

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

WALMART INC.

v.

U.S. DEPARTMENT OF JUSTICE,
ET AL.

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CIVIL NO. 4:20-CV-817-SDJ

MEMORANDUM OPINION AND ORDER

Walmart Inc. has filed suit against the United States Department of Justice (DOJ), the United States Drug Enforcement Administration (DEA), Acting Attorney General Monty Wilkinson, and DEA Acting Administrator D. Christopher Evans¹ to resolve a dispute concerning the obligations of pharmacists and pharmacies under the Controlled Substances Act.² Asserting a single cause of action under the Declaratory Judgment Act, Walmart seeks judicial declarations broadly addressing DOJ's litigation positions interpreting the Controlled Substances Act and its implementing regulations in relation to an enforcement action threatened by DOJ against Walmart.

Before the Court is DOJ's Rule 12(b)(1) motion to dismiss Walmart's suit for lack of subject-matter jurisdiction. DOJ contends that the Court lacks subject-matter jurisdiction because Walmart's complaint fails to present a justiciable "case or

¹ The lawsuit originally named then-Attorney General William Barr and then-DEA Acting Administrator Timothy Shea as defendants. Acting Attorney General Monty Wilkinson and DEA Acting Administrator D. Christopher Evans have been substituted as defendants pursuant to Federal Rule of Civil Procedure 25(d).

² Defendants are collectively referenced as "DOJ" in this Memorandum Opinion and Order.

controversy” under Article III, § 2 of the United States Constitution and because Congress has not waived sovereign immunity for this suit against the United States. Because the Court concludes that sovereign immunity bars Walmart’s suit, DOJ’s motion is granted and this case is dismissed for want of subject-matter jurisdiction.

I.

A.

In recent years, the United States has confronted a growing opioid epidemic, which has presented one of the worst drug crises in our history as well as a national health emergency.³ Although the crisis began in the 1990s, it has continued unabated, and has even accelerated, over the last twenty-five years.⁴ The Centers for Disease Control and Prevention (CDC) has reported that, from 2000 to 2014, drug-overdose deaths in the United States increased by 137 percent, including a 200 percent rise in overdose deaths involving the abuse of pain-relieving prescription drugs and heroin.⁵ Data collected by the National Institute on Drug Abuse shows that

³ *Ending America’s Opioid Crisis*, Archived Trump White House Website, <http://trumpwhitehouse.archives.gov/opioids> (noting that, in October 2017, President Trump declared the opioid epidemic a national health emergency).

⁴ Office of the Inspector General, *Review of the Drug Enforcement Administration’s Regulatory and Enforcement Efforts to Control the Diversion of Opioids*, United States Department of Justice (Sept. 2019), <https://oig.justice.gov/reports/2019/e1905.pdf> (hereinafter “OIG Report”) (noting that, in 1998, 2.5 million Americans admitted to abusing prescription drugs and that, by 2001, that number had nearly doubled to 4.8 million and that, by 2003, DEA estimated that the number of people abusing prescription drugs approximately equaled the number who abused cocaine—about two to four percent of the U.S. population).

⁵ Rose A. Rudd et al., *Increase in Drug and Opioid Overdose Deaths—United States, 2000–2014*, CDC Morbidity and Mortality Weekly Report (Jan. 1, 2016), www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

nearly eighty percent of people who began abusing illicit opioids during the 2000s began by abusing a prescription opioid.⁶ The yearly cost to human life resulting from the opioid epidemic is exemplified by CDC data revealing that, in 2017, the United States experienced more than 70,237 overdose deaths, of which 47,600 (nearly seventy percent) involved an opioid—an average of 130 opioid overdose deaths each day.

At the same time, doctors can and do prescribe opioids to treat patients with acute and chronic pain, patients who have recently undergone surgery or experienced injuries, and patients suffering from medical conditions such as cancer and inflammatory, neurological, and musculoskeletal conditions.⁷ Because of their beneficial uses, opioid medications have long been approved by the Food and Drug Administration and have benefited millions of Americans. The challenge for regulatory authorities has thus been to ensure that legitimately made opioids intended for lawful purposes are not subject to “diversion”: that is, the sale or exchange of opioids as illicit substances in the illegitimate drug market.⁸

⁶ National Institute on Drug Abuse, *Prescription Opioids and Heroin Research Report*, National Institutes of Health (Jan. 2018), <https://www.drugabuse.gov/download/19774/prescription-opioids-heroin-research-report.pdf?v=fc86d9fdda38d0f275b23cd969da1a1f>.

⁷ Pain Management Best Practices Inter-Agency Task Force, *Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations*, United States Department of Health and Human Services (May 9, 2019), <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>.

⁸ See OIG Report, *supra* note 4 (observing that DEA has confirmed that controlled pharmaceuticals, including opioids, can be diverted from legitimate channels through theft or fraud during the manufacturing and distribution process by anyone involved in the process, including medical and pharmacy staff and individuals involved in selling or using pharmaceuticals).

B.

Congress enacted the Controlled Substances Act (CSA), Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242–84 (1970) (codified as amended at 21 U.S.C. §§ 801–904), in 1970 to, among other things, “provide meaningful regulation over legitimate sources of drugs to prevent diversion into illegal channels.” *Gonzales v. Raich*, 545 U.S. 1, 10, 125 S.Ct. 2195, 162 L.Ed.2d 1 (2005). Through the CSA, Congress implemented “a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.” *Id.* at 13 (citing 21 U.S.C. §§ 841(a)(1), 844(a)).

Under the CSA, controlled substances are categorized into five schedules based on their potential for abuse or dependence, their accepted medical use, and their accepted safety for use under medical supervision. *See* 21 U.S.C. § 812. For example, Schedule II controlled substances have a currently accepted medical use in the United States, or a currently accepted medical use with severe restrictions, but these drugs also have a high potential for abuse, which may lead to severe psychological or physical dependence. *See* 21 U.S.C. § 812(b)(2). Schedule II drugs are “the most powerful and dangerous drugs that can be lawfully prescribed” and include “many pharmaceutical opioids” such as hydrocodone, morphine, oxycodone, and methadone. *United States v. Ruan*, 966 F.3d 1101, 1122 (11th Cir. 2020).

