

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