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## INTRODUCTION

As Defendants admit, regulated parties routinely seek pre-enforcement review of purported statutory or regulatory obligations affecting their conduct. Dkt. 43 (“MTD”) at 15. In such cases, the threat of enforcement and resulting practical dilemma about whether to comply or risk liability give rise to Article III injury; the Declaratory Judgment Act (“DJA”) is specifically designed to provide a procedural vehicle for the regulated party threatened with enforcement to obtain review; and such non-monetary actions for prospective relief rarely implicate sovereign immunity. These are basic and long-established principles of federal jurisdiction—nothing unusual.

Walmart’s action fits comfortably within the scope of those precepts. It makes no difference that Walmart seeks relief from Defendants’ baseless *interpretations* of the Controlled Substances Act (“CSA”) and its regulations, rather than from the statutory or regulatory duties themselves. Walmart’s Complaint expressly and plausibly alleged threats of enforcement, including by pointing to other enforcement actions premised on the interpretations at issue. Those allegations demonstrate a “case or controversy” between the parties. Likewise, because Defendants are empowered to sue Walmart over alleged violations of the CSA, Walmart may seek resolution of their legal dispute without the need for its own private right of action. The DJA exists specifically to permit a party in Walmart’s position to rely on the counterparty’s cause of action—here, DOJ’s cause of action under the CSA. And since *Ex parte Young*, 209 U.S. 123 (1908), sovereign immunity has not stood in the way of claims of this sort—a principle now codified (and expanded) in 5 U.S.C. § 702’s waiver.

Defendants’ contrary arguments rest on mischaracterizations of this suit. Walmart does not ask the Court to enjoin an enforcement action, to interfere with prosecutorial discretion, or to declare Walmart “innocent” of any fact-bound allegations. Rather, this case is simply an ordinary

attempt by a regulated entity subject to plausible threats of enforcement—indeed, in this case a years-long governmental investigation that, according to Defendants, remains ongoing—to obtain certainty about the scope of its statutory and regulatory duties, and thereby guide its conduct going forward. To be sure, as with any DJA action, this Court’s rulings might have preclusive effect for enforcement actions. But that is not a basis to dismiss for lack of jurisdiction.

Less than three weeks after moving to dismiss this action for lack of a case or controversy, Defendants sued Walmart in the District of Delaware, asserting liability on many of the same theories and interpretations at issue in this action. *See United States v. Walmart Inc.*, No. 1:20-cv-1744, Compl. (D. Del. Dec. 22, 2020) (“Enforcement Compl.”). That new filing belies Defendants’ claim that Walmart’s suit was premised on speculation and hypotheticals, and confirms beyond doubt the existence of a real legal dispute between the parties. And this action remains critical to the speedy resolution of that dispute—in particular, to provide urgently needed guidance on Walmart’s (and the industry’s) *current* and *future* conduct. As Defendants have admitted, resolving this action “would require no discovery and no findings of fact,” Opposition to Motion to Transfer at 4, *In re Nat’l Prescription Opiate Litig.*, No. 2804 (J.P.M.L. Dec. 4, 2020); it is thus uniquely able to provide clarity on an expedited basis. That is why Walmart filed this action; it is why industry groups and professional associations have weighed in with *amicus* support; and it remains just as relevant today as it was in October.

For all of these reasons, and as further explained below, this Court should deny Defendants’ motion to dismiss and proceed to the merits.

### **COUNTERSTATEMENT OF THE ISSUES**

1. Article III allows parties who face credible threats of enforcement to go to court to remove the cloud of uncertainty from their conduct. In light of Defendants’ actions and threats—and now their recently filed enforcement suit—is there an Article III “case or controversy” over the scope of Walmart’s CSA obligations?

2. The DJA gives would-be defendants the right to sue their anticipated adversaries, borrowing the cause of action the adversary would have asserted in its litigation. Does the Act allow Walmart to seek declaratory relief given that Defendants can sue (and since have sued) Walmart under the CSA?
3. Title 5 U.S.C. § 702 waives the sovereign immunity of the United States over any suit “seeking relief other than money damages and stating a claim that an agency . . . acted or failed to act in an official capacity or under color of legal authority.” Has Congress thus waived Defendants’ sovereign immunity from Walmart’s request for declaratory relief as to Defendants’ unlawful acts with respect to the CSA?

### **STANDARD OF REVIEW**

Unless a defendant submits evidence to contest jurisdictional facts, the court must evaluate its subject matter jurisdiction by “tak[ing] the well-pled factual allegations of the complaint as true and view[ing] them in the light most favorable to the plaintiff.” *T.B. ex rel. Bell v. Nw. Indep. Sch. Dist.*, 980 F.3d 1047, 1051 (5th Cir. 2020). “A dismissal for lack of jurisdiction” based on the pleadings “will not be affirmed unless it appears certain that the plaintiff cannot prove any set of facts in support of his claim that would entitle plaintiff to relief.” *Williams ex rel. J.E. v. Reeves*, 954 F.3d 729, 734 (5th Cir. 2020).

### **ARGUMENT**

To sue the United States, its agencies, or its officers in their official capacities, a plaintiff needs three things. *First*, as in any federal litigation, there must be a “case or controversy” within the meaning of Article III of the Constitution—that is, “a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant” judicial intervention. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). *Second*, there must be a cause of action—*i.e.*, a statutory or judicially created entitlement for that plaintiff to ask the court to resolve that controversy. *See Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127–29 (2014). And finally, if applicable, the United States must have waived its sovereign immunity from suit, by statute or otherwise. *Loeffler v. Frank*, 486 U.S. 549, 554 (1988).

Walmart's suit meets these requirements. The Complaint establishes (and recent actions have confirmed) that there is a case or controversy concerning the scope of Walmart's duties under the CSA and its regulations, with Defendants' expansive interpretations casting a shadow over the conduct of Walmart's pharmacies and pharmacists. There is also a cause of action: The DJA specifically allows a would-be defendant to bring an anticipatory action if its adversary would have a right to sue in federal court, as Defendants could (and have since done) under the CSA. Finally, there is an unambiguous statutory waiver of sovereign immunity that applies to this action: "An action ... seeking relief other than money damages and stating a claim that an agency ... acted or failed to act in an official capacity ... shall not be dismissed ... on the ground that it is against the United States." 5 U.S.C. § 702. Walmart's suit is such a case. On all three issues, Defendants' arguments fundamentally mischaracterize the nature of this action and misstate the critical principles of federal jurisdiction at issue.