To prevent the diversion of controlled substances, the CSA imposes requirements for the distributing and dispensing of such substances. The CSA also grants the Attorney General broad authority to prevent, detect, and investigate the

diversion of controlled substances. *See, e.g.*, 21 U.S.C. §§ 821–24, 827, 880. In turn, the Attorney General has delegated that authority to the DEA Administrator. *See* 28 C.F.R. § 0.100(b). Under that authority, DEA regulates every link in the controlled-substance supply chain. Any person who manufactures, distributes, or dispenses (including by prescribing, *see* 21 U.S.C. § 802(10)) a controlled substance must register, and maintain that registration, with DEA, *see* 21 U.S.C. § 822, and registrants are subject to numerous regulatory requirements and oversight provisions. All pharmacies, for example, wishing to distribute or dispense controlled substances must register with DEA. 21 U.S.C. § 822(a). Once registered, a pharmacy, its agents, and its employees may distribute or dispense controlled substances only to the extent authorized by their registration and in conformity with the CSA. *See* 21 U.S.C. § 822(b).

Except under certain limited circumstances, controlled substances that constitute prescription drugs under the Federal Food, Drug, and Cosmetic Act may not be dispensed without an accompanying prescription. *See* 21 U.S.C. § 829. To be valid under the CSA, any such prescription “must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). In this regard, although Section 1306.04(a) imposes a responsibility on medical practitioners to issue valid prescriptions, it also imposes a “corresponding responsibility” on the pharmacist. The regulation provides that any order “purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription” under the

CSA, and “the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” 21 C.F.R. § 1306.04(a) (citing 21 U.S.C. § 829). Similarly, a pharmacist’s conduct must adhere to the usual course of his or her professional practice. 21 C.F.R. § 1306.06.

A registrant who dispenses a drug without a valid prescription may be subject to civil penalties or, under certain circumstances, criminal penalties. *See* 21 U.S.C. § 842(a)(1), (c). The CSA also authorizes the Attorney General to seek declaratory and injunctive relief for such violations of law. 21 U.S.C. § 843(f).

The CSA also regulates distributors of controlled substances. A “distributor” is defined as a person or entity that delivers (other than by administering or dispensing) a controlled substance. 21 U.S.C. § 802(11). Distributors are required to register with DEA and, among other requirements, to maintain effective controls against the diversion of controlled substances for illegitimate uses. 21 U.S.C. § 823(b)(1). Distributors are also required by regulation to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and to notify DEA of such “suspicious orders” when discovered by the registrant. 21 C.F.R. § 1301.74(b). The regulation defines “suspicious orders” to include “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” *Id.*

DOJ has taken the position that any failure by a distributor to detect and report a suspicious order is a violation of law under 21 U.S.C. § 842(a)(5), which states

that it is unlawful for any person “to refuse or negligently fail to make, keep, or furnish any record, report, notification, . . . or information required under this subchapter” The CSA provides that a person who violates 21 U.S.C. § 842(a)(5) is subject to a civil penalty not to exceed \$10,000 for each violation on or before November 2, 2015, and not to exceed \$15,691 for each violation after November 2, 2015. *See* 21 U.S.C. § 842(c)(1)(A), (B); 28 C.F.R. § 85.5.

C.

Walmart, a retail giant and the largest public company in the world, operates approximately 5,000 stores in the United States. *Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm’n*, 945 F.3d 206, 212 (5th Cir. 2019). Although Walmart is not principally a pharmacy, it provides pharmacy services to its customers, including dispensing controlled substances such as opioids. For a period of time, Walmart also acted as a distributor of controlled substances, including opioids, by buying opioids directly from manufacturers and shipping them to its own pharmacies.

As a result of disagreements with DOJ concerning the proper interpretation of the CSA and its implementing regulations, Walmart has filed with this Court a Complaint for Declaratory Relief asserting a single cause of action under the Declaratory Judgment Act (DJA), 28 U.S.C. § 2201. Walmart requests that the Court enter nine judicial declarations concerning the obligations of pharmacies and pharmacists under the CSA and its regulations. According to Walmart, the declarations are necessary because “DOJ and DEA are placing pharmacists and pharmacies in an untenable position by threatening to hold them liable for violating

DOJ’s unwritten expectations for handling opioid prescriptions.” (Dkt. #1 at 1). In Walmart’s view, such “unwritten expectations” are in tension with “state pharmacy and medical practice laws, the expert judgment of federal health agencies, and even DEA’s own public statements.” (Dkt. #1 at 1).

As told by Walmart, the history of its dispute with DOJ begins in 2016, when the United States Attorney’s Office for the Eastern District of Texas commenced a criminal investigation of Walmart’s pharmacy operations. Walmart maintains that, after DOJ’s leadership recognized that there was no basis for a criminal indictment of Walmart and DOJ formally declined to prosecute Walmart, DOJ nonetheless continued the investigation of Walmart by creating a working group of government attorneys to explore a potential civil-enforcement action against the company. (Dkt. #1 ¶¶ 110–13). At the time Walmart filed its declaratory action, it averred that, on information and belief, DOJ intended to pursue a civil-enforcement action against Walmart based on legal positions concerning the nature of pharmacists’ and pharmacies’ legal obligations under the CSA and its implementing regulations—legal positions that Walmart asserts are wrong as a matter of law. Walmart characterized DOJ’s threatened civil-enforcement action as an “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—that would effectively impose strict liability based on hindsight.” (Dkt. #1 ¶ 119).

