

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

WALMART INC.,
Plaintiff,

v.

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

Defendants.

Civil Action No. 4:20-cv-00817-SDJ

**BRIEF OF *AMICI CURIAE* OF THE CHAMBER OF COMMERCE OF THE
UNITED STATES OF AMERICA, THE WASHINGTON LEGAL FOUNDATION, THE
NATIONAL RETAIL FEDERATION, AND THE RETAIL LITIGATION CENTER, INC.
IN SUPPORT OF PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

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Other Authorities

Clyde Wayne Crews, Jr., Ten Thousand Commandments, 2018 Edition,
 Competitive Enterprise Institute (2018),
https://cei.org/sites/default/files/Ten_Thousand_Commandments_2018.pdf3

Database of Environmental Settlements Between 1/20/2009 and 1/29/2017,
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DOJ, Justice Manual, § 1-20.100, <https://www.justice.gov/jm/1-20000-limitation-use-guidance-documents-litigation#1-20.100>.....12

Heritage Explains: Overcriminalization, Heritage Foundation,
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U.S. Chamber of Commerce, *Sue and Settle: Damage Done 2013–2016* (May 2017),
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U.S. Chamber of Commerce, *Sue and Settle: Regulating Behind Closed Doors*, at 7 (2013),
<https://www.uschamber.com/sites/default/files/documents/files/SUEANDSETTLEREPORT-Final.pdf>14

INTRODUCTION AND INTERESTS OF AMICI CURIAE¹

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.

Washington Legal Foundation (“WLF”) is a public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as *amicus curiae* to oppose civil liability unmoored from any statute or regulation. *See, e.g., Domino’s Pizza, LLC v. Robles*, 140 S. Ct. 122 (2019); *Merck & Co. v. U.S. Dep’t of Health & Human Servs.*, 962 F.3d 531 (D.C. Cir. 2020).

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.

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

¹ *Amici curiae* state that no party’s counsel authored this brief in whole or in part, no party or party’s counsel contributed money intended to fund preparing or submitting this brief, and no person other than *amici curiae*, their members, or their counsel contributed money intended to fund preparing or submitting this brief.

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 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.

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.

When trying to regulate the private sector, federal agencies have increasingly avoided notice and comment procedures under the Administrative Procedure Act (“APA”). Rather than use the APA’s procedures—which were developed to provide regulated entities with notice and an adequate opportunity to comment before the imposition of new substantive rules of conduct—agencies increasingly issue *de facto* regulations in the guise of interpretive guidance.

Predicating civil liability on interpretive guidance created without a transparent regulatory process goes against the requirements of the APA and due process and, here, violates binding regulations issued by the Department of Justice (“DOJ”). The Chamber, WLF, NRF, and RLC have an interest in seeing that agencies respect administrative law principles, stop unlawfully enforcing non-binding guidance, and operate consistently with due process and the rule of law.

BACKGROUND

Free enterprise depends on a stable and predictable regulatory environment, in which businesses can operate and invest without unwittingly running afoul of the law.

In the modern administrative state, the scope of regulation makes compliance difficult in the best of circumstances. The “growth of the Executive Branch, 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), has led to thousands of regulations from myriad agencies. Mandates range from ensuring food safety and regulating battery transportation, to preventing money laundering and imposing export controls. Regulations touch employment, scientific research, securities offerings, marketing, accounting, supply chains, and more. Many statutes and regulations provide agencies with the discretion to seek substantial civil and criminal penalties. It has been estimated that “nearly 5,000 federal statutes and more than 300,000 regulations contain potential criminal penalties,”² though it is impossible to provide a full accounting.

Given the high stakes of this enforcement environment, companies build compliance programs to keep pace. Some estimate annual regulatory compliance costs at nearly \$2 trillion. *See* CEI, *Ten Thousand Commandments* (2018).³ Federal Register public notices “normally exceed 24,000 annually, including uncounted guidance documents and other proclamations with potential regulatory effect,” *id.* at 5. The tracking of obligations is a herculean task. *See PDR Network, LLC v. Carlton & Harris Chiropractic, Inc.*, 139 S. Ct. 2051, 2061–62 (2019) (Kavanaugh, J., concurring) (“[I]t ‘is totally unrealistic to assume that more than a fraction of the persons and entities affected by a regulation—especially small contractors scattered across the country—would have knowledge of its promulgation or familiarity with or access to the Federal

² *Heritage Explains: Overcriminalization*, Heritage Foundation, <https://www.heritage.org/crime-and-justice/heritage-explains/overcriminalization> (last visited Nov. 24, 2020).

