No. 21-40157

In the United States Court of Appeals for the Fifth Circuit

WALMART INC.,

Plaintiff-Appellant,

v.

UNITED STATES DEPARTMENT OF JUSTICE; UNITED STATES DRUG ENFORCEMENT ADMINISTRATION; ACTING ADMINISTRATOR D. CHRISTOPHER EVANS; MERRICK GARLAND, U.S. ATTORNEY GENERAL,

Defendants-Appellees.

On Appeal from the United States District Court for the Eastern District of Texas, Sherman Division
Civil Action No. 4:20-cv-00817-SDJ

BRIEF OF THE U.S. CHAMBER OF COMMERCE, THE RETAIL LITIGATION CENTER, INC., THE NATIONAL RETAIL FEDERATION, AND THE INDEPENDENT WOMEN'S LAW CENTER AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT IN SUPPORT OF REVERSAL

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that, in addition to the persons and entities listed in Plaintiff-Appellant's Certificate of Interested Persons, the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the Judges of this Court may evaluate possible disqualification or recusal:

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Independent Women's Law Center is a project of the Independent Women's Forum, a nonprofit, tax-exempt organization incorporated in Virginia. Independent Women's Forum has no parent corporation, and no publicly held company has 10% or greater ownership in Independent Women's Forum.

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Legislative History

Secondary Sources

INTERESTS OF *AMICI CURIAE*[1]

The **Chamber of Commerce of the United States of America** is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and organizations of every size, in every industry sector, from every region of the country. An important function of the Chamber is to represent its members' interests in matters before Congress, the Executive Branch, and the courts. The Chamber files *amicus curiae* briefs in cases that raise issues of concern to the nation's business community, including in the district court in this litigation.

The **Retail Litigation Center, Inc.** ("RLC") is the only trade organization dedicated to representing the retail industry in the courts. The RLC's members include many of the country's largest and most innovative retailers, employ millions of workers throughout the United States, provide goods and services to tens of millions of consumers, and account for tens of billions of dollars in annual sales. The RLC provides courts with retail-industry perspectives on legal issues impacting

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), counsel for *amici curiae* state that no party's counsel authored the brief in whole or in part, and that no person other than *amici curiae*, their members, or their counsel contributed money that was intended to fund preparing or submitting this brief. All parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(a)(2).

its members and highlights the industry-wide consequences of significant cases. Since its founding, the RLC has participated as an *amicus* in more than 150 cases.

The **National Retail Federation** ("NRF") is the world's largest retail trade association, representing diverse retailers from the United States and more than 45 countries. Retail is the nation's largest private-sector employer, contributing $3.9 trillion to annual GDP and supporting one in four U.S. jobs. For over a century, NRF has been a voice for every retailer and every retail job, communicating the impact retail has on local communities and global economies. NRF submits *amicus curiae* briefs in cases raising significant legal issues for the retail community.

Independent Women's Law Center ("IWLC") is a project of Independent Women's Forum ("IWF"), a nonprofit, non-partisan 501(c)(3) organization founded by women to foster education and debate about legal, social, and economic issues. IWF promotes policies that advance women's interests by expanding freedom, encouraging personal responsibility, and limiting the reach of government. IWLC supports this mission by advocating—in the courts, before administrative agencies, in Congress, and in the media—for individual liberty, equal opportunity, and respect for the American constitutional order.

There is no denying the magnitude of the opioid crisis in America. It is a devastating social and economic problem—one that deserves serious solutions. Although the dispute in this case relates to the opioid epidemic, *amici*'s participation

is not because of the subject matter. Rather, *amici* focus on legal principles that impact regulated entities in *any* context. The Government has many tools at its disposal to combat the opioid crisis, and *amici* support the Government's use of appropriate tools in accordance with constitutional, statutory, and regulatory constraints. But when the Government evades the procedural requirements of the Administrative Procedure Act ("APA") by relying on subregulatory guidance—and particularly when it threatens enforcement actions based on such guidance—it creates substantial regulatory uncertainty and disrupts the activities of the nation's business community.