Walmart specifically objects to DOJ's "unsupported legal positions" concerning so-called "red flags" that a prescription may be improper. (Dkt. #1 ¶ 124). According to Walmart, "[n]otwithstanding the text of the [CSA] and its implementing regulations," DOJ has taken the legal position that large categories of prescriptions raise "unresolvable" "red flags" and therefore cannot be filled by a pharmacist properly exercising her responsibility under the CSA. (Dkt. #1 ¶ 129). By way of example, Walmart points to DOJ's position that "*any* prescription filled by a patient before the next regularly scheduled refill presents a red flag that can never be resolved" and DOJ's position that "so-called 'trinity' combinations of drugs may also present unresolvable red flags."⁹ (Dkt. #1 ¶ 129). Walmart goes on to state that, based on DOJ's "unsupported red-flag requirements, DOJ intends to sue Walmart on a theory that many facially valid prescriptions are presumptively invalid" and therefore could not be filled under any circumstances or could not be filled "absent investigation by the pharmacist, requiring intrusion into the doctor-patient relationship and second guessing of the doctor's medical judgment." (Dkt. #1 ¶ 135).¹⁰ In Walmart's view, DOJ's "enforcement position" creates novel legal obligations beyond those in the existing statutes and regulations and therefore cannot be imposed without notice-and-comment rulemaking, if at all.

⁹ Walmart describes a "trinity" combination as a prescription that combines an opioid, a benzodiazepine, and a muscle relaxer. (Dkt. #1 ¶ 60).

¹⁰ Walmart has also asserted that DOJ's enforcement position that pharmacists must document their resolution of red flags is unsupported by the text of the CSA and its implementing regulations. (Dkt. #1 ¶ 132).

Walmart further asserts that, on information and belief, DOJ “intend[s] to seek massive retroactive liability on Walmart under the view that its corporate-level policies violated the CSA.” (Dkt. #1 ¶ 142). Specifically, Walmart maintains that DOJ intends to take the enforcement position that Walmart was required to analyze and share certain information across all of Walmart’s stores, including information about a particular pharmacist’s refusal to fill a specific prescription, as well as the prescribing and prescription-filling practices of particular doctors and patients. As described by Walmart, under this legal theory, DOJ intends to assert that Walmart, as a corporation, had an obligation to “categorically block” prescriptions written by particular doctors based on certain criteria, such as a doctor’s prescribing opioids to a large number of patients, a doctor’s prescribing the same pharmaceutical regimen to multiple patients, or a customer’s having an erratic fill history or filling the same type of prescription at multiple pharmacies. (Dkt. #1 ¶ 142). Walmart contends that DOJ’s legal theory and enforcement position on such “suspicious orders” is not only untethered to the CSA’s text but is also in tension with the substance of the CSA’s implementing regulations, which Walmart notes specifically exclude prescription-drug dispensers from the requirement that CSA registrants must “design and operate” a system to detect suspicious orders. (Dkt. #1 ¶¶ 143–44).¹¹

¹¹ With respect to distribution, Walmart claims that DOJ intends to take the enforcement position that the CSA required Walmart not only to report suspicious orders of opioids but also to investigate and clear such orders before shipping. (Dkt. #1 ¶ 146). According to Walmart, “[t]his requirement exists nowhere in the text of the CSA or its implementing regulations” and derives instead from “informal agency guidance—which DOJ itself has stated is not a sufficient basis for enforcement.” (Dkt. #1 ¶ 146).

Walmart has requested that this Court enter the following judicial declarations:

- A. Pharmacists may be liable under the CSA and its regulations only when they fill a prescription that they know was not issued for a legitimate medical purpose by a prescriber acting in the usual course of the prescriber's professional practice or when pharmacists knowingly abandon all professional norms;
- B. The CSA does not require pharmacists to second-guess a registered and licensed doctor's decision that a prescription serves a legitimate purpose;
- C. The CSA and its regulations do not require pharmacists to refuse to fill entire categories of prescriptions without regard to individual facts and circumstances;
- D. The CSA and its regulations do not require pharmacists to document in writing why filling a prescription was appropriate;
- E. Pharmacies do not have an affirmative obligation under the CSA and its regulations to analyze and share aggregate prescription data across its stores and with line pharmacists;
- F. Pharmacies do not have an affirmative obligation under the CSA and its regulations to impose corporation-wide refusals-to-fill for particular doctors;
- G. The CSA and its regulations do not require distributors not to ship suspicious orders after reporting them;
- H. The CSA and its regulations did not impose monetary penalties for failure to report suspicious orders to DEA during the time Walmart self-distributed; and
- I. Defendants must follow their own regulations and may not base any enforceable legal positions on the alleged violation of agency guidance

rather than obligations found in the statute or duly promulgated rule or regulation.

(Dkt. #1 at 52–53).¹²

II.

A.

Federal district courts exercise limited subject-matter jurisdiction. When a specific basis for subject-matter jurisdiction over a claim is absent, a district court has no power to adjudicate the claim. *See Home Builders Ass’n of Miss. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998) (quoting *Nowak v. Ironworkers Local 6 Pension Fund*, 81 F.3d 1182, 1187 (2d Cir. 1996)) (“A case is properly dismissed for lack of subject matter jurisdiction when the court lacks the statutory or constitutional power to adjudicate the case.”). Accordingly, Federal Rule of Civil Procedure 12(b)(1) allows a defendant to move for the dismissal of claims based on a “lack of subject-matter jurisdiction.” FED. R. CIV. P. 12(b)(1). DOJ has moved to dismiss Walmart’s declaratory-relief claim based on lack of subject-matter jurisdiction, thereby invoking Rule 12(b)(1).