**I. A CASE OR CONTROVERSY EXISTS BETWEEN THE PARTIES.**

Walmart and its pharmacists currently labor under the shadow of massive potential liability created by Defendants' expansive view of the CSA. Article III poses no conceivable obstacle to Walmart's attempt to eliminate that cloud through this declaratory judgment action.

**A. Walmart and Its Pharmacists Face the Threat of Liability Under Defendants' Overbroad Interpretation of the CSA.**

Both Article III and the DJA limit federal courts to the resolution of cases or controversies. *See* U.S. Const. art. III, § 2; 28 U.S.C. § 2201(a). To meet that requirement, the Supreme Court has specified that there must be "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127; *see also Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (same).

In the context of disputes between the government and regulated parties, the Supreme Court has repeatedly recognized that such a controversy exists—and regulated parties may obtain “pre-enforcement review”—where circumstances “render the threatened enforcement sufficiently imminent.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014). For example, in *Susan B. Anthony List*, the Court allowed a suit to proceed where the plaintiff wished to make statements that were “arguably proscribed” by Ohio law. *Id.* at 162. An “actual arrest, prosecution, or other enforcement action is not [an Article III] prerequisite” to suing, the Court explained; “threatened enforcement of a law” alone satisfies Article III by creating a controversy between the government and the regulated party. *Id.* at 158. Similarly, in *Abbott Laboratories v. Gardner*, the Court allowed the plaintiffs to pursue a pre-enforcement challenge to certain regulatory labeling rules. 387 U.S. 136 (1967). “[T]he regulation [was] directed at them in particular” and “require[d] them to make significant changes in their everyday business practices” or “risk serious criminal and civil penalties.” *Id.* at 153, 154. There was “no question” that this risk satisfied Article III. *Id.*

Under those principles, this case easily satisfies the requirements of Article III. Walmart and its pharmacists dispense prescriptions every day. As it stands, they do so under a cloud of doubt and potential liability created by Defendants’ threats about the CSA—threats based on a view of the law at substantial variance from Walmart’s and, as the *amici* briefs show, the pharmacy industry’s. For example, Walmart’s Complaint explained that Defendants have asserted:

- Some categories of prescriptions are *per se* invalid and can never be dispensed by pharmacists under the CSA. *See* Compl. ¶¶ 116, 166.
- Pharmacists must identify, resolve, and document red flags before dispensing prescriptions, or else they violate the CSA. *See* Compl. ¶ 132.
- Any deviation from state standards of professional conduct necessarily means that the pharmacist has dispensed controlled substances outside the ordinary course of pharmacy practice, in violation of federal law. *See* Compl. ¶ 137.

- Pharmacies must categorically block prescriptions from supposedly problematic (but still licensed and registered) doctors, or else they too run afoul of the CSA. *See* Compl. ¶ 142.
- Pharmacies must, as a matter of federal law, aggregate, analyze, and share data about prescriptions across their stores. *See* Compl. ¶¶ 142–43.

Because of these positions, pharmacists and pharmacies face precisely the same kind of dilemma as the regulated entities in *Abbott Labs*: They must either substantially change their conduct to comply with Defendants’ expansive interpretations of the CSA and its regulations, or run the risk that Defendants will sue them (or, worse, prosecute them) for violations. It has been clear for over 50 years that a party facing that dilemma has a “case or controversy” with the government.

Walmart’s practical dilemma is actually worse than the typical *Abbott Labs* scenario. Even if Walmart *complies* with Defendants’ overbroad view of federal law (as it has partially done in response to Defendants’ threats, Compl. ¶ 80), the company and its pharmacists risk (and have been subject to) enforcement actions by *state* regulators alleging that they have interfered with the prescribing doctor’s medical judgment or the pharmacist’s duty to evaluate each prescription case-by-case. *See* Compl. ¶¶ 86–90. And Walmart cannot repel those efforts by pointing to mere *threats* by Defendants; only *actual* federal law can trigger the Supremacy Clause. That additional factor further heightens the immediacy and reality of the controversy. *See Texas v. United States*, 809 F.3d 134, 155–62 (5th Cir. 2015) (government’s unlawful interpretation of immigration law interacted with state regulatory scheme to produce cognizable injury).

The threat that Defendants would seek to enforce their views against Walmart was all too real when Walmart filed this case. Walmart alleged that Defendants warned that it was violating federal law and threatened to sue it under the theories set forth above. *E.g.*, Compl. ¶¶ 18, 57, 161. Those threats were plausible; indeed, they dovetail with Defendants’ recently filed enforcement actions against other pharmacies, which assert the very theories Walmart challenges here. *See*,

*e.g.*, *United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207, Compl. ¶ 21 (E.D.N.C. Oct. 30, 2020); *United States v. Farmville Disc. Drug, Inc.*, No. 4:20-cv-0018, Compl. ¶ 19 (E.D.N.C. Jan. 29, 2020). In fact, Defendants filed another such enforcement action on *the same day* that they moved to dismiss here. *United States v. Ridley's Fam. Mkts. Inc.*, No. 1:20-cv-00173, Compl. ¶¶ 21–23, 42, 45, 48, 49, 54, 58, 64, 67, 68, 72, 87, 92, 95, 99 (D. Utah Dec. 4, 2020) (seeking liability for failure to resolve “red flags,” failure to document “red flags,” and failure to comply with state law, as well as corporate liability for faulty corporate policies and oversight).<sup>1</sup>

Of course, even if Article III required Walmart to keep operating under this pall of uncertainty until it faced an “actual arrest, prosecution, or other enforcement action”—which it does not, *Susan B. Anthony*, 573 U.S. at 158—that has since occurred. As noted above, less than three weeks after telling this Court that any controversy between Walmart and Defendants was speculative, hypothetical, contrived, and unripe, Defendants filed a detailed, 160-page complaint against Walmart in the District of Delaware, asserting many of the precise overreaching theories that Walmart alleged had been threatened against it. *See* Enforcement Compl. ¶¶ 21–26 (alleging liability because, among other things, Walmart failed to share information between pharmacies, filled categories of prescriptions that are supposedly *per se* illegal, and failed to abide by ostensible professional standards found nowhere in the statute or regulations). At this point, Defendants can hardly continue to object that there is no “case or controversy” between them and Walmart. There is a most concrete one, and Defendants obviously knew as much when they filed their motion to dismiss.

