# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA

Plaintiff,

v.

WALMART INC. AND WAL-MART STORES EAST, LP, C.A. No. 20-1744-CFC

Defendants.

# BRIEF OF AMICI CURIAE OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE NATIONAL RETAIL FEDERATION, AND THE WASHINGTON LEGAL FOUNDATION IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE COMPLAINT

Daryl Joseffer Michael B. Schon

U.S. CHAMBER LITIGATION CENTER 1615 H Street, NW Washington, DC 20062 (202) 463-5337

Stephanie A. Martz NATIONAL RETAIL FEDERATION 1101 New York Avenue, NW Suite 1200 Washington, DC 20005

Cory L. Andrews John M. Masslon II

WASHINGTON LEGAL FOUNDATION 2009 Massachusetts Avenue, NW Washington, DC 20036 (202) 588-0302 Christopher Kelly (DE Bar No. 2754) Megan L. Brown Stephen J. Obermeier Wesley E. Weeks

WILEY REIN LLP 1776 K Street, NW Washington, DC 20006 (202) 719-7000 ckelly@wiley.law

Counsel for Amici Curiae

# **TABLE OF CONTENTS**

I.	INTE	EREST	S OF AMICI CURIAE1		
II.	SUMMARY OF THE ARGUMENT				
III.	ARGUMENT				
	A.	DOJ's "Collective Knowledge" Theory Runs Counter to Traditional Principles of Agency and Scienter			
		1.	Knowledge cannot be imputed from principal to agent5		
		2.	Even if knowledge could be imputed to a company's agent, scienter must be shown in a specific employee and cannot be imputed under any circumstances		
		3.	These core principles have been applied in numerous contexts to reject a "collective" approach to scienter7		
	В.		s Collective Scienter Theory Threatens to Harm American ness and the Public		

# **TABLE OF AUTHORITIES**

# Cases

<i>In re Alpharma Inc. Sec. Litig.</i> , 372 F.3d 137 (3d Cir. 2004)4,5,7
<i>In re Apple Computs., Inc.</i> , 127 F. App'x 296 (9th Cir. 2005)
<i>In re Cerner Corp. Sec. Litig.</i> , 425 F.3d 1079 (8th Cir. 2005)13
<i>Chaney v. Dreyfus Serv. Corp.</i> , 595 F.3d 219 (5th Cir. 2010)6
<i>Ezra Charitable Tr. v. Tyco Int'l Ltd.</i> , 466 F.3d 1 (1st Cir. 2006)
<i>FCC v. Fox Television Stations, Inc.</i> , 567 U.S. 239 (2012)
<i>First Equity Corp. v. Standard &amp; Poor's Corp.</i> , 690 F. Supp. 256 (S.D.N.Y. 1988)
<i>Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.</i> , 561 U.S. 477 (2010)
<i>Garfield v. NDC Health Corp.</i> , 466 F.3d 1255 (11th Cir. 2006)
U.S. ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908 (4th Cir. 2003)9
<i>Higgins v. Shenango Pottery Co.</i> , 256 F.2d 504 (3d Cir. 1958)
<i>Kushner v. Beverly Enters., Inc.,</i> 317 F.3d 820 (8th Cir. 2003)
<i>Lilley v. Charren</i> , 17 F. App'x 603 (9th Cir. 2001)13

<i>Mizzaro v. Home Depot, Inc.</i> , 544 F.3d 1230 (11th Cir. 2008)6
<i>Nat'l Mining Ass'n v. McCarthy</i> , 758 F.3d 243 (D.C. Cir. 2014)16
<i>New York Times Co. v. Sullivan</i> , 376 U.S. 254 (1964)9
<i>Nolte v. Capital One Fin. Corp.</i> , 390 F.3d 311 (4th Cir. 2004)
PDR Network, LLC v. Carlton & Harris Chiropractic, Inc., 139 S. Ct. 2051 (2019)11, 12
<i>In re Radian Sec. Litig.</i> , 612 F. Supp. 2d 594 (E.D. Pa. 2009)
Saba v. Compagnie Nationale Air France, 78 F.3d 664 (D.C. Cir. 1996)7
Southland Sec. Corp. v. Inspire Ins. Sols., Inc., 365 F.3d 353 (5th Cir. 2004)
<i>Staub v. Proctor Hosp.</i> , 562 U.S. 411 (2011)6
Suez Equity Inv., L.P. v. Toronto-Dominion Bank, 250 F.3d 87 (2d Cir. 2001)
<i>United States v. Harra</i> , 985 F.3d 196 (3d Cir. 2021)15
United States v. Philip Morris USA Inc., 566 F.3d 1095 (D.C. Cir. 2009)6
United States v. Sci. Applications Int'l Corp., 626 F.3d 1257 (D.C. Cir. 2010)
<i>Woodmont, Inc. v. Daniels</i> , 274 F.2d 132 (10th Cir. 1959)6

# Statutes

21 U.S.C. § 821	
Other Authorities	
21 C.F.R. § 1301.74(b)	
28 C.F.R. § 0.100(b)	
Restatement (Second) of Agency § 275 (Am. L. Inst. 1958)	5, 6, 7

#### I. INTERESTS OF AMICI CURIAE<sup>1</sup>

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents an underlying membership of more than three million businesses and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of concern to the Nation's business community.

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.

Washington Legal Foundation ("WLF") is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise,

<sup>&</sup>lt;sup>1</sup> *Amici curiae* state that no party's counsel authored this brief in whole or in part and no one other than *amici curiae*, their members, or their counsel contributed money intended to fund preparing or submitting this brief.

individual rights, limited government, and the rule of law. It often appears as *amicus curiae* to oppose penalizing individuals and businesses who lack sufficient knowledge of wrongdoing. And WLF's Legal Studies division, the publishing arm of WLF, regularly publishes scholarly articles on the importance of scienter.