Because Rule 12(b)(1) applies, the Court must consider whether the attack on the complaint is facial or factual. *Cell Sci. Sys. Corp. v. La. Health Serv.*, 804 F.App’x 260, 263 (5th Cir. 2020) (per curiam). A facial attack, which consists of a Rule 12(b)(1)

¹² Several weeks after this action was filed, DOJ commenced an enforcement action against Walmart for violations of the CSA premised on Walmart’s alleged failures to meet requirements imposed by the CSA and its regulations on pharmacists, pharmacies, and distributors. *See Complaint, United States v. Walmart Inc.*, No. 1:20-cv-1744 (D. Del. Dec. 22, 2020), (Dkt. #1). Walmart has not sought to amend its allegations or requested relief in the action before this Court following the filing of DOJ’s enforcement suit.

motion unaccompanied by supporting evidence, challenges jurisdiction based solely on the pleadings. *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981). When ruling on a facial attack, the court must presume that factual allegations in the complaint are true and determine whether they establish subject-matter jurisdiction. *Id.* By contrast, a Rule 12(b)(1) motion presents a factual attack when the motion is accompanied by supporting evidence that contradicts the jurisdictional allegations in the complaint. *Id.* DOJ's dismissal motion presents a facial attack, challenging subject-matter jurisdiction based on Walmart's pleadings. *See generally* (Dkt. #43); *see also* (Dkt. #43 at 6 n.2) (confirming that the allegations in Walmart's complaint "are presumed true for purposes of this motion").

B.

In its dismissal motion, DOJ advances two bases for its argument that the Court lacks subject-matter jurisdiction over Walmart's declaratory-judgment action. First, DOJ asserts that, in urging this Court "to opine on its legal culpability in a hypothetical suit untethered from any factual context," Walmart requests that the Court issue an advisory opinion. Second, DOJ contends that Walmart has failed to provide any "unequivocally expressed" waiver of sovereign immunity by the federal government.¹³

¹³ DOJ also argues that Walmart has failed to plead any cause of action underlying its declaratory-judgment claim because the DJA is strictly procedural and does not provide Walmart a substantive cause of action. (Dkt. #43 at 1–2). This argument, however, does not implicate the Court's subject-matter jurisdiction. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998) ("It is firmly established by our cases that the absence of a valid . . . cause of action does not implicate subject-matter jurisdiction . . .").

Because both alleged infirmities with Walmart’s complaint challenge the Court’s subject-matter jurisdiction, the Court can turn to either issue to resolve this case. *See Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 578, 119 S.Ct. 1563, 143 L.Ed.2d 760 (1999) (“[T]here is no unyielding jurisdictional hierarchy.”); *see also Meyers v. Oneida Tribe of Indians of Wis.*, 836 F.3d 818, 821–23 (7th Cir. 2016) (confirming that a court need not decide whether the plaintiff has Article III standing before dismissing on grounds of sovereign immunity). Here, the Court concludes that DOJ’s assertion of sovereign immunity is dispositive of the question of subject-matter jurisdiction.

III.

A.

Walmart brought the instant declaratory action against DOJ, the Attorney General, in his official capacity, DEA, and the Acting DEA Administrator, also in his official capacity. (Dkt. #1 ¶¶ 27–30). As Walmart itself has recognized, *see* (Dkt. #66 at 3), to sue the United States, its agencies, or its officers in their official capacities, a plaintiff must not only present a “case” or “controversy” within the meaning of Article III of the Constitution, but must also demonstrate that the United States has waived its sovereign immunity from suit or that sovereign immunity is inapplicable. *See, e.g., Danos v. Jones*, 652 F.3d 577, 581 (5th Cir. 2011) (citing *FDIC v. Meyer*, 510 U.S. 471, 475, 114 S.Ct. 996, 127 L.Ed.2d 308 (1994)); *see also United States v. Mitchell*, 463 U.S. 206, 212, 103 S.Ct. 2961, 77 L.Ed.2d 580 (1983) (“It is axiomatic

that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction.”).

“A waiver of sovereign immunity ‘cannot be implied but must be unequivocally expressed.’” *United States v. Mitchell*, 445 U.S. 535, 538, 100 S.Ct. 1349, 63 L.Ed.2d 607 (1980) (quoting *United States v. King*, 395 U.S. 1, 4, 89 S.Ct. 1501, 23 L.Ed.2d 52 (1969)). And any waiver of the United States’ sovereign immunity “will be strictly construed, in terms of its scope, in favor of the sovereign.” *Lane v. Pena*, 518 U.S. 187, 192, 116 S.Ct. 2092, 135 L.Ed.2d 486 (1996).

B.

Walmart contends that the waiver of immunity in 5 U.S.C. § 702 applies in this case. This provision of the Administrative Procedure Act (APA) provides that “a[n] action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party.” 5 U.S.C. § 702. This language, which Congress added to Section 702 through a 1976 amendment to the statute, was intended to “broaden the avenues of judicial review of agency action by eliminating the defense of sovereign immunity in cases covered by the amendment.” *Bowen v. Massachusetts*, 487 U.S. 879, 891–92, 108 S.Ct. 2722, 101 L.Ed.2d 749 (1988).

As the Fifth Circuit has observed, at least two Circuit Courts of Appeals have held that Section 702’s language waives sovereign immunity “for all actions seeking

equitable, nonmonetary relief against an agency, even if there has been no ‘agency action’ within the meaning of the APA.” *Doe v. United States*, 853 F.3d 792, 799 (5th Cir. 2017) (citing *Trudeau v. FTC*, 456 F.3d 178 (D.C. Cir. 2006), and *Presbyterian Church (U.S.A.) v. United States*, 870 F.2d 518, 525 (9th Cir. 1989)). The Fifth Circuit, however, has taken a different approach to Section 702. In *Alabama–Coushatta Tribe of Texas v. United States*, the court determined that Section 702 “contains two separate requirements for establishing a waiver of sovereign immunity.” 757 F.3d 484, 489 (5th Cir. 2014). The plaintiff must first “identify some ‘agency action,’” as that term is defined in 5 U.S.C. § 551(13), that is “affecting him in a specific way, which is the basis for entitlement to judicial review.” *Id.* “Agency action” is defined by 5 U.S.C. § 551(13) as “the whole or part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.” 5 U.S.C. § 551(13); *see also id.* § 701(b)(2) (providing that the term “agency action” “ha[s] the meaning[] given [it] by section 551”). The plaintiff must also show that he has “suffered legal wrong because of the challenged agency action, or is adversely affected or aggrieved by that action within the meaning of the relevant statute.” *Alabama–Coushatta Tribe*, 757 F.3d at 489 (quotation omitted).