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<sup>1</sup> DOJ’s complaints in these other lawsuits are judicially noticeable documents that may be considered in assessing Defendants’ motion to dismiss. *See, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011).

Along with the disputes over Walmart’s *dispensing* practices, there is also a controversy respecting Walmart’s *distribution*-related claims. The Article III test is easily met “if all of the acts that are alleged to create liability already have occurred.” 10B Wright & Miller, Fed. Prac. & Proc. Civ. § 2757 (4th ed. 2020). Although Walmart no longer self-distributes controlled substances, Defendants have threatened to sue it (and have now sued it) for alleged historical failures to file suspicious order reports and for shipping allegedly suspicious orders. Compl. ¶¶ 146, 155; *see also* Enforcement Compl. ¶¶ 27–37. Walmart contends that the CSA did not impose civil penalties for failing to file such reports at the time in question and that the CSA’s regulations did not (and still do not) require distributors to hold or investigate suspicious orders. *See* Compl. ¶¶ 145–61. That too is a plain “case or controversy” under Article III, and one that a declaration would materially resolve.

#### **B. Defendants’ Counterarguments Fail.**

Despite the above, Defendants insist they have no real controversy with Walmart. They claim that even if a regulated entity has an “urgent need to clarify legal obligations” due to the government’s threats—as Walmart has pleaded, and as Defendants hardly dispute—the regulated entity’s “only recourse” is to wait to make its legal arguments until the government initiates the threatened enforcement action. MTD 19, 20 (emphasis in original).

That disregards the point of a pre-enforcement declaratory judgment action and ignores Supreme Court precedent. The plaintiff in *Susan B. Anthony* could have made its statements and then raised the First Amendment as a defense; the manufacturers in *Abbott Labs* could have ignored FDA’s regulations and challenged their legality in enforcement proceedings. But Article III does not force someone “subject to” “the threatened enforcement of a law” to suffer “actual arrest, prosecution, or other enforcement action.” *Susan B. Anthony*, 573 U.S. at 158. Defendants’ lone citation does not contradict this well-established point. *Perez v. Mortgage Bankers*

*Association* held that agencies need not engage in notice and comment procedures before changing an interpretive rule. 575 U.S. 92 (2015). Nothing in that decision suggests that only “final agency action” can create a case or controversy under Article III, or that parties must wait for enforcement proceedings to raise any challenge. Again, *Susan B. Anthony* forecloses both contentions.

In addition, as explained above, now that Defendants *have* initiated an enforcement action against Walmart, resting on the precise theories at issue in this case, there is no serious doubt that an Article III controversy exists—or that Walmart was correct when it alleged that the threat of enforcement was both real and immediate. *See MedImmune*, 549 U.S. at 127.

Defendants also object that Walmart wants an advisory opinion to “hold in readiness” for a future enforcement action. MTD 17–18 (quoting *Pub. Serv. Comm’n of Utah v. Wycoff Co.*, 344 U.S. 237 (1952)). Of course, the entire point of any declaratory judgment action is to obtain legal resolution of a dispute that can be later used in the anticipated coercive action. This argument thus proves too much. Walmart is not seeking “advice” on hypothetical issues that might or might not arise. Instead, it seeks clarity on a real, concrete legal dispute between the parties about how Walmart and its pharmacists must conduct their day-to-day business on a current and future basis. The DJA exists to provide such clarity in the face of plausible threats of enforcement, *see infra* pp. 12–13, and courts routinely grant it without violating Article III.

Defendants’ cited cases are not to the contrary. Unlike Walmart, the plaintiff in *Wycoff* “offered no evidence whatever of any past, pending or threatened action,” “[d[id] not request an adjudication that it has a right to do, or to have, anything in particular,” and did not seek a judgment “that the [agency] [wa]s without power to enter any specific order or take any concrete regulatory step.” 344 U.S. at 240, 244. The Court accordingly rebuffed its request “simply to establish” that it was engaged in “interstate commerce” for hypothetical future litigation that might implicate that

subsidiary question. *Id.* at 244–45. Here, by contrast, Walmart has plausibly alleged a threat of future enforcement against it, pointed to enforcement actions against others, and requested a set of declarations to clarify the legal bounds of Walmart’s statutory and regulatory duties.

Defendants’ two out-of-circuit district court decisions are equally inapposite. In *Ohio Hospital Association v. Shalala*, the court found it lacked “equitable jurisdiction” over an attempt to stop the HHS Secretary from threatening to bring False Claims Act litigation during settlement negotiations, because it was the Attorney General—who was not named as a defendant—who had the authority to “pursue a prosecution.” 978 F. Supp. 735 (N.D. Ohio 1997), *aff’d*, 201 F.3d 418 (6th Cir. 1999) (reaching only this ground). That the hospital association could not sue the wrong officeholder regarding past conduct when the right officeholder had not threatened suit says nothing about whether Walmart can sue Defendants in response to their very real threats to enforce the CSA against Walmart. So too for *New Jersey Hospital Association v. United States*, where the court held that a similar lawsuit (though this time including the Attorney General) was not justiciable. *See* 23 F. Supp. 2d 497, 503 (D.N.J. 1998). Unlike Walmart’s suit here, the hospital association there “ha[d] not established a threat to the ongoing operations of its member hospitals,” nor had any of its member hospitals “yet been sued,” unlike the multiple recent lawsuits against pharmacies and now Defendants’ enforcement action against Walmart. *Id.* at 504.