SUMMARY OF THE ARGUMENT

Businesses that face liability for purported violations of regulatory obligations have an interest in ensuring those obligations are created, refined, and enforced in accordance with law. Free enterprise and sound policymaking depend on the regularity of agency process. And fundamental fairness requires that liability attach only to violations of clearly established rules.

Contrary to these principles, federal administrative agencies have increasingly avoided notice-and-comment procedures under the APA when regulating the private sector. Those procedures promote regulatory certainty by providing regulated entities with notice and an adequate opportunity to comment before the imposition of new substantive rules of conduct. Rather than follow those procedures, agencies

increasingly issue *de facto* regulations in the guise of interpretive guidance—even though, under the APA, such agency pronouncements do not carry the force and effect of law. Worse, agencies often seek to enforce such interpretive guidance by threat of enforcement action—even when the guidance is contrary to statute—and then attempt to evade judicial review when businesses call their bluff by bringing a pre-enforcement suit.

In addition to being unlawful, these agency tactics are costly to our national economy. They create substantial regulatory uncertainty as businesses must decide whether to comply with agency directives that, under the APA, are not binding but which agencies may nevertheless use to goad compliance, to extract concessions or, in some cases, "to indirectly promulgate novel legal standards and thereby reshape" entire industries without direct substantive authority from Congress or the procedural safeguards envisioned by the APA. *See* Matthew C. Turk, *Regulation by Settlement*, 66 U. Kan. L. Rev. 259, 292 (2017). Meanwhile, companies that try to get ahead of these problems through pre-enforcement litigation must overcome a familiar pattern of agency stonewalling whereby the agency will suddenly insist that its guidance is not intended to be binding, final, or subject to judicial review. *See, e.g.*, *Texas v. United States*, 809 F.3d 134, 170–78 (5th Cir. 2015); *Chamber of Commerce of the United States v. Reich*, 74 F.3d 1322, 1326–27 (D.C. Cir. 1996).

Basing civil liability on interpretive guidance created without a transparent regulatory process, and for which judicial review is difficult to obtain, flouts the requirements of the APA and due process. To prevent federal agencies from engaging in this abuse of process, courts should continue to allow regulated entities to use the Declaratory Judgment Act both as an appropriate way to obtain pre-enforcement relief, and as an opportunity to conform their conduct to the requirements of the law when threatened with prosecution. *See Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). In this case, the district court erred in cutting off that important avenue of review by finding that Wal-Mart's action was barred by sovereign immunity.

ARGUMENT

I. The Administrative Procedure Act's Fundamental Distinction Between Binding Legislative Rules And Non-Binding Interpretive Rules Is Critical To The National Economy.

A. The APA Imposes Procedural Safeguards That Apply When Agencies Regulate Private Conduct.

The APA draws a fundamental distinction between legislative and non-legislative rules. "[L]egislative rules" are "issued through the notice-and-comment process" and "have the 'force and effect of law.'" *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302–03 (1979)). Non-legislative rules, by contrast, are issued without notice-and-comment

procedures and "do not have the force and effect of law." *Id.* at 97 (internal quotation marks omitted); *see* 5 U.S.C. § 553(b)(A).

The distinction is important. When federal administrative agencies enact binding regulations that direct private conduct, "[n]otice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019). Indeed, in the early days of our Republic, rules affecting private conduct were enacted "only by [the people's] elected representatives in a public process." *Gundy v. United States*, 139 S. Ct. 2116, 2134 (2019) (Gorsuch, J., dissenting). When, in the 20th century, Congress began rapidly delegating its substantive authority "to unrepresentative agencies," *Batterton v. Marshall*, 648 F.2d 694, 703 n.47 (D.C. Cir. 1980), it enacted the APA to remedy agencies' "distance from the elective process" by restoring "direct lines to the public voice" through "'public participation in the rulemaking process,'" *U.S. Dep't of Lab. v. Kast Metals Corp.*, 744 F.2d 1145, 1152 & n.11 (5th Cir. 1984) (quoting S. Doc. No. 248, 79th Cong., 2d Sess. 19–20 (1946)) (brackets and ellipsis omitted).[2]