C.

Under the controlling Fifth Circuit standard, the parties dispute whether Walmart has met Section 702’s waiver requirements and particularly whether Walmart has identified any “agency action” within the meaning of 5 U.S.C. § 551(13).

Walmart contends that the litigation positions taken by DOJ in advance of its threatened enforcement action meet 5 U.S.C. § 551(13)'s definition of "agency action" because they fall within the definitions of "rule" as provided in 5 U.S.C. § 551(4), "order" as provided in 5 U.S.C. § 551(6), and "sanction" as provided in 5 U.S.C. § 551(10). The term "rule" is defined to include "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4).¹⁴ The term "order" is defined as "the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing." 5 U.S.C. § 551(6). The term "sanction" "includes the whole or a part of an agency (A) prohibition, requirement, limitation, or other condition affecting the freedom of a person; (B) withholding of relief; (C) imposition of penalty or fine; (D) destruction, taking, seizure, or withholding of property; (E) assessment of damages, reimbursement, restitution, compensation, costs, charges, or fees; (F) requirement, revocation, or suspension of a license; or (G) taking other compulsory or restrictive action." 5 U.S.C. § 551(10). Walmart correctly notes that none of these agency actions needs to be "final" to trigger Section 702's immunity waiver. *See Alabama–Coushatta Tribe*, 757 F.3d at 489 (explaining that "there is no requirement

¹⁴ In its entirety, the definition reads as follows: "rule' means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing." 5 U.S.C. § 551(4).

of finality” for an immunity waiver under Section 702 “when judicial review is sought pursuant to a statutory or non-statutory cause of action that arises completely apart from the general provisions of the APA”).

DOJ contends that none of Walmart’s grievances outlined in its complaint meets the definition of “agency action” in 5 U.S.C. § 551(13). Specifically, DOJ points to Walmart’s claim that “DOJ intends to sue” Walmart for “filling red flag prescriptions” and that DOJ “intends to assert that . . . guidance letters . . . have the force of law.” (Dkt. #68 at 4). DOJ goes on to argue that, however framed, DOJ’s *intention* to take action does not constitute “an agency statement of general or particular applicability . . . designed to implement, interpret, or prescribe law or policy,” (*i.e.*, a rule), or a “final disposition . . . of an agency,” (*i.e.*, an order), or a “prohibition, requirement, limitation, or other condition affecting the freedom of a person” or “other compulsory restrictive action,” (*i.e.*, a sanction). (Dkt. #68 at 4–5) (quoting 5 U.S.C. § 551(4), (6), (10)).

1.

The Court agrees that Walmart has failed to identify an “agency action,” as that term is defined in 5 U.S.C. § 551(13), that has adversely affected Walmart. Therefore, Section 702’s waiver of sovereign immunity is inapplicable.

Contrary to Walmart’s assertions, DOJ’s statements of an intent to sue Walmart based on DOJ’s legal theories interpreting the CSA do not meet the definitions of “rule,” “order,” or “sanction” under 5 U.S.C. § 551(4), (6), (10). As DOJ has made clear, and Walmart does not dispute, DOJ’s referenced statements of intent

to sue Walmart were made in the context of settlement negotiations between the parties. (Dkt. #76 at 51:21–22). A professed “intent” to sue is necessarily contingent until suit is filed. And a contingent “intent” to sue may never come to fruition if pre-suit settlement negotiations are successful. Moreover, even after a threatened suit is filed, the government’s legal theories may change for purposes of litigation. A “rule,” by contrast, is a fixed “statement” from a government agency “designed to implement, interpret, or prescribe law or policy.” For this reason, legal theories associated with a nebulous “intent” to sue do not qualify as “rules” under 5 U.S.C. § 551(4), nor do they constitute “a final disposition . . . of an agency” and therefore are not “orders” under 5 U.S.C. § 551(6).

Walmart’s argument that DOJ’s threatened “intent to sue” meets the definition of “sanction” in 5 U.S.C. § 551(10) is equally unavailing. Walmart focuses on the final, catchall phrase at the end of the definition of “sanction,” which defines the term to include an agency’s “taking other compulsory or restrictive action.” 5 U.S.C. § 551(10). In Walmart’s view, this language may be read to broadly include DOJ’s threatened intent to file a lawsuit against Walmart based on DOJ’s legal theories interpreting the CSA. Read in the context of the definition of “sanction” as a whole, however, the residual phrase is not so expansive as Walmart suggests. To begin with, it is unlikely that, at the end of a list of concrete punishments that agencies impose on regulated entities, such as fines, seizure or withholding of property, and revocation or suspension of a license, the catchall phrase of the same list would embrace an agency’s contingent “intent” to initiate a legal action. An agency’s assertion that it is

contemplating filing a lawsuit that would presumably request judicial relief is different in kind than the affirmative, concrete punishments meted out by agencies themselves and described as specific items in subparts (A) through (F) of Section 551(10).

The Court’s understanding of this statutory definition is supported by a familiar tool of statutory interpretation—the canon of *eiusdem generis*. This interpretive canon has “deep roots in our legal tradition.” *United States v. Koutsostamatis*, 956 F.3d 301, 306–07 (5th Cir. 2020) (citing *Archbishop of Canterbury’s Case*, (1596) 76 Eng. Rep. 519, 520–21 (KB) (using *eiusdem generis*)). Because courts have used canons such as *eiusdem generis* to interpret texts for centuries, courts may “presume that ‘Congress legislates with knowledge of [these] basic rules of statutory construction.’” *Id.* at 307 (alteration in original) (quoting *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 496, 111 S.Ct. 888, 112 L.Ed.2d 1005 (1991)). “The *eiusdem generis* canon applies when a drafter has tacked on a catchall phrase at the end of an enumeration of specifics” ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 199 (2012). As the Fifth Circuit has confirmed, “[w]here it applies, *eiusdem generis* limits general terms which follow specific ones to matters similar to those specified.” *Koutsostamatis*, 956 F.3d at 308 (quotation omitted). Thus, “when a list of specific X’s is followed by the catchall phrase ‘other X’s,’ *eiusdem generis* ‘implies the addition of *similar* after the word *other*.’” *Id.* (quoting SCALIA & GARNER, *supra*, at 199).