In a related vein, Defendants characterize Walmart as asking the Court to “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.” MTD 18. But the issues presented in Walmart’s Complaint are firmly moored in the parties’ concrete legal dispute, embodied in Defendants’ plausible threats of enforcement that affect the real-world conduct of Walmart (and other pharmacies). Defendants’ related complaint that Walmart seeks only “vague declarations”

(MTD 19) similarly misfires. There is nothing vague about a request to declare, for example, that “[t]he CSA and its regulations do not require pharmacists to document in writing why filling a prescription was appropriate,” or that “[t]he CSA and its regulations do not require distributors not to ship suspicious orders after reporting them.” Compl., Prayer for Relief 1(D), 1(G). If any requested declarations were seen as “nebulous” (MTD 19), that might be reason to refine them through litigation on the merits. But it would not be grounds to dismiss the entire case for lack of jurisdiction under Article III.

Changing focus, Defendants next protest that Walmart’s suit is “based solely on Walmart’s own speculation as to what the federal government may be planning.” MTD 18; *see also* MTD 20 (complaining that Walmart “does not plead the basis on which it purports to have ascertained [Defendants’] legal positions”). At the motion-to-dismiss stage, however, it is Walmart’s plausible allegations that count. Walmart plausibly alleged that Defendants claimed it was violating the CSA and threatened to sue, just as they have sued other pharmacies on the same theories. *See supra* pp. 6–7. If Defendants did *not* believe those theories of the law or did *not* intend to sue Walmart based on them, they easily could have said so. *Cf. Deutsch v. Annis Enters., Inc.*, 882 F.3d 169, 173 n.1 (5th Cir. 2018) (courts may consider conflicting evidence to resolve factual issues related to jurisdiction). In any event, Walmart’s “speculation” was proven correct within a mere matter of weeks, making clear that Defendants’ suggestion to this Court that this controversy is contrived was disingenuous.

Finally, Defendants claim that Walmart “effectively mount[s] an improper programmatic challenge to agency operations” and DEA’s enforcement scheme. MTD 20. But asking this Court to resolve disputes about how specific distribution- and dispensing-related provisions regulate specific aspects of pharmacy operations does not jeopardize DEA’s end-to-end control over

controlled substances. Doing so bears no resemblance to the cases in which courts have rejected “programmatically” attacks. Granting Walmart’s requested relief would not subject Defendants to “general orders compelling compliance with broad statutory mandates,” or raise “[t]he prospect of pervasive oversight” by federal courts. *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 66–67 (2004). To the contrary, it would simply remove the cloud of uncertainty currently making it impossible for Walmart and its pharmacists to do their jobs without fear of federal or state liability. Article III has always allowed pre-enforcement suits of precisely that type. *See, e.g., Abbott Labs.*, 387 U.S. at 154–55.

## **II. WALMART HAS A CAUSE OF ACTION.**

Walmart also has a cause of action. The DJA allows would-be defendants (like Walmart) to bring anticipatory suits against their adversaries, relying on their opponents’ underlying claims (like Defendants’ then-threatened and now-actual suit under the CSA). Nothing Defendants say undermines Walmart’s invocation of that statute.

### **A. The Declaratory Judgment Act Allowed Walmart to Anticipate Defendants’ Then-Threatened Suit Under the CSA.**

The DJA provides that “[i]n 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.” 28 U.S.C. § 2201(a). The Act does not provide a freestanding cause of action for any party to have any issue resolved in federal court, and in that sense “does not provide an additional cause of action.” *Okpalobi v. Foster*, 244 F.3d 405, 423 n.31 (5th Cir. 2001) (en banc). But it *does* allow a party facing a threatened lawsuit to preemptively invoke the cause of action underlying that suit and to seek relief in advance of it.

Indeed, that is the point. The Act relieves potential defendants “from the Damoclean threat of impending litigation which a harassing adversary might brandish, while initiating suit at his

leisure.” *Domain Prot., LLC v. Sea Wasp, LLC*, No. 18-cv-0792, 2019 WL 6255733, at \*6 (E.D. Tex. Nov. 22, 2019). To that end, the Act “afford[s] one threatened with liability an early adjudication without waiting until an adversary should see fit to begin an action.” *Id.*; *see also MedImmune*, 549 U.S. at 128–29 (“[W]here threatened action by *government* is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat.”). Determining whether the Act allows declaratory plaintiffs to obtain such “early adjudication” often depends on whether the *declaratory defendant* could sue. For example, that principle controls federal question jurisdiction over declaratory judgment actions, which courts commonly determine by “look[ing] to the character of the threatened action.” *Medtronic, Inc. v. Mirowski Fam. Ventures, LLC*, 571 U.S. 191, 197–98 (2014). If a “coercive action brought by the declaratory judgment defendant ... would necessarily present a federal question,” then jurisdiction exists because the declaratory action “also arises under” the same federal law. *Id.* But “jurisdiction is lacking” if the threatened suit arises under state law and the federal issue arises only as a defense by the declaratory plaintiff. *Wright & Miller, supra*, § 2767. “[I]t is the character of the threatened action ... which will determine whether there is federal-question jurisdiction.” *Wycoff*, 344 U.S. at 248; *see Gaar v. Quirk*, 86 F.3d 451, 454 (5th Cir. 1996); *Severe Records, LLC v. Rich*, 658 F.3d 571, 581–82 (6th Cir. 2011).

The same principle controls the cause of action inquiry. As the Fifth Circuit has explained, the DJA “operates procedurally to broaden the class of litigants who might bring into federal court causes of action arising under federal law,” enabling a party to obtain a declaration regarding a claim that “could have been litigated in federal court in a coercive action brought by the declaratory defendant.” *Lowe v. Ingalls Shipbuilding*, 723 F.2d 1173, 1179 (5th Cir. 1984). In such cases, “the underlying cause of action which is ... actually litigated is the declaratory defendant’s, not

the declaratory plaintiff's." *Id.* In other words, the Act "permits a party to bootstrap its way into federal court" by "bring[ing] a federal action corresponding to the one that the opposing party might have brought." *Superior Oil Co. v. Pioneer Corp.*, 706 F.2d 603, 607 (5th Cir. 1983).