[2] Of course, notice and comment is not a perfect substitute for democratic accountability. And the growth of the administrative state, "which now wields vast power and touches almost every aspect of daily life," *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 499 (2010), continues to surface additional shortcomings. However, by affording the public an opportunity to have a say before new obligations are imposed, and by allowing the public notice that such obligations

In addition to providing a measure of democratic accountability, notice and comment improves the quality of agency decisionmaking. Regulators are "not omniscient," *United States v. Marine Shale Processors*, No. 90-cv-1240, 1994 WL 285053, at *1 (W.D. La. June 20, 1994), and hearing from the public affords them "a chance to avoid errors and make a more informed decision," *Allina Health Servs.*, 139 S. Ct. at 1816. Such process becomes even more important as federal agencies move to regulate an ever-growing swath of the economy through myriad rules relating to the environment, consumer protection, financial services, healthcare, and other activities. The issues involved are often complex, and an agency undoubtedly benefits from the opportunity "to educate itself before adopting a final order." *City of Arlington, Tex. v. FCC*, 668 F.3d 229, 245 (5th Cir. 2012) (quoting *United States v. Johnson*, 632 F.3d 912, 931 (5th Cir. 2011)).

Indeed, this is evident from the fact that agencies often modify their proposals in response to comments they receive through the rulemaking process. That includes the Drug Enforcement Agency ("DEA") which, in 2020, "revised" a proposed regulation after a commenter identified an "inconsistency" the agency had missed, *see* Implementation of the Combat Methamphetamine Epidemic Act of 2005, 85

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are under consideration, notice and comment promotes accountability, "fairness," and "mature consideration of rules of general application." *Chrysler Corp.*, 441 U.S. at 303 (internal quotation marks omitted).

Fed. Reg. 68,450, 68,455 (Oct. 29, 2020), and, in 2016, "modified" "the regulatory text accompanying [a] new drug code" based on comments received during the notice period, *see* Establishment of a New Drug Code for Marihuana Extract, 81 Fed. Reg. 90,194, 90,195 (Dec. 14, 2016).

When agencies deprive themselves of exposure to the viewpoints of interested persons, they increase the risk of unintentional errors and unintended consequences, as these examples show. To be sure, agencies sometimes find that notice and comment prevents them from acting as nimbly as they would prefer. But Congress conditioned their exercise of legislative authority on the procedures it believed would "afford safeguards to private interests." *Kast Metals Corp.*, 744 F.2d at 1152 n.11 (quoting S. Doc. No. 248, 79th Cong., 2d Sess. 19–20 (1946)); *see also Chrysler Corp.*, 441 U.S. at 303 ("[A]gency discretion is limited not only by substantive, statutory grants of authority, but also by the procedural requirements [of the APA]."). And agencies are obligated to comply with those procedures.

Non-legislative rules, by contrast, "do not have the force and effect of law" and so "the notice-and-comment requirement 'does not apply.'" *Perez*, 575 U.S. at 96–97 (quoting 5 U.S.C. § 553(b)(A)). The APA's different treatment of these "rules reflects the congressional judgment that such rules, because they do not directly guide public conduct, do not merit the administrative burdens of public input proceedings." *Kast Metals Corp.*, 744 F.2d at 1153. Agencies may properly use

non-legislative rules to provide interpretive guidance and "advise the public of the agency's construction of the statutes and rules which it administers," *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 99 (1995) (internal quotation marks omitted), but never to impose binding obligations. "Being in nature hortatory, rather than mandatory, interpretive rules can never be violated." *United States v. Clayton*, 506 F.3d 405, 409 n.3 (5th Cir. 2007).