³ Clyde Wayne Crews, Jr., *Ten Thousand Commandments, 2018 Edition*, Competitive Enterprise Institute at 3 (2018), https://cei.org/sites/default/files/Ten_Thousand_Commandments_2018.pdf.

Register.’’)) (quoting *Adamo Wrecking Co. v. United States*, 434 U.S. 275, 290 (1978) (Powell, J., concurring)).

Compliance programs are frustrated, not furthered, when agencies enforce subregulatory guidance, created without notice, as if it were binding law. When burdensome obligations stem from loose policymaking, even businesses with robust compliance programs are left guessing. Facing potentially crushing liability, many companies acquiesce and settle, seeming to validate the subregulatory guidance and encouraging further aggrandizement by government. This is why courts demand that agencies observe basic procedural requirements and fundamental fairness in the creation, interpretation, and enforcement of substantive obligations on regulated entities.

This is a case where a company did not acquiesce and has not settled. This gives the Court an all-too-rare opportunity to stop the otherwise inexorable trend toward regulation by post-hoc enforcement.

ARGUMENT

I. CORE ADMINISTRATIVE LAW PRINCIPLES EMPHASIZE PREDICTABILITY AND FAIRNESS IN REGULATORY ENFORCEMENT.

Only “legislative rules” “issued through the notice-and-comment process . . . 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)). Nonlegislative rules, by contrast, are issued without notice-and-comment and “do not have the force and effect of law.” *Perez*, 575 U.S. at 97 (internal quotation marks omitted); *see* 5 U.S.C. § 553(b)(A). Where an agency attempts to enforce interpretive policy created without notice and comment, “it must be prepared to support the policy just as if the policy statement had never been issued.” *Nat’l Min. Ass’n v. McCarthy*,

758 F.3d 243, 253 (D.C. Cir. 2014) (Kavanaugh, J.) (quoting *Pacific Gas & Elec. Co. v. Fed. Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974)).

A. Agencies' Power to Regulate Private Conduct Exists Only as Authorized by Congress and May Be Exercised Only in a Manner Consistent with the APA.

In our constitutional structure, the power to make laws is vested in the Congress and the power to administer those laws is vested in the Executive Branch. Where Congress authorizes the Executive Branch to “fill” the “gaps” in the application of broad statutes, *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 165 (2007), the Executive may do so only through the “procedural requirements imposed by Congress . . . in the APA,” *Chrysler Corp.*, 441 U.S. 281, 303 (1979); *see also id.* at 302 (“the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes”). Those procedures arise from due process concerns and are intended to ensure that binding regulations are promulgated in a manner that affords “public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies.” *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044 (D.C. Cir. 1987) (citations, internal quotations, and alterations omitted).

For example, the APA requires agencies to engage in “reasoned decisionmaking.” *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983); *see Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (“One of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions.”). And the courts require an agency to explain the bases for its actions. *See e.g., Texas v. EPA*, 829 F.3d 405, 425 (5th Cir. 2016); *United States v. Garner*, 767 F.2d 104, 118 (5th Cir. 1985). These requirements apply whether the agency proceeds through formal or informal rulemaking (or adjudication). *See U.S. Postal Serv. v. Postal Regul. Comm'n*, 785 F.3d 740, 755

(D.C. Cir. 2015) (under the APA, “it does not matter whether it is a formal or informal adjudication or a formal or informal rulemaking proceeding—all are subject to arbitrary and capricious review[.]”) (citation omitted)).