The patent cases that "frequently" arise under the DJA illustrate this elementary point. *Wright & Miller, supra*, § 2761. Without the Act, a person accused of patent infringement is in a "difficult position," lacking a cause of action to clear his name and living with the patent holder's threat hanging over his head. *Id.* But the Act makes it possible for the accused infringer to sue for a declaration that his conduct has been lawful. *Id.* In that "anticipatory" suit, there is a cause of action within the court's jurisdiction so long as the court could have entertained the coercive suit threatened by the patent holder under the federal patent laws. *Bell & Beckwith v. United States*, 766 F.2d 910, 912–13 (6th Cir. 1985). Of course, patent cases are not unusual in this regard; "a wide variety of cases" have confirmed that the Act opens the courthouse door to suits anticipating coercive actions under other statutes. *Id.*

Walmart's request for declaratory relief is no different. No one disputes—least of all Defendants—that federal courts have jurisdiction over government enforcement actions under the CSA. The DJA therefore provided a "corresponding" anticipatory cause of action to Walmart. *Superior Oil*, 706 F.2d, at 607. Because the scope of Walmart's and its pharmacists' obligations under the CSA "could have been litigated in federal court in a coercive action" by the government, Walmart had a right to raise the issue anticipatorily under the DJA. *Lowe*, 723 F.2d at 1179.

### **B. Defendants' Counterarguments Fail.**

Defendants respond first with bromides about the DJA: It does not authorize "at-will advisory opinion[s]"; "does not confer subject matter jurisdiction"; and "does not create a substantive cause of action." MTD 14. These truisms are irrelevant here. Walmart does not seek an advisory opinion; it seeks to resolve a concrete dispute with adversaries who are threatening its

everyday operations. *See supra* pp. 5–6. Walmart also does not need the Act to “confer subject matter jurisdiction” or “create a substantive cause of action.” As just explained, the CSA, combined with the general federal-question statute, perform those essential roles. The DJA merely allows Walmart to invoke them in this inverted posture. *See supra* pp. 13–14.

Defendants next assert that Walmart cannot piggyback off of the CSA for the underlying cause of action because “Walmart could not possibly bring this suit under the CSA itself,” as the CSA “contains no private right of action.” MTD 15. This unsupported theory is wrong. “[T]he plaintiff need not show that it would state a claim absent the declaratory judgment statute.” *TTEA v. Ysleta del Sur Pueblo*, 181 F.3d 676, 681 (5th Cir. 1999). “Rather, it may show that there would be jurisdiction over a claim *against it*.” *Id.* (emphasis added). Patent laws are again instructive. Those laws do not create a “private right of action” for accused infringers to sue patent holders. And yet one of the most classic uses of the DJA is to allow alleged infringers to sue. *See, e.g., MedImmune*, 549 U.S. at 127; *Texas v. W. Publ’g Co.*, 882 F.2d 171, 175 (5th Cir. 1989); *E. Edlmann & Co. v. Triple-A Specialty Co.*, 88 F.2d 852, 853–54 (7th Cir. 1937).

Indeed, Defendants do not actually believe that the absence of an underlying private right of action defeats a declaratory plaintiff’s attempt to go to court. In the very next paragraph, they admit that the DJA allows parties to, for example, go to court to preempt anticipated claims by other private parties. MTD 15–16 (citing *Gaar*, 86 F.3d at 453–54). Such cases could not proceed if a declaratory plaintiff needs its own “private right of action.” MTD 15. Rather, these cases—like Walmart’s—can proceed under the DJA because the issues “could have been litigated in federal court in a coercive action brought by the declaratory defendant.” *Lowe*, 723 F.2d at 1179.

Defendants respond that ordinary declaratory cases are a “far cry from the present suit, where Walmart seeks to block the exercise of unreviewable prosecutorial discretion.” MTD 16.

But Walmart does not seek to block anything; it asks only for a declaration about the scope of the CSA. Of course, any ruling about the scope of federal law could have downstream consequences on enforcement actions that the government has brought or might bring, as a matter of *res judicata* or (after appeal) precedent. That, however, does not distinguish this case from a suit seeking a declaration that a criminal statute is unconstitutional, for instance, which Defendants agree is justiciable. *See, e.g., Nat'l Rifle Ass'n of Am. v. Magaw*, 132 F.3d 272, 277 (6th Cir. 1997). That is why there is no “absolute” rule against “pre-enforcement lawsuits that might interfere with agency enforcement discretion,” *Minn. Citizens Concerned for Life v. FEC*, 113 F.3d 129, 132 (8th Cir. 1997), as the host of cases discussed above illustrates.

### **III. THE UNITED STATES HAS WAIVED ITS SOVEREIGN IMMUNITY.**

Defendants also argue the United States has not waived its sovereign immunity. MTD 9–14. But actions seeking prospective relief from government officials have never been subject to sovereign immunity, a rule that the immunity waiver in 5 U.S.C. § 702 now codifies. That waiver applies precisely to this kind of case: a challenge to unlawful agency action, seeking declaratory relief, that does not arise under the general provisions of the APA. *See Doe v. United States*, 853 F.3d 792, 798–99 (5th Cir. 2017).

#### **A. The Plain Text of the APA Waives Sovereign Immunity.**

For over a century, federal courts have declined to extend sovereign immunity to actions seeking prospective relief from government officials. *See Ex parte Young*, 209 U.S. at 123; *Kentucky v. Graham*, 473 U.S. 159, 167 n.14 (1985) (“official-capacity actions for prospective relief are not treated as actions against the State”). For cases involving federal officers, that principle was later codified and expanded in 5 U.S.C. § 702, which operates by categorically waiving immunity for such claims. *See Am. Rd. & Transp. Builders Ass'n v. EPA*, 865 F. Supp. 2d 72, 83 (D.D.C. 2012).

The 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. As the Fifth Circuit has explained, Congress added this provision “to broaden the avenues for judicial review of agency action by eliminating the defense of sovereign immunity in cases covered by the amendment.” *Doe*, 853 F.3d at 798–99. And Congress accomplished that goal. By its terms, § 702 waives immunity over any action that does not seek “money damages” and that asserts a claim based on action taken “in an official capacity or under color of legal authority.”