Courts have generally rejected "collective knowledge" theories of scienter, under which pieces of information known to different employees are combined to impute scienter—a subjective mental state. *Amici* have a strong interest in defending this traditional rule because the proper standard for corporate scienter is critical under myriad statutes and regulatory programs.

#### II. SUMMARY OF THE ARGUMENT

This case seeks to hold a company responsible for the acts of its employees in filling allegedly improper prescriptions without any allegation that the employees who filled the prescription possessed knowledge of irregularities in the prescriptions. Under the "collective scienter" approach that the Department of Justice ("DOJ") seeks to apply, a corporation can be found to "knowingly" violate a regulation if one employee, acting in good faith, makes a report of information to a compliance department, and another employee—however distant from the first—fills a prescription without knowing the reported information. This transparent attempt to sidestep DOJ's burden of showing that someone in a company "knowingly" violated the law is improper.

2

At its core, DOJ's collective approach to scienter is inconsistent with common law principles regarding agency and intent. While it is sometimes permissible to impute an agent's knowledge to the principal, no principle of law allows the reverse. Nor is it ever permissible to impute intent (as opposed to knowledge).

DOJ's approach is not only wrong; it will have deeply troubling, far-reaching effects. It runs the risk of dampening incentives for companies to invest in robust compliance programs. If DOJ uses a company's own findings as a repository of information that it then imputes to all employees as if they are part of an interconnected "hive" mind, it will effectively transform laws requiring scienter into strict liability regimes. This Court should reject DOJ's "collective scienter" approach and enforce the traditional requirement that DOJ must allege that a particular person knowingly violated the law.

#### III. ARGUMENT

## A. DOJ's "Collective Knowledge" Theory Runs Counter to Traditional Principles of Agency and Scienter.

While this appears to be the first case in which DOJ has tested its "collective knowledge" theory under the Controlled Substances Act ("CSA"), the Government is not writing on a blank slate. Courts, including the Third Circuit, have rejected this approach in a variety of contexts. As Walmart notes in its brief, "in seeking to establish corporate liability, the Government cannot rely on the mental states of disparate employees who played no role in the transaction or conduct in question."

Op. Br. in Sup. of Mot. to Dismiss (ECF No. 27) at 7 (summarizing case law on corporate scienter).

Consistent with these principles, the Third Circuit has rejected attempts by plaintiffs to use collective knowledge allegations to meet scienter requirements in the securities context. In a complaint with parallels to DOJ's filing in this case, the plaintiffs in the Alpharma Securities Litigation alleged, in part, that "Alpharma's New Jersey headquarters was alerted to the violation of the company's revenue recognition policy by employees" and therefore the scienter requirement was met because the individual defendants "had access to this information." In re Alpharma Inc. Sec. Litig., 372F.3d137, 150–51 (3d Cir. 2004).<sup>2</sup> The Court rejected the attempt to impute knowledge and intent to defendant executives, based on reports by an employee of suspected irregularities; "[T]he mere fact that the information was sent to Alpharma's headquarters and therefore was available for review by the individual defendants is insufficient" to "giv[e] rise to a strong inference that [defendants] acted with the required state of mind." Id. (noting that the complaint did not allege "that the allegations of improper accounting were ever passed up the chain of command" to defendants).

<sup>&</sup>lt;sup>2</sup>*In re Alpharma Securities Litigation* has since been abrogated because then-Judge Alito and his colleagues on the Third Circuit applied a too lenient standard to plaintiffs' allegations under the PSLRA. *See In re Radian Sec. Litig.*, 612 F. Supp. 2d 594, 607 (E.D. Pa. 2009).

Though *In re Alpharma Securities Litigation* involved the heightened pleading standard applicable to securities fraud, the logic of the decision does not turn on that heightened standard. The Third Circuit described the allegation that information would have been known to defendants as "wholly conclusory" and "tenuous," *id.*, which would not satisfy the pleading standard under Rule 12(b)(6). Moreover, as explained below, the Third Circuit's approach to collective knowledge in *In re Alpharma Securities Litigation* is consistent with traditional principles of agency law and scienter that apply in a wide variety of legal contexts—not just securities law. These principles apply here.

## 1. Knowledge cannot be imputed from principal to agent.

A corporation acts only through its agents. Thus, a "corporation can be held to have a particular state of mind only when that state of mind is possessed by a single individual." *First Equity Corp. v. Standard & Poor's Corp.*, 690 F. Supp. 256, 260 (S.D.N.Y. 1988) (Mukasey, J.). And in certain defined circumstances, under principles of agency law, an agent's knowledge can be imputed to the agent's principal. *See Higgins v. Shenango Pottery Co.*, 256 F.2d 504, 509 (3d Cir. 1958); Restatement (Second) of Agency § 275 (1958).

But this is not what DOJ alleges. The complaint alleges that pharmacists employed by Walmart informed Walmart's compliance department of suspicious activity. Compl. (ECF No. 1)¶142. Turning the traditional agency paradigm on its head, DOJ seeks to take the information reported by one agent to the compliance department and then impute that report *from the principal to yet another agent*. That is a bridge too far—no principle of law allows a court to impute knowledge from an individual to a company and then back to other individual employees. And for good reason. There is no mosaic theory of corporate scienter.

# 2. Even if knowledge could be imputed to a company's agent, scienter must be shown in a specific employee and cannot be imputed under any circumstances.

While an agent's *knowledge* may sometimes be imputed to the principal, courts hold that scienter—the employee's subjective state of mind—cannot be imputed.<sup>3</sup> As the Supreme Court noted in *Staub v. Proctor Hospital*, "[t]he Restatement of