Where an agency seeks to “impose *legally binding* obligations or prohibitions on regulated parties,” the agency must also comply with certain procedural requirements. *Nat’l Min. Ass’n*, 758 F.3d at 251 (emphasis added). To promulgate “legislative rules,” for example, an agency must provide the public with notice and opportunity to comment on the proposal. *See* 5 U.S.C. § 553; *Chrysler Corp.*, 441 U.S. at 301–03 (“In order for a regulation to have the ‘force and effect of law,’ it must have certain substantive characteristics and be the product of certain procedural requisites.”).

Notice and comment procedures are “[h]ardly trivial,” *Texas v. EPA*, 389 F. Supp. 3d 497, 503 (S.D. Tex. 2019). These “requirements assist in the substantive formation of a rule by ensuring ‘that the broadest base of information [is] provided to the agency by those most interested and perhaps best informed on the subject of the rulemaking at hand.’” *Id.* at 503–04 (quoting *Phillips Petroleum Co. v. Johnson*, 22 F.3d 616, 620 (5th Cir. 1994)). The Fifth Circuit recognizes that “the vast majority of agency rulemaking, which produces nuanced and detailed regulations[,] greatly benefit[s] from expert and regulated entity participation.” *Dialysis Patient Citizens v. Burwell*, No. 4:17-CV-16, 2017 WL 365271, at *5 (E.D. Tex. Jan. 25, 2017) (citing *United States v. Johnson*, 632 F.3d 912, 932 (5th Cir. 2011)).

Enforcing compliance with such procedures is critical “to assure[] that the agency will have before it the facts and information relevant to a particular administrative problem, as well as suggestions for alternative solutions.” *Am. Hosp. Ass’n*, 834 F.2d at 1044; *Make The Rd. New York v. Wolf*, 962 F.3d 612, 634 (D.C. Cir. 2020) (a “central purpose of notice-and-

comment rulemaking is to subject agency decisionmaking to public input and to obligate the agency to consider and respond to the material comments and concerns that are voiced.”). This “gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision.” *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019) (citing 1 K. Hickman & R. Pierce, *Administrative Law* § 4.8 (6th ed. 2019)).

Notice and comment is particularly important in the “consideration of rules having a substantial impact on those regulated.” *City of Arlington, Tex. v. FCC*, 668 F.3d 229, 245 (5th Cir. 2012) (“The process allows the agency to educate itself before adopting a final order.”), *aff’d*, 569 U.S. 290 (2013). As Judge Posner observed, “[t]he greater the public interest in a rule, the greater reason to allow the public to participate in its formation.” *Hoctor v. U.S. Dep’t of Agric.*, 82 F.3d 165, 171 (7th Cir. 1996). Agency rules can impose sweeping changes to the national economy and entire industries, in policy areas as varied and important as the environment, consumer protection, financial services, and health care. These areas are tremendously complex and implicate a web of stakeholders, including state governments and multiple components of the federal government,⁴ which should have the chance to weigh in on significant changes to their rights and responsibilities.

⁴ For example, the DEA policies here implicate federal and state regulation of complex nationwide pharmaceutical dispensing practices. States have responsibility for licensing and regulating pharmacists and the Department of Health and Human Services, Department of Veterans Affairs, and other federal agencies may have an interest in the issues addressed by DEA’s interpretive rule. Policy changes will affect incentives, costs, and responsibilities for an enormous amount of economic activity and the daily interactions of Americans with care providers. Tradeoffs remain subject to debate among state and federal policymakers, economists, and medical professionals, among others looking to promote novel solutions to a perceived public health crisis.

Even with the best intentions, many aspects of regulated industries are not appreciated by regulators until they receive comments during the notice and comment process. Indeed, agencies will often modify their proposed regulations in response to comments they receive from stakeholders. For example, in finalizing a rule in 2016, the DEA “modified” “the regulatory text accompanying” a proposed Administration Controlled Substances Code Number after a commenter flagged an ambiguity in how the “new drug code w[ould] be applicable” to certain substances. 81 Fed. Reg. 90,194, 90,195 (Dec. 14, 2016); *see also* 85 Fed. Reg. 68,450, 68,455 (Oct. 29, 2020) (“appreciat[ing]” a commenter for “noting [an] inconsistency” between a regulatory definition and the statutory text, and accordingly “revis[ing] the definition” in the final rule). By creating new obligations without notice and comment, agencies cut off this vital input, depriving policymakers of the ability to balance competing interests and evidence, and all but ensuring errors or unintended consequences. *See also* Stephen G. Breyer et al., *Administrative Law and Regulatory Policy* 519 (7th ed. 2011) (“The purpose of the [notice and comment] procedure is to enlighten the decisionmaker by exposure to the viewpoints of interested persons, and to enable those persons to have a say.”).