The Fifth Circuit has interpreted the latter phrase to require a plaintiff who seeks review of “agency action” “pursuant to a ... cause of action that arises completely apart from the general provisions of the APA” to “identify some ‘agency action’ affecting him in a specific way”—with “agency action” defined broadly to include “the whole or part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.” *Alabama-Coushatta Tribe of Tex. v. United States*, 757 F.3d 484, 489 (5th Cir. 2014) (quoting 5 U.S.C. § 551(13)). The plaintiff must also be “adversely affected or aggrieved by that [agency] action.” *Id.* For example, in *Doe*, the plaintiff sought a declaratory judgment for violations of his due process rights in the course of another person’s criminal prosecution. 853 F.3d at 794. Because the government had “accus[ed] [the plaintiff] of a crime without providing a public forum in which [he could seek] to vindicate his rights,” it “failed to act and failed to provide relief or a remedy to [the plaintiff],” allowing him to proceed in court. *Id.* at 800; *see also, e.g., Alexander v. Trump*, 753 F. App’x 201

(5th Cir. 2018) (per curiam) (sufficient “agency action” existed where plaintiff alleged that the FBI failed to investigate the supposed murder plot against him).

The § 702 waiver encompasses Walmart’s Complaint, just as it did the claims in *Doe* and *Alexander*. Walmart seeks declaratory relief against federal agencies and their principal officers, claiming they have acted unlawfully in construing and enforcing the CSA. *See, e.g.*, Compl. ¶ 172. That sort of claim would never have implicated sovereign immunity under the old *Ex parte Young* framework, for declaratory relief is a form of “prospective” relief under that rule. *See Williams*, 954 F.3d at 736–37. And Walmart’s claims are covered by the congressional § 702 waiver as construed by the Fifth Circuit, because its suit is *all about* “agency action”—meaning actions DOJ and DEA have taken, are taking, and have threatened to take. To highlight just a few examples from Walmart’s Complaint:

- “DEA has recently advised pharmacists *not* to fill prescriptions that are ‘doubtful, questionable, or suspicious.’” Compl. ¶ 51 (citing DEA, *The Pharmacist’s Manual* 42 (2020)).
- “DOJ intends to sue Walmart for filling prescriptions when there were what DEA calls ‘red flags[.]’” Compl. ¶ 57.
- “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.” Compl. ¶ 115.
- “DOJ has incorrectly asserted that the CSA and its implementing regulations require pharmacists to take certain procedural steps when dealing with red flags.” Compl. ¶ 132.
- “Defendants also intend to seek massive retroactive liability on Walmart under the view that its corporate-level policies violated the CSA.” Compl. ¶ 142.
- “DOJ intends to assert that the ‘duties’ outlined in various DEA guidance letters to pharmaceutical distributors have the force of law, including a duty not to ship orders identified as suspicious by the registrant’s SOM system until they have been investigated. This purported duty originated in a December 2007 letter from Deputy Assistant DEA Administrator Joseph Rannazzisi.” Compl. ¶¶ 148–49.

- “Defendants intend to seek civil penalties related to Walmart’s purported failure to submit suspicious order reports.” Compl. ¶ 155.
- “In a criminal complaint recently filed by DOJ ... , the Department declared that “[t]here is no medical basis for the simultaneous prescription of any version of the three “trinity” drugs.” Compl. ¶ 60 (quoting *United States v. Rodriguez*, No. 19-cv-1055, Compl. (N.D. Tex. May 2, 2019)).

These actions—all reinforced by the Enforcement Complaint—fall within the statutory definition of “agency action,” even if they would not qualify as “final” agency action allowing suit under the APA. The term “agency action” includes “the whole or a part of an agency rule,” 5 U.S.C. § 551(13), with “rule,” in turn, defined as “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,” *id.* § 551(4). The definition of a “rule” is not limited to those formal rulemakings that have the force of law and trigger the APA’s familiar notice-and-comment procedures. *See U.S. Dep’t of Labor v. Kast Metals Corp.*, 744 F.2d 1145, 1151 (5th Cir. 1984) (explaining that “the definition of a rule is broad,” and “the rigors of the APA do not apply to all such administrative actions”). In addition, the statutory definition of “agency action” also sweeps in any “order,” which is defined in turn to include “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). It also includes any “sanction,” defined to mean any “prohibition, requirement, limitation, or other condition affecting the freedom of a person,” or any “other compulsory or restrictive action.” *Id.* § 551(10). And, unlike in APA cases, none of these agency actions needs to be “final” to trigger the immunity waiver under § 702. *See Alexander*, 753 F. App’x at 206 & n.4 (distinguishing between “agency action” sufficient to overcome jurisdictional bar and “[f]inal agency action[]” required for APA claim); *see also infra* p. 23 (explaining that Defendants miss the mark by complaining about the lack of “final” agency action).

For example, like the other statements and threats of enforcement that Walmart alleges Defendants have made about the CSA, the December 2007 letter from Deputy Assistant DEA Administrator Joseph Rannazzisi meets the definition of a “rule,” “order,” or “sanction.” The letter itself declares that its purpose “is to reiterate the responsibilities of controlled substance manufacturers and distributors.” Motion for Partial Summary Judgment by Walmart Inc., Dkt. 21 at Ex. 3; *see also* Notice of Proposed Rulemaking, Suspicious Orders of Controlled Substances, 85 Fed. Reg. 69282, 69286–87 (Nov. 2, 2020) (claiming that proposed regulations codifying the duty not to ship suspicious orders merely track existing agency interpretations in the letters); *cf. Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 435 (D.C. Cir. 1986) (“The term ‘agency action’ encompasses an agency’s interpretation of law.”). Other agency rules or orders challenged in the Complaint grow out of Defendants’ own litigation against other pharmacies and pharmacists. In *Rodriguez*, for example, DOJ has sought to create a *per se* prohibition on filling an entire category of prescriptions.