B. Regulating Private Conduct Without Observance Of APA Safeguards Creates Substantial Regulatory Uncertainty And Disrupts Business Activities.

Significant problems arise when agencies ignore these fundamental APA distinctions and seek to impose binding obligations through non-legislative rules that have not been adopted through APA rulemaking procedure. Such actions threaten the "fundamental principle in our legal system . . . that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012).

A common way that agencies undermine this principle is by threatening enforcement based on positions not set forth in statutes or binding legislative rules. The APA is clear that "[s]ubstantive rules not subjected to notice and comment may not be enforced against a party." *W & T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019); *accord Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (per Kavanaugh, J.) ("As a legal matter, the Final Guidance is

meaningless" and "may not be the basis for an enforcement action against a regulated entity."). But the law's clarity has not stopped agencies from repeatedly trying to enforce positions articulated in "guidance," "voluntary standards," or other informal documents. *See* U.S. Dep't of Justice, *Memorandum for Heads of Civil Litigating Components re Limiting Use of Agency Guidance Document in Affirmative Civil Enforcement Cases* (Jan. 25, 2018), https://www.justice.gov/file/1028756/download.

A recent Supreme Court decision illustrates the problem. In *Allina Health Services*, the Department of Health and Human Services attempted to change Medicare reimbursement rates by "post[ing] on a website a spreadsheet" announcing payments for 3,500 hospitals under a revised formula that had not been developed through notice and comment. 139 S. Ct. at 1810. This action impacted "millions of people and billions of dollars." *Id.* at 1816; *see also id.* at 1808–09. The Supreme Court correctly rejected HHS's use of an Internet post to set policy, explaining that HHS "can't evade its notice-and-comment obligations" where its action "established or changed a 'substantive legal standard.'" *Id.* at 1810, 1817.

This Court has confronted similarly lawless action. In *Texas v. United States,* 809 F.3d 134 (5th Cir. 2015), the Department of Homeland Security promulgated a "policy statement" exempt from notice and comment, but then applied that statement "in a way that indicate[d] it [wa]s binding" and not merely guidance. *Id.* at 173; *see*

id. at 170–78. This Court enjoined enforcement of the policy statement on the ground that it was, in fact, a binding legislative rule promulgated without notice and comment. *Id.* at 178, 188; *see also Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020–21 (D.C. Cir. 2000) ("If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, . . . then the agency's document is for all practical purposes 'binding.'").

This type of agency behavior carries high costs even when it is ultimately corrected by the courts. When an agency goes outside of notice-and-comment rulemaking to adopt a dubious interpretation of a statute or rule (or takes some other action straining the limits of its authority), affected businesses face a "painful choice." *CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011). They can risk enforcement, relying on the agency's selection of non-binding procedure—which, in many cases, may be accompanied by an affirmative disclaimer of enforceability, *see* Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 Duke L.J. 1311, 1361 (1992)—or they may begin implementation of burdensome compliance measures that may not be required by the statute and that the public and regulated parties have not had an opportunity to

critique through notice and comment, as envisioned by the APA. *See CSI Aviation Servs.*, 637 F.3d at 412.

Both choices have drawbacks. As to the first, experience proves that agency pledges not to enforce guidance sometimes are "a charade, intended to keep the proceduralizing courts at bay." *Appalachian Power Co.*, 208 F.3d at 1023 (quoting Peter L. Strauss, *The Rulemaking Continuum*, 41 Duke L.J. 1463, 1485 (1992)). Although an agency may claim its guidance is not enforceable, in practice, businesses know that "there is little to deter the agency, despite its reservation of discretion to decide variantly, from relentlessly applying the stated positions as though they had the full force of law." Anthony, *supra*, 41 Duke L.J. at 1361. Companies that do not "fall in line" may soon find themselves defending an enforcement action based upon a supposed obligation not found in statute or regulation, *Appalachian Power Co.*, 208 F.3d at 1023, or may be forced to wait under "the risk of prosecution at an uncertain point in the future," *CSI Aviation Servs.*, 637 F.3d at 412.