Section 551(10) lists six types of “sanction,” including “prohibition, requirement, limitation, or other condition affecting the freedom of a person,” “imposition of penalty or fine,” “withholding of relief,” “destruction, taking, seizure, or withholding of property,” “assessment of damages, reimbursement, restitution, compensation, costs, charges, or fees,” and “requirement, revocation or suspension of a license.” 5 U.S.C. § 551(10). These specific terms are then followed by the general, catchall phrase “or taking other compulsory or restrictive action.” *Id.* Applying the *ejusdem generis* canon, the Court understands the residual phrase in Section 551(10) to encompass only agency actions similar to the preceding list of specific items. DOJ’s contingent threat to sue Walmart, apparently made in the context of settlement negotiations, is not similar to the concrete punishments otherwise itemized in Section 551(10), such as revocation of a license, imposition of a fine, and seizure of property.

For all of these reasons, Walmart’s proposed interpretation of the defined APA terms “rule,” “order,” and “sanction” cannot be reconciled with the statutory text.

2.

Walmart also cannot identify any precedent that stands for the proposition that a threat to file an enforcement action constitutes “agency action” supporting a waiver of sovereign immunity under Section 702, and the Court is unaware of any such precedent. The cases upon which Walmart primarily relies to support its position are unhelpful to Walmart’s cause.

According to Walmart, the decision in *Doe v. United States* confirms that the Fifth Circuit generously construes the term “sanction” as defined by 5 U.S.C.

§ 551(10). *See* (Dkt. #78 at 2) (citing *Doe*, 853 F.3d at 800). However, *Doe* applied only the plain text of several definitions in the APA, including the term “sanction.” In that case, the plaintiff filed suit against the United States claiming that the government violated his Fifth Amendment due process rights by accusing him of a crime during the course of a criminal proceeding in which he was not named as a defendant. 853 F.3d at 794. The Fifth Circuit noted that the term “sanction,” as defined in 5 U.S.C. § 551(10), includes “withholding of relief,” that the term “relief” is defined to include the grant of a “remedy,” and that “agency action” also includes a “failure to act.” *Id.* at 799–800 (citing 5 U.S.C. § 551(10)(B), (11)(A), (11)(C), (13)). The court went on to conclude that, in accusing the plaintiff of a crime without providing a public forum in which he could vindicate his rights, “namely a hearing or trial in a criminal court proceeding” in which the plaintiff could “defend the serious charges against him,” the government had failed to act and failed to provide relief or a remedy to the plaintiff. *Id.* at 800. Thus, the Fifth Circuit applied a specific aspect of the definition of the term “sanction,” *i.e.*, the act of “withholding relief,” according to its plain meaning and in conjunction with other “agency action” terms defined in Section 551, to conclude that sovereign immunity was waived. Nothing in *Doe* suggests that courts should give an expansive construction to the term “sanction” or, for that matter, any other term defined in 5 U.S.C. § 551.

Walmart also contends that *Alexander v. Trump*, 753 F.App’x 201 (5th Cir. 2018) (per curiam), supports its argument that Section 702’s sovereign-immunity waiver encompasses Walmart’s complaint. *See* (Dkt. #66 at 23–25, 29). Although

Alexander confirms that “final” agency action is not needed here because judicial review is being sought based on a cause of action that arises apart from the general provisions of the APA, the decision is otherwise unhelpful to Walmart. The case concerned a “failure to act” claim brought by a plaintiff who had testified in a murder trial and claimed that, in retaliation for his testimony, a “hit” had been put out on him that involved the hiring of local law enforcement officials and members of the Federal Bureau of Investigation (FBI) to murder the plaintiff. *Alexander*, 753 F.App’x at 203–04. The plaintiff filed suit against, among others, FBI Director Christopher Wray for failing to investigate and stop the harm allegedly suffered by the plaintiff. *Id.* at 204. Although the court determined that the claims against Director Wray should be dismissed for failure to state a claim upon which relief could be granted, the court held that the district court had subject-matter jurisdiction because sovereign immunity had been waived under Section 702. *Id.* at 206. Specifically, the *Alexander* court noted that the APA’s definition of “agency action” includes a “failure to act” and that the plaintiff’s suit met this definition by alleging that the FBI failed to act by not investigating and preventing his harm. *Id.* (quoting 5 U.S.C. § 551(13)). *Alexander* involved a specific application of the text of the “failure to act” definition found in 5 U.S.C. § 551, which is not at issue in this case.

As with *Doe*, nothing in *Alexander* instructs courts to apply expansive interpretations of the terms defined in 5 U.S.C. § 551, nor does *Doe* or *Alexander* support Walmart’s suggestion that this Court should apply the APA’s definition of “agency action” “liberally” to broaden the scope of Section 702’s sovereign-immunity

waiver. *See* (Dkt. #66 at 27). And it would be surprising if the Fifth Circuit were to make such a suggestion given that the Supreme Court has instructed courts to follow precisely the opposite approach in considering asserted waivers of the federal government’s immunity from suit—construing the scope of statutory waivers strictly in favor of the sovereign and interpreting ambiguities in favor of immunity. *See, e.g., Lane*, 518 U.S. at 192 (confirming that “[a] waiver of the Federal Government’s sovereign immunity must be unequivocally expressed in statutory text” and “will be strictly construed, in terms of its scope, in favor of the sovereign”); *United States v. Williams*, 514 U.S. 527, 531, 115 S.Ct. 1611, 131 L.Ed.2d 608 (1995) (noting that, in examining a purported waiver of sovereign immunity, the Court will “constru[e] ambiguities in favor of immunity”). The Fifth Circuit adheres to the same principles when analyzing immunity-waiver claims, as the *Doe* decision cited by Walmart makes clear. 853 F.3d at 796 (explaining that “a waiver of sovereign immunity cannot be implied but must be unequivocally expressed” and that the scope of any such waiver is strictly construed in favor of the sovereign (quotation omitted)); *see also Tsolmon v. United States*, 841 F.3d 378, 382 (5th Cir. 2016) (“Waiver of sovereign immunity is strictly construed, meaning uncertainty is decided in favor of the government.”).