Walmart meets the second prong of the Fifth Circuit’s test for § 702’s immunity waiver as well, because it is adversely affected by Defendants’ actions. Indeed, those actions create profound jeopardy for Walmart and its pharmacists—and pharmacists generally—when they dispense controlled substances. *See* Brief for the National Association of Chain Drug Stores and the American Pharmacists Association as Amici Curiae Supporting Plaintiff, Dkt. 39 at 6; Brief for Association of American Physicians & Surgeons as Amicus Curiae Supporting Plaintiff, Dkt. 48 at 3. If they dispense those substances by exercising their own professional judgment, they risk massive civil penalties under Defendants’ interpretation of the CSA. But if they comply with Defendants’ overbroad view, they might cut patients off from medications that they desperately

need, trigger more lawsuits from impugned physicians, and face additional enforcement actions by disapproving state regulators. *See* Compl. ¶¶ 8, 17, 19, 51–56.

Any doubt over whether § 702 extends to this suit must be resolved in Walmart’s favor, for three separate reasons. *First*, that is how subject-matter jurisdiction is treated at the motion-to-dismiss stage in every case; “[a] dismissal for lack of jurisdiction” based on the pleadings “will not be affirmed unless it appears certain that the plaintiff cannot prove any set of facts in support of his claim that would entitle plaintiff to relief.” *Williams*, 954 F.3d at 734.

*Second*, other Courts of Appeals do not require even “agency action” to trigger the waiver. *See Navajo Nation v. Dep’t of Interior*, 876 F.3d 1144, 1172 & n.36 (9th Cir. 2017) (noting the other circuits’ “near-unanimity” in holding that this provision waives “any” and “all” “immunity for non-monetary claims,” and observing that the Fifth Circuit “appears to be alone in holding to the contrary”); *Trudeau v. FTC*, 456 F.3d 178, 187 (D.C. Cir. 2006) (reasoning that § 702’s waiver “is not limited to APA” and “hence that it applies regardless of whether the elements of an APA cause of action are satisfied”). The “agency action” element should be applied liberally to minimize the gap between the Fifth Circuit and every other circuit’s reading of the law. (Walmart also preserves for appeal its objection to Fifth Circuit precedent on this point.)

*Finally*, a more demanding threshold for “agency action” in this context would create a troubling gap in the law. The Fifth Circuit’s rule only matters when, as here, the agency’s actions create a concrete controversy under Article III. *See supra* pp. 4–7. If agency action sufficient to *create* such a controversy still does not qualify as “agency action” as defined in the APA, parties facing real-world harm from specific agency misconduct will have no way to stop that misconduct unless the agency decides, in its discretion, to take further steps and thereby exacerbate the harm. Such a regime conflicts with the “strong presumption favoring judicial review of administrative

action,” *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 489 (2015), not to mention elementary notions of fairness and of a government subject to the rule of law.

**B. Defendants’ Counterarguments Fail.**

Defendants first object that Walmart “fails to make even a passing reference to sovereign immunity” in its Complaint. MTD 10.<sup>2</sup> But there was no need for Walmart to do so. “The waiver of sovereign immunity is a legal matter relating to the Court’s jurisdiction,” and so “[i]t is sufficient” for a plaintiff to “correctly argue[] that the APA provides the requisite waiver of immunity in [its] opposition to Defendant’s motion to dismiss.” *McKoy v. Spencer*, 271 F. Supp. 3d 25, 32 (D.D.C. 2017); *see also, e.g., Z Street, Inc. v. Koskinen*, 44 F. Supp. 3d 48, 63 (D.D.C. 2014) (same). And the Fifth Circuit has held more generally that “it is well settled that where a complaint fails to cite the statute conferring jurisdiction, the omission will not defeat jurisdiction if the facts alleged in the complaint satisfy the jurisdictional requirements.” *Hildebrand v. Honeywell, Inc.*, 622 F.2d 179, 181 (5th Cir. 1980). *Doe* applied this teaching in the sovereign immunity context to hold that § 702 waived immunity even though the complaint did not specifically plead a waiver or use the term “agency action” to describe the challenged conduct. *See* 853 F.3d at 798–99. Walmart has amply pleaded the facts establishing that sovereign immunity does not bar this suit; that is more than enough to defeat Defendants’ dismissal bid. *See supra* pp. 18–21.<sup>3</sup>

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<sup>2</sup> Although Defendants suggested in their reply in support of their motion to stay summary judgment briefing that this is a pleading defect warranting dismissal, Dkt. 54 at 7, they do not actually make that argument in their motion to dismiss. As a result, this argument is waived. *Cf. Whitmire v. Terex Telelect, Inc.*, 390 F. Supp. 2d 540, 548 (E.D. Tex. 2005) (finding waived issues “not raise[d] or brief[ed] ... in [plaintiff’s] responsive brief”).

<sup>3</sup> If the Court disagrees, Walmart would seek leave to amend its complaint to specifically cite § 702. Such leave should be freely granted, *see* Fed. R. Civ. P. 15(a)(2), particularly to fix technical defects that cause no harm to the opposing party.

Defendants next assert that Walmart cannot overcome sovereign immunity because it has not identified “final agency action.” MTD 11. But that is the wrong question. As *Alabama-Coushatta* made clear, the lack of *final* agency action matters “when judicial review is sought pursuant only to the general provisions of the APA.” 757 F.3d at 489; *see also* 5 U.S.C. § 704 (authorizing APA review of “final agency action”). When review is sought “pursuant to a statutory or non-statutory cause of action that arises completely apart from the general provisions of the APA,” however, “[t]here is no requirement of ‘finality,’” only of “agency action.” *Alabama-Coushatta*, 757 F.3d at 489; *see also id.* (noting that “[t]he requirement of ‘finality’ comes from § 704 and has been read into § 702 in cases where review is sought pursuant only to the general provisions of the APA”); *Alexander*, 753 F. App’x at 206 & n.4 (distinguishing between “agency action” sufficient to overcome jurisdictional bar and “[f]inal agency action” required for APA claim). Defendants’ misstatement of the test is telling—they cannot plausibly assert that there is not “agency action” here under the Fifth Circuit’s jurisprudence.