By contrast, where the agency simply wishes to inform the public of its policy views or clarify how it interprets a statute or regulation, the APA permits the agency to dispense with notice-and-comment rulemaking. *See* 5 U.S.C. § 553(b)(A). Critically, these nonlegislative, “interpretive rules . . . do not have the force and effect of law and are not accorded that weight in the adjudicatory process[.]” *Perez*, 575 U.S. at 97 (citation and internal quotations omitted); *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001); *see also Nat’l Min. Ass’n*, 758 F.3d at 251–52 (finding agency action to be an interpretive rule because “[a]s a legal matter,” it was “meaningless” and “impose[d] no obligations or prohibitions on regulated entities”). Indeed, an “action based on a violation of

an interpretive rule does not state a legal claim. 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) (internal quotations omitted) (quoting *Drake v. Honeywell, Inc.*, 797 F.2d 603, 607 (8th Cir. 1986)).

B. Agencies May Not Evade the Requirements of the APA by Using Subregulatory Guidance to Regulate Private Behavior.

Agencies cannot evade notice-and-comment rulemaking by relying on the use of subregulatory guidance to yoke the private sector. Of course, it is not improper, and may be desirable sometimes for an agency to inform the private sector of the agency’s thinking on an issue. But an agency may not—consistent with the APA—use “guidance” to impose substantive, binding regulations on which it then predicates enforcement proceedings to impose civil (or criminal) liability. *See Perez*, 575 U.S. at 97; *Chrysler Corp.*, 441 U.S. at 302–03.

That enforcing agencies might prefer the expedience of bypassing notice-and-comment-rulemaking is beside the point. Impatience does not meet the high standard for dispensing with them under the APA.⁵ The Fifth Circuit “reads the good cause exception narrowly ‘to avoid providing agencies with an ‘escape clause’ from the requirements Congress prescribed.”” *Dialysis Patient Citizens*, 2017 WL 365271, at *4 (quoting *Garner*, 767 F.2d at 120); *see also Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015) (“The ‘APA’s notice and comment exemptions must be narrowly construed.”” (citations omitted)), *aff’d United States v. Texas*, 136 S. Ct. 2271

⁵ By relying on informal guidance, agencies also may seek to avoid requirements imposed by Congress to subject rules to scrutiny and further control, including the Paperwork Reduction Act (44 U.S.C. §§ 3501-3520), the Regulatory Flexibility Act (5 U.S.C. §§ 601-612), and the Congressional Review Act (5 U.S.C. §§ 801-808). Indeed, by conjuring new obligations through guidance and subsequent enforcement, agencies may prevent Congress from reviewing their innovations.

(per curiam); 5 U.S.C. §§ 553, 706(2)(D) (The court must set aside agency action made “without observance of procedure required by law.”). And, as the Fifth Circuit recently held, “[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) (citation omitted).

Texas v. United States illustrates the problem. There, the court enjoined an agency’s purported “policy statement” where it was “applied by the agency in a way that indicate[d] it [wa]s binding[.]” 809 F.3d at 170–76 (5th Cir. 2015) (citation and internal quotations omitted). Specifically, the court concluded that the so-called “policy statement” impacted enforcement decisions and contained “specific instructions for granting or denying” agency action. *Id.* at 174–75. Because the policy statement did not fit the APA’s interpretive rule exception, it was enjoined for failure to comply with the APA’s notice-and-comment requirement. *See id.* at 178, 188; *see also Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 946–49 (D.C. Cir. 1987) (per curiam) (finding unlawful purported policy statements that were in fact procedurally invalid legislative rules because they described specific requirements that the agency treated as binding).