Unquestioning compliance, on the other hand, may be deeply problematic. Even when the obligation at issue has no basis in the statute, and thus is entirely unlawful, many businesses may undertake extraordinary efforts to comply with the obligation in an abundance of caution. Compliance efforts may require businesses to devote substantial resources to revise their business practices and operations,

leading to potential disruptions in areas such as production and customer service, as well as decreased profits. Moreover, despite the high resource and financial costs of revising business practices to accommodate a questionable agency interpretation, "[t]he agency may try to have it both ways—that is, to hold affected parties to the standards set in the enforcement policy, but deny the document a role as a safe harbor." Anthony, *supra*, 41 Duke L.J. at 1340. Similarly, the agency may reverse course after costly implementation takes place. After all, "such bureaucratic pirouetting" is commonplace even where an agency *is* constrained by rulemaking procedures, *Guedes v. Bureau of Alcohol, Tobacco, Firearms and Explosives*, 140 S. Ct. 789, 791 (2020) (statement of Gorsuch, J.)—let alone where an agency skirts rulemaking procedures. In short, the agency's use of informal procedure, coupled with a reservation of discretion, "affords the agency scope for unpredictable behavior, without diminishing the prospective compliance burden on the private party." Anthony, *supra*, 41 Duke L.J. at 1361.

These problems are compounded further where an agency elects to enforce an obligation not contained in any statute or regulation. Such actions may seek crushing amounts in damages, fines, or penalties—pressuring companies to seek protective settlements even where enforcement is unlawful. Companies know that even though their practices may comply with the best reading of a statute or regulation, the agency may assert in litigation an aggressive claim to judicial deference. *See, e.g.*, Kent

Barnette & Christopher Walker, Chevron *in the Circuit Courts*, 116 Mich. L. Rev. 1, 6 (2017) (finding that, as an empirical matter, "agency interpretations were significantly more likely to prevail under *Chevron* deference (77.4%) than . . . de novo review (38.5%)"). And even where they are likely to prevail, companies may conclude that litigating against the Government is such an expensive and time-consuming process that a quick settlement is preferred.

The resulting skew often creates law by consent decree, insulating the Government's interpretations of statutes and regulations from judicial scrutiny and making it more difficult for other parties, who may not always be privy to settlement terms, to understand the agency's view of their legal obligations. *See generally* William L. Kovacs et al., U.S. Chamber of Commerce, *Sue and Settle Updated: Damage Done 2013-2016* (2017), https://www.uschamber.com/sites/default/files/u.s._chamber_sue_and_settle_2017_updated_report.pdf. Indeed, agencies often issue press releases touting settlements achieving large sums and "voluntary" compliance with conditions the agency may lack authority to impose through regulations. Settlement conditions that are "non-germane" to the purported violation may resemble "an out-and-out plan of extortion." *See Competitive Enter. Inst. v. FCC*, 970 F.3d 372, 388 (D.C. Cir. 2020) (quoting *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987)).

These tactics have become so common that in some industries "the legal center of gravity now consists of a body of settlement agreements" rather than traditional, textual sources of law. Turk, *supra*, 66 U. Kan. L. Rev. at 292; *see also* William Yeatman, *Executive Lawmaking in EPA-Justice Department-Volkswagen Settlement*, Notice & Comment (Oct. 1, 2016), http://yalejreg.com/nc/executive-lawmaking-in-epa-justice-department-volkswagen-settlement-by-william-yeatman/. "Time and again," agencies have used regulatory settlements "on a systematic scale to indirectly promulgate novel legal standards and thereby reshape" entire industries in a manner that could never be sustained through regulation. Turk, *supra*, 66 U. Kan. L. Rev. at 292.

Companies that try to get ahead of these *in terrorem* tactics by bringing pre-enforcement challenges are often met with familiar agency tactics. The agency may pivot and claim that regulated entities should not regard its non-legislative pronouncements as binding. *See Appalachian Power Co.*, 208 F.3d at 1021 ("EPA claims . . . that the Guidance is a policy statement, rather than an interpretative rule, and is not binding.").