Finally, Walmart has also pointed to the D.C. Circuit’s decision in *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430 (D.C. Cir. 1986), which Walmart contends endorses its position that “enforcement threats are reviewable agency actions” under Section 702’s sovereign-immunity waiver. (Dkt. #78 at 3). *Ciba-Geigy*, however, addressed only the

question of whether particular agency actions present a sufficiently ripe controversy under Article III and did not analyze any question of sovereign-immunity waiver under Section 702. *See Ciba-Geigy*, 801 F.2d at 434 (“The sole question before us is whether Ciba-Geigy’s complaint presents a controversy ripe for judicial review.”).

In *Ciba-Geigy*, a pesticide manufacturer sought declaratory and injunctive relief when the Environmental Protection Agency (EPA) required the company to change the labeling of its registered pesticide without affording the company an adjudicatory hearing as required by the applicable statute. *Id.* at 431, 433. In an exchange of letters between the pesticide manufacturer and EPA, in which the manufacturer requested clarification from EPA on the procedure by which the label changes at issue would be implemented, EPA ultimately sent a letter from its Director of Pesticide Programs confirming that the labeling changes were effective and subject to enforcement without the adjudicatory hearing requested by the manufacturer. *Id.* at 433.

Addressing the ripeness of the parties’ dispute as the only issue on appeal, the D.C. Circuit applied the “framework for analyzing the ripeness of pre-enforcement agency action” by examining “both the fitness of the issue for judicial decision and the hardship to the parties of withholding court consideration.” *Id.* at 434 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967)). The court concluded that EPA’s letter “unequivocally stated EPA’s position on the question whether registrants were entitled to a cancellation hearing before labeling changes could be required” and “gave no indication that it was subject to further

agency consideration or possible modification.” *Id.* at 436–37. The court further concluded that EPA’s Director of Pesticide Programs spoke for EPA on the issue and that his letter had “significant” legal effect because “[i]t is well settled that the authoritative interpretation of an executive official has legal consequence” *Id.* at 437 (quotation and brackets omitted). Under the circumstances, the *Ciba-Geigy* court concluded that “the letter from the head of EPA’s Pesticide Division, speaking for the agency charged with administering” the applicable statute regulating pesticides, was entitled to deference from the courts. *Id.* Based on these conclusions, the court determined that the manufacturer’s case was sufficiently ripe to meet the “case” or “controversy” requirements of Article III.

Ciba-Geigy does not support Walmart’s sovereign-immunity waiver arguments. To begin with, *Ciba-Geigy* provided no analysis of Section 702’s waiver of sovereign immunity and, instead, was concerned entirely with ripeness issues arising from a pre-enforcement suit. The distinction matters because, in answering the ripeness question, the *Ciba-Geigy* court applied a “presumption of reviewability” that worked in favor of finding the parties’ dispute to be ripe, *id.* at 434, while waivers of the federal government’s sovereign immunity are strictly construed, and ambiguities are interpreted in favor of immunity. Furthermore, the agency action at issue in *Ciba-Geigy* was meaningfully different from that presented here. *Ciba-Geigy* involved an “authoritative interpretation of an executive official” of EPA concerning its interpretation of a statute, memorialized in a letter, that was not subject to “further agency consideration or possible modification.” *Id.* at 436–37. Although similar

undertakings by DOJ or DEA in this case might well meet the definitions of “rule,” “order,” or “sanction” under 5 U.S.C. § 551(4), (6), (10) and support a waiver of immunity under Section 702, no such “agency action” is before the Court. Assertions by DOJ officials of a contingent intent to sue Walmart for violating the CSA, apparently made in the course of settlement negotiations, are necessarily subject to “further agency consideration or possible modification,” and are markedly different in kind from the agency action at issue in *Ciba-Geigy*.

* * *

For all of these reasons, the Court must reject Walmart’s overreaching interpretation of the defined APA terms “rule,” “order,” and “sanction” to include DOJ’s threat to sue Walmart for violations of the CSA. Such threats simply do not constitute “agency action” as defined in 5 U.S.C. § 551(13), and therefore the Fifth Circuit’s standard for waiver of sovereign immunity under Section 702 is not met in this case.

3.

Unable to point to any identifiable “agency action” within the meaning of Section 702, Walmart’s declaratory action undertakes a sweeping challenge to DOJ’s and DEA’s administration and enforcement of the CSA and its regulations. The all-encompassing judicial declarations requested by Walmart demonstrate the breadth of its challenge to the government. For example, Walmart requests that this Court declare that DOJ and DEA “must follow their own regulations and may 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.” (Dkt. #1 at 53). On its face, such a declaration would purport to embrace every aspect of the government’s administration and enforcement of the CSA. Similarly, Walmart requests that the Court declare that “[p]harmacists may be liable under the CSA and its regulations only when they fill a prescription that they know was not issued for a legitimate medical purpose by a prescriber acting in the usual course of the prescriber’s professional practice or when pharmacists knowingly abandon all professional norms.” (Dkt. #1 at 53). Again, such a declaration would purport to comprehensively address the standard of liability for pharmacists under any and all circumstances arising from the provisions of the CSA and its regulations.