The key point is this: “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, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency’s document is for all practical purposes ‘binding.’” *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020–21. Through such an interpretation, the agency “has given the [regulated] their ‘marching orders’ and . . . expects [them]

to fall in line.” *See id.* at 1023 (quoting *Natural Res. Defense Council, Inc. v. Thomas*, 845 F.2d 1088, 1094 (D.C. Cir. 1988)).

This is anathema to our constitutional system and the rule of law. “A fundamental principle in our legal system is 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) (citations omitted). Although agencies with rulemaking authority may enjoy the power to issue certain “marching orders,” any such power may be exercised only through the lawful procedures of the APA.

C. DOJ Regulations Confirm that Its Components May Not Use Subregulatory Guidance as the Basis for Enforcement Actions.

Consistent with these principles, DOJ has clarified that use of subregulatory guidance as the basis of an enforcement action is impermissible. Recognizing the importance of regulatory predictability to sound policy and fair enforcement, DOJ recently ordered in the Justice Manual a prohibition upon the use of non-binding, subregulatory guidance as the basis for enforcement actions. As a component agency within DOJ, DEA is subject to these regulations.

DOJ began this clarification in a 2017 memorandum from the Attorney General instructing DOJ components that, “[e]ffective immediately,” they could “not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch[.]”⁶ In early 2018, the Associate Attorney General issued a memorandum to DOJ litigators

⁶ Memorandum For All Components re Prohibition on Improper Guidance Documents, Office of the Attorney General, at 1 (Nov. 16, 2017), <https://www.justice.gov/opa/press-release/file/1012271/download>.

to confirm that DOJ was prohibited from “us[ing] its enforcement authority to effectively convert agency guidance documents into binding rules.”⁷

DOJ cemented these principles in its Justice Manual, explaining that “[c]riminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies[.]”⁸ DOJ also promulgated final rules to restrict its own use of subregulatory guidance. *See* Prohibition on the Issuance of Improper Guidance Documents Within the Justice Department, Interim Final Rule and Request For Comments, 85 Fed. Reg. 50,951 (Aug. 19, 2020) (codified at 28 C.F.R. Part 50); Processes and Procedures for Issuance and Use of Guidance Documents, Interim Final Rule and Request For Comments, 85 Fed. Reg. 63,200 (Oct. 7, 2020) (codified at 28 C.F.R. Part 50). Echoing longstanding judicial constructions of the APA and fair notice requirements, these rules provide that “[c]riminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation.” 28 C.F.R. § 50.27(b)(1).

DOJ’s *own rules* confirm that reliance upon subregulatory guidance in enforcement is improper. Doing so—in violation of DOJ regulations—creates *de facto* rules with the force of law contrary to the APA, principles of due process, and fundamental fairness.

⁷ Memorandum for the Heads of Civil Litigating Components and United States Attorneys, Office of the Associate Attorney General at 2 (Jan. 25, 2018), <https://www.justice.gov/file/1028756/download>.

⁸ DOJ, Justice Manual, § 1-20.100, <https://www.justice.gov/jm/1-20000-limitation-use-guidance-documents-litigation#1-20.100>.

II. ENFORCEMENT OF SUBREGULATORY GUIDANCE PROLIFERATES UNCERTAINTY AND CREATES NEW LAW WITHOUT PROCESS.

If courts do not rein in agencies' enforcement of subregulatory guidance, the regulated community will be left guessing whether it is bound by such guidance. This puts the regulated community in an untenable position on two fronts.

First, the regulated community must decide whether to implement costly compliance measures or take at face value agency representations that "guidance" is indeed guidance. Experience justifies wariness about agency representations. *See Appalachian Power Co.*, 208 F.3d at 1020–21, 23 (observing that disclaimers of enforceability are "a charade, intended to keep the proceduralizing courts at bay") (quoting Robert A. Anthony, *Interpretative Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 Duke L.J. 1311, 1361 (1992); Peter L. Strauss, Comment, *The Rulemaking Continuum*, 41 Duke L.J. 1463, 1485 (1992)). At the same time, it is hard to justify a shift in compliance where obligations are unclear, particularly if a regulated entity disagrees with an agency's informal opinion.