Then, the agency may erect hurdles to judicial review, asserting that the controversy is not "ripe" or that its position is not "final." The courts, of course, are rightly skeptical of these tactics, and litigants may be able to obtain review by showing that challenged action is for all practical purposes final and treated by the

agency as binding. *See, e.g.*, *Sackett v. EPA*, 566 U.S. 120, 126–27 (2012) (rejecting EPA's argument that compliance order was not "final"); *Texas v. EEOC*, 933 F.3d 433, 440–46 (5th Cir. 2019) (rejecting EEOC's argument that binding guidance on employer use of criminal records was nonfinal); *Ipsen Biopharmaceuticals, Inc. v. Azar*, 943 F.3d 953, 954, 959 (D.C. Cir. 2019) (rejecting HHS's argument that letter interpreting manufacturer drug reporting requirements in Social Security Act was nonfinal); *Appalachian Power Co.*, 208 F.3d at 1020–23 (rejecting EPA's argument that guidance interpreting Clean Air Act was nonbinding). *But see Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1263, 1267–69 (D.C. Cir. 2018) (agreeing with FTC that staff letter interpreting Telemarketing and Consumer Fraud and Abuse Prevention Act was nonfinal).

But as this case demonstrates, getting to court for clarity can require navigating a maze of procedural obstacles even though Congress sought to ensure that judicial review would be readily available when agencies impose substantive obligations. In some cases, companies lack the resources to run the gauntlet of protracted fights about reviewability and may be cowed by unlawful government action—especially in controversial areas. In addition, review can be difficult to obtain where, as in this case, an agency adopts a statutory interpretation based on scattered, informal letters and PowerPoint presentations that cannot be easily

challenged under the APA's cause of action. ROA.21 (Compl. ¶ 12); ROA.53 (Compl. ¶¶ 125–26); ROA.64 (Compl. ¶ 166).

II. When Agencies Blur The Distinction Between Binding Legislative Rules And Non-Binding Interpretations, The Declaratory Judgment Act Provides An Appropriate Remedy.

Where an agency treats its interpretation of a statute or regulation as authoritative and threatens in any form to pursue enforcement on the basis of that interpretation, the Declaratory Judgment Act provides an appropriate remedy. Indeed, it is well settled that "where threatened action by *government* is concerned," the Declaratory Judgment Act authorizes the object of the threat to "bring[ ] suit to challenge the basis for the threat." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128–29 (2007); *see also, e.g.*, *Steffel v. Thompson*, 415 U.S. 452 (1974); *Abbott Laboratories*, 387 U.S. at 148, 152–53. This is a vital safety valve for private parties to obtain review of a disputed question of law where the impacts on private conduct are manifest and immediate.

In the court below, however, the Government sought to resist this well-established route by claiming that only "the APA or the federal Constitution" could provide Wal-Mart with a "cause of action" and that those did not apply here. ROA.569. But that is as convenient as it is mistaken. Wal-Mart alleged that the Government threatened prosecution under the Controlled Substances Act. Because the Declaratory Judgment Act permits a declaratory plaintiff to "bring 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), Wal-Mart's cause of action "arises under" the Controlled Substances Act, *Medtronic, Inc. v. Mirowski Fam. Ventures, LLC*, 571 U.S. 191, 198 (2014). Given the Government's "genuine threat of enforcement," Wal-Mart was not required to "expose [it]self to liability before bringing suit to challenge the basis for the threat." *MedImmune, Inc.*, 549 U.S. at 129.