Nor are Defendants correct that sovereign immunity precludes Walmart’s claim because Walmart has an “adequate remedy at law”—namely, “defending itself” against DOJ’s (now-filed) enforcement action. MTD 12. As with the “finality” requirement, this element appears only in § 704, not in § 702. *See* 5 U.S.C. § 704; *see also* MTD 12 (citing 5 U.S.C. § 704). Defendants’ cited cases prove as much. In each, the final-agency-action and no-adequate-remedy requirements applied because the plaintiffs alleged violations of the general provisions of the APA. *See Quicken Loans Inc. v. United States*, 152 F. Supp. 3d 938, 945 (E.D. Mich. 2015); *Greater N.Y. Hosp. Ass’n v. United States*, No. 98 Civ. 2741, 1999 WL 1021561, at \*4 n.5 (S.D.N.Y. Nov. 9, 1999) (“treat[ing] plaintiffs’ claims as arising under both” APA and DJA); *N.J. Hosp. Ass’n v. United States*, 23 F. Supp. 2d 497 (D.N.J. 1998) (alleged violations of APA, Fifth Amendment, and False

Claims Act); *Parke, Davis & Co. v. Califano*, 564 F.2d 1200 (6th Cir. 1977). This case, by contrast, is a declaratory judgment action relying directly on the CSA. Walmart is not suing under the APA and therefore need not satisfy its requirements. Moreover, raising defenses in the enforcement action is certainly *not* an adequate remedy. Walmart needs an expeditious resolution of its concrete dispute with Defendants concerning its *present* and *future* conduct—a resolution that is not likely ever to be obtained in the enforcement action concerning its alleged past conduct, and certainly not one that will be obtained in that action expeditiously. And that resolution is needed most acutely in Texas, where Walmart has more pharmacies than it does in any other state.

Finally, Defendants argue that § 701(a)(2)—which strips courts of jurisdiction to review action “committed to agency discretion by law”—defeats this suit because “whether to bring an enforcement proceeding is the paradigmatic example of presumptively unreviewable action.” MTD 13. Again, however, Walmart is not seeking to enjoin an enforcement action. Nor is Walmart requesting a “procla[mation]” that Walmart is “innocent of violations of the [CSA].” MTD 1. Even if Walmart obtains the requested clarification of its legal obligations, Defendants’ new enforcement action against Walmart will go forward. To be sure, such relief might carry implications for the enforcement action, such as through principles of *res judicata* or collateral estoppel, but that does not make this case any different from any other pre-enforcement challenge to agency action on constitutional or statutory grounds. Those typical downstream effects of litigation do not somehow transform the suit into a forbidden attack on prosecutorial discretion.

It is little surprise, then, that Defendants’ authorities are easily distinguished. The canonical decision in *Heckler v. Chaney* rejected an effort by prison inmates to compel the FDA to *take enforcement action* to prevent violations of the Federal Food, Drug, and Cosmetic Act with respect to the drugs used for capital punishment. *See* 470 U.S. 821, 823 (1985). The remaining

cases similarly involved challenges to agency decisions to initiate proceedings or to grant discretionary relief. *See Pub. Citizen, Inc. v. EPA*, 343 F.3d 449 (5th Cir. 2003) (decision not to issue notice of deficiency); *Perales v. Casillas*, 903 F.2d 1043, 1045 (5th Cir. 1990) (decision “to grant voluntary departure and work authorization”). Here, by contrast, Walmart is asking for a declaration about *what the law requires*, not *how Defendants should enforce it* or *whether Walmart complied with it*. That former question is emphatically not one “committed to agency discretion,” even if Defendants desperately want to hide their views of the CSA from judicial scrutiny.

### **CONCLUSION**

The Court should deny Defendants’ motion to dismiss.

Dated: January 6, 2021

Respectfully submitted,

/s/ Michael A. Carvin

Michael A. Carvin\*

D.C. Bar No. 366784

Benjamin C. Mizer\*

D.C. Bar No. 499651

Yaakov M. Roth\*

D.C. Bar No. 995090

William G. Laxton, Jr.\*

D.C. Bar No. 982688

JONES DAY

51 Louisiana Avenue, N.W.

Washington, D.C. 20001.2113

Telephone: (202) 879-3939

Facsimile: (202) 626-1700

macarvin@jonesday.com

bmizer@jonesday.com

yroth@jonesday.com

wglaxton@jonesday.com

Karen P. Hewitt\*

California Bar No. 145309

JONES DAY

4655 Executive Drive, Suite 1500

San Diego, CA 92121-3134

Telephone: (858) 314-1200

Facsimile: (844) 345-3178

kphewitt@jonesday.com

Jason S. Varnado  
Texas Bar No. 24034722  
Andrew J. Junker  
Texas Bar No. 24106155  
JONES DAY  
717 Texas, Suite 3300  
Houston, TX 77002-2172  
Telephone: (832) 239-3939  
Facsimile: (832) 239-3600  
jvarnado@jonesday.com  
ajunker@jonesday.com

David W. Ogden\*  
D.C. Bar No. 375951  
Charles C. Speth\*  
D.C. Bar No. 979809  
WILMER CUTLER PICKERING  
HALE AND DORR LLP  
1875 Pennsylvania Avenue NW  
Washington, DC 20006  
Telephone: (202) 663-6000  
Facsimile: (202) 663-6363  
David.Ogden@wilmerhale.com  
Charles.Speth@wilmerhale.com

/s/ Clyde M. Siebman  
Clyde M. Siebman  
Texas Bar No. 18341600  
Elizabeth S. Forrest  
Texas Bar No. 24086207  
SIEBMAN FORREST BURG  
& SMITH, LLP  
Federal Courthouse Square  
300 N. Travis  
Sherman, TX 75090  
Telephone: (903) 870-0070  
Facsimile: (903) 870-0066  
clydesiebman@siebman.com  
elizabethforrest@siebman.com

\*Admitted *pro hac vice*

Attorneys for Plaintiff  
WALMART INC.

**CERTIFICATE OF SERVICE**

I hereby certify that on January 6, 2021, I electronically filed the foregoing motion with the Clerk of the Court using the CM/ECF system.

By: /s/ Clyde Siebman  
*Counsel for Walmart Inc.*