The Fifth Circuit has made clear that Congress has not waived sovereign immunity for such “programmatically challenges,” which it has described as “challenges that seek wholesale improvement of an agency’s programs by court decree, rather than through Congress or the agency itself where such changes are normally made.” *Alabama–Coushatta Tribe*, 757 F.3d at 490 (quotation omitted); *see also Louisiana v. United States*, 948 F.3d 317, 321 (5th Cir. 2020) (same). The principle that courts cannot entertain such broad-ranging efforts to reform a federal agency’s programs was articulated in *Lujan v. National Wildlife Federation*, where the Supreme Court held that a challenge “to the entirety of the ‘land withdrawal review program’ is ‘not [a challenge to] an ‘agency action’ within the meaning of § 702.” *Alabama–Coushatta Tribe*, 757 F.3d at 490 (alteration in original) (quoting *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 890, 110 S.Ct. 3177, 111 L.Ed.2d 695 (1990)).

In *Alabama–Coushatta Tribe*, the court considered a lawsuit filed by the Alabama–Coushatta Tribe of Texas against the United States and various agencies claiming that the government had breached its duty under federal law to protect 400,000 acres of land and associated natural resources in Texas that were subject to aboriginal title of the Tribe. *Id.* at 486. The court concluded that the Tribe’s complaint was “structured as a blanket challenge to *all* of the Government’s actions with respect to *all* [drilling] permits and [oil and gas] leases granted for natural resource extraction on a significantly large amount of land” in Texas. *Id.* at 490. The court held that Section 702 did not waive sovereign immunity for such an expansive attack on the government’s administration of the land at issue and that therefore subject-matter jurisdiction was absent. *Id.* at 489–92.

The same principles apply here. On its face, Walmart’s complaint requests judicial declarations broadly addressing the government’s administration and enforcement of the CSA and its regulations as to pharmacists and pharmacies. Impliedly acknowledging the breadth of some of the declarations it has requested, Walmart noted at the hearing on DOJ’s motion that it has also made requests for specific judicial declarations. *See* (Dkt. #76 at 29:2–15). Walmart is correct—it has included in its complaint certain requests for specific declarations, such as a declaration that the CSA and its regulations do not require distributors not to ship suspicious orders after reporting them to federal authorities. *See* (Dkt. #1 at 53). But, as the Fifth Circuit explained in *Alabama–Coushatta Tribe*, the identification of certain specific agency actions to be remedied cannot save a complaint from the

sovereign-immunity bar when it “remains that the challenge is directed at the federal agencies’ broad policies and practices.” 757 F.3d at 491.

As the Fourth Circuit recently explained, the APA’s definition of “agency action” limits the scope of judicial review in important respects. *City of New York v. Dep’t of Defense*, 913 F.3d 423, 431 (4th Cir. 2019). At the outset, “each of the terms that comprise the definition of ‘agency action’ is limited to those acts that are ‘circumscribed’ and ‘discrete.’” *Id.* (citing *Norton v. S. Utah Wilderness All. (SUWA)*, 542 U.S. 55, 62, 124 S.Ct. 2373, 159 L.Ed.2d 137 (2004)). Thus, challenges to agency action, “whether it be a particular action or a failure to act,” “must identify specific and discrete governmental conduct, rather than launch a ‘broad programmatic attack’ on government’s operations.” *Id.* The distinction between discrete acts, which are subject to judicial review, and programmatic challenges, which are not, “is vital to the APA’s conception of the separation of powers.” *Id.* “Courts are well-suited to reviewing specific agency decisions, such as rulemakings, orders, or denials. We are woefully ill-suited, however, to adjudicate generalized grievances asking us to improve an agency’s performance or operations.” *Id.* When courts undertake such generalized review of agency operations, they are necessarily “forced either to enter a disfavored ‘obey the law’ injunction . . . or to engage in day-to-day oversight of the executive’s administrative practices.” *Id.* “Both alternatives are foreclosed by the APA, and rightly so.” *Id.*

Walmart’s complaint runs afoul of these separation-of-powers limitations embodied in the APA’s definition of “agency action.” To be sure, Walmart has

identified certain specific examples of conduct by DOJ and DEA that it believes misconstrue the CSA, but the declaratory relief Walmart requests goes well beyond such particular complaints. Were this Court to declare that DOJ and DEA “must follow their own regulations and may 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,” as Walmart requests, it would be engaging in precisely the type of “obey the law” jurisprudence the Supreme Court has made clear exceeds the power of the judiciary. *See SUWA*, 542 U.S. at 66–67 (“If courts were empowered to enter general orders compelling compliance with broad statutory mandates, they would necessarily be empowered, as well, to determine whether compliance was achieved—which would mean that it would ultimately become the task of the supervising court, rather than the agency, to work out compliance with the broad statutory mandate, injecting the judge into day-to-day agency management.”). Walmart’s identification of some specific aspects of DOJ’s administration of the CSA that affect Walmart does not change the fact that, ultimately, Walmart seeks wholesale review of DOJ enforcement practices as to the CSA. Section 702 does not waive the government’s sovereign immunity for such a sweeping challenge.


IV.

For the foregoing reasons, the Court concludes that Walmart has failed to allege “agency action” sufficient to meet the requirements of sovereign-immunity waiver under 5 U.S.C. § 702, which is necessary to maintain its claims against the

federal government.¹⁵ Defendants' Motion to Dismiss for Lack of Jurisdiction, (Dkt. #43), is therefore **GRANTED**, and this case is **DISMISSED** for lack of subject-matter jurisdiction.

It is further **ORDERED** that Walmart's Motion for Partial Summary Judgment, (Dkt. #21), is **DENIED as moot**.

So ORDERED and SIGNED this 4th day of February, 2021.


SEAN D. JORDAN
UNITED STATES DISTRICT JUDGE

¹⁵ Because the Court concludes that the United States has not waived its sovereign immunity for Walmart's suit, the Court need not address DOJ's arguments that Walmart has failed to allege a justiciable "case or controversy" under Article III and that Walmart has also failed to plead a cause of action.