At least two other Circuits have recognized that a declaratory suit is appropriate where the Government threatens prosecution under the Controlled Substances Act. *See Monson v. DEA*, 589 F.3d 952 (8th Cir. 2009); *New Hampshire Hemp Council, Inc. v. Marshall*, 203 F.3d 1 (1st Cir. 2000). In both cases, the DEA threatened to prosecute farmers based on its view that industrial hemp was captured by the Controlled Substances Act's definition of "marijuana," and in both cases the courts recognized that the farmers' claims were reviewable over DEA's opposition. As the First Circuit explained, the DEA's "emphatic position"—which was expressed through the DEA's enforcement "conduct in New Hampshire and elsewhere" and not through any rule or formal guidance—called out for judicial review "not because there is anything wrong with the agency expressing its view but because, that view having been expressed, *there ought to be a way to resolve the legal correctness of its position without subjecting an honest businessman to*

criminal penalties." *New Hampshire Hemp Council, Inc.*, 203 F.3d at 5 (emphasis added).

The First Circuit's recognition of this fundamental need for review of disputed agency interpretations with harsh real-world effects underscores why the Declaratory Judgment Act is an important tool in curbing agency abuse when agencies treat non-legislative interpretations as binding and threaten enforcement on that basis. The threat of enforcement and the unavailability of pre-enforcement judicial review "would reasonably prompt a regulated industry, unwilling to risk substantial penalties by defying the statute, to undertake costly compliance measures or forego a line of business." *NRA v. Magaw*, 132 F.3d 272, 287 (1997). This has deleterious effects on our economy and can create socially and economically harmful outcomes, especially when a reviewing court ultimately would have vindicated the conduct and position of affected companies. Section I.B., *supra*.

The Declaratory Judgment Act provides a critical way for companies in this position to obtain review and relieve themselves "from the Damoclean threat of impending litigation which [the Government] might brandish, while initiating suit at [its] leisure—or never." 10B Charles Alan Wright & Arthur R. Miller et al., *Federal Practice & Procedure* § 2751 (4th ed. supp. 2021) (internal quotation marks omitted). Meanwhile, in that class of cases where the Government's position might

prevail, the Declaratory Judgment Act serves the salutary purpose of permitting these "actual controversies to be settled before they ripen into violations of law." *Id.*

Without the ability to bring a Declaratory Judgment Act action, regulated entities that cannot obtain APA review (but disagree with an agency interpretation of a statute or regulation) must either refuse to comply with agency demands, at the risk of substantial penalty if proven wrong during a subsequent enforcement action, or they must give up their rights and comply with agency demands. That dilemma—which "put[s] the challenger to the choice between abandoning his rights or risking prosecution—is 'a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.'" *MedImmune, Inc.*, 549 U.S. at 129 (quoting *Abbott Laboratories*, 387 U.S. at 152).

III. The Sovereign Immunity Of The United States Does Not Bar Federal Courts From Providing Prospective Declaratory And Injunctive Relief.

In this case, the district court denied Wal-Mart's request for pre-enforcement review of the Government's action on the ground of sovereign immunity. That was error, and this Court should reverse so that federal administrative agencies do not abuse the rights of businesses in this Circuit with impunity.

It is axiomatic that, "[a]bsent a waiver, sovereign immunity shields the Federal Government and its agencies from suit." *Dep't of Army v. Blue Fox, Inc.*,

525 U.S. 255, 260 (1999) (internal quotation marks omitted). In 1976, Congress adopted such a waiver by amending the APA to provide 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.

5 U.S.C. § 702; *see* Pub.L. 94–574, 90 Stat. 2721, 94th Cong., 2d Sess. (1976).

The weight of judicial and academic authority recognizes that "the 'APA's waiver of sovereign immunity applies to any suit whether under the APA or not.'" *Trudeau v. FTC*, 456 F.3d 178, 186 (D.C. Cir. 2006) (per Garland, J.) (quoting *Chamber of Commerce*, 74 F.3d at 1328); *accord Presbyterian Church (U.S.A.) v. United States*, 870 F.2d 518, 525 (9th Cir. 1989); *Red Lake Band of Chippewa Indians v. Barlow*, 846 F.2d 474, 476 (8th Cir.1988); *see also, e.g.*, Richard H. Fallon Jr. et al., *Hart and Weschler's the Federal Courts and the Federal System* 865 (6th ed. 2009) ("Though codified in the APA, the waiver applied to any suit, whether or not brought under the APA."); 14 Wright & Miller § 3659 ("[T]he APA . . . waiver of immunity applies . . . even when review is not available under the APA itself."). That is because "[t]here is nothing in the language of the second sentence of § 702 that restricts its waiver to suits brought under the APA" or to those that involve "agency action." *Trudeau*, 456 F.3d at 186–87.