Second, if an agency seeks to enforce subregulatory guidance, the regulated entity may have little recourse and faces a quandary. It can refuse to comply and face substantial penalties (the agency will likely claim that guidance is unreviewable and entitled to deference).⁹ Or, it can settle at substantial cost and comply, transmogrifying guidance into law. Enforcing obligations hitherto undiscovered in the statute or regulations on pain of billions of dollars in damages encourages settlements, creating law by consent decree and insulating the government's

⁹ Although agencies may claim deference for subregulatory guidance, such claims are erroneous. *See Nat'l Min. Ass'n*, 758 F.3d at 251–52; *Bussian v. RJR Nabisco, Inc.*, 223 F.3d 286, 297 (5th Cir. 2000).

interpretations from judicial scrutiny. At times, the government’s demands for results it cannot obtain through regulation resemble “an out-and-out plan of extortion.” *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)). Regulation by settlement lets agencies direct “national policy out of the light of public scrutiny and the procedural safeguards of the Administrative Procedure Act.”¹⁰ “Time and again, regulatory settlements have been used on a systematic scale to indirectly promulgate novel legal standards and thereby reshape” entire industries. See Matthew C. Turk, *Regulation by Settlement*, 66 U. Kan. L. Rev. 259, 292 (2017).

Knowing this, agencies can use uncertainty about guidance coupled with enormous liability as a cudgel to extract settlements regardless of the merit of the guidance. If a party sues to challenge the agency’s approach, the agency will insist that there has not yet been enforcement and that its findings are non-final, insulated from judicial review. This is a familiar modus operandi for the government, about which courts are rightly skeptical. See e.g., *Sackett v. EPA*, 566 U.S. 120 (2012) (rejecting United States’ argument that EPA compliance order was not subject to judicial review in pre-enforcement challenge); *Texas v. EEOC*, 933 F.3d 433 (5th Cir. 2019) (rejecting United States’ argument that EEOC guidance on employers’ use of criminal records was not reviewable); *Ipsen Biopharmaceuticals, Inc. v. Azar*, 943 F.3d 953, 954 (D.C. Cir. 2019) (rejecting United States’ argument that Centers for Medicare and Medicaid Services’ interpretation of the Social Security Act in letter to manufacturer on drug reporting requirements was nonfinal

¹⁰ U.S. Chamber of Commerce, *Sue and Settle: Regulating Behind Closed Doors*, at 7 (2013), <https://www.uschamber.com/sites/default/files/documents/files/SUEANDSETTLEREPORT-Final.pdf>; see U.S. Chamber of Commerce, *Sue and Settle: Damage Done 2013–2016* (May 2017), https://www.uschamber.com/sites/default/files/u.s._chamber_sue_and_settle_2017_updated_report.pdf.

and not reviewable); *Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023 (D.C. Cir. 2016) (rejecting United States' argument that Fair Labor Standards Act violation notification letters were nonfinal and unreviewable). Although in rare cases, parties may risk financial ruin to challenge these tactics, many are cowed into settling.¹¹ Regulated entities may be particularly vulnerable to *in terrorem* tactics in highly politicized environments, such as the vital debate about the opioid-abuse epidemic.

Whatever the government's rationale for avoiding compliance with the APA's procedures, the public interest requires courts to reject abusive tactics. There is "no public interest in the perpetuation of unlawful agency action. To the contrary, there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (citation and quotation omitted); *see also Damus v. Nielsen*, 313 F. Supp. 3d 317, 342 (D.D.C. 2018) ("The public interest is served when administrative agencies comply with their obligations under the APA."). Enforcing compliance with the APA helps ensure that regulatory obligations are clear and transparent. This Court should not condone agency tactics that subvert the requirements of the APA.

CONCLUSION

The Court should grant Walmart's motion for partial summary judgment.

¹¹ *See* Database of Environmental Settlements Between 1/20/2009 and 1/29/2017, https://www.uschamber.com/sites/default/files/doj_enrd_foia_on_caa_cwa_esa_settlements_data_base.pdf (documenting hundreds of settlements obtained via Freedom of Information Act request).

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document has been served via the Court's CM/ECF system on November 30, 2020, to all counsel of record.

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