The district court recognized that this Court has reached a somewhat different conclusion. Under this Court's precedents, "sovereign immunity is not waived by § 702 unless there has been 'agency action,' as that term is defined in § 551(13)." *Doe v. United States*, 853 F.3d 792, 799 (5th Cir. 2017). For this "agency action" though, there is "no requirement of 'finality'"—that is, of "final agency action" within the meaning of 5 U.S.C. § 704—where, as here, "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." *Alabama-Coushatta Tribe of Texas v. United States*, 757 F.3d 484, 489 (5th Cir. 2014). Accordingly, the district court erred when it held that a "threat to sue" or "intent to sue" is not "agency action" subject to the APA's immunity waiver. ROA.603–04.

Wal-Mart explains the reasons why. The APA defines "agency action" broadly to include "the whole or [a] part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." *Alabama-Coushatta Tribe*, 757 F.3d at 489 (quoting 5 U.S.C. § 551(13)). Clear and repeated enforcement threats—of the type set forth in the Complaint in this case—are a "sanction" for these purposes, and thus agency action, because they effect a "prohibition, requirement, limitation, or other condition affecting the freedom of a person," or reflect "other compulsory or restrictive action." 5 U.S.C. § 551(10). Such threats also constitute a "rule" where, as here, the threats are "designed to

implement, interpret, or prescribe law or policy" with "future effect." 5 U.S.C. § 551(4). Wal-Mart Br. 28–41; *see also Ciba-Geigy Corp. v. EPA*, 801 F.2d 430 (D.C. Cir. 1986) (holding review appropriate where the agency had "provided its final word on the matter '[s]hort of an enforcement action'").

Wal-Mart's position is also confirmed by the long tradition of federal courts granting injunctive relief to restrain state or federal officers "who are violating, *or planning to violate*, federal law," where, as here, the officers are named as defendants. *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326–27 (2015) (emphasis added); *cf. Danos v. Jones*, 652 F.3d 577, 583 (5th Cir. 2011). In these cases, courts determine either that immunity is waived by Section 702, or that "there is no sovereign immunity to waive" because "it never attached in the first place." *Chamber of Commerce*, 74 F.3d at 1329 (enjoining enforcement of executive order that would implement Procurement Act in conflict with the National Labor Relations Act); *cf. Ex Parte Young*, 209 U.S. 123 (1908) (enjoining state attorney general from instituting suit in conflict with Fourteenth Amendment). The message "is clear": "courts will 'ordinarily presume that Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command.'" *Chamber of Commerce*, 74 F.3d at 1328 (quoting *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 681 (1986)).

If this Court were to affirm the district court's erroneous conclusion that a threat to sue is not agency action, the Declaratory Judgment Act will be stripped of its protective utility, and the Federal Government will be free in this Circuit to use threats of enforcement to abridge the rights of businesses with impunity, create new law without process, and obtain compliance with agency positions neither set forth in statute nor in binding legislative rules adopted pursuant to the APA. This Court should reverse.

CONCLUSION

For all these reasons, this Court should reverse the judgment of the district court and remand for a judgment on the merits.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 17, 2021, I caused the foregoing to be served upon all counsel of record via the Clerk of Court's CM/ECF notification system.

/s/ *Megan L. Brown*
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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 5,512 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). *See* Fed. R. App. P. 29(a)(4)(G), (a)(5).

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word for Windows, version 10 in Times New Roman font 14-point type face.

Dated: May 17, 2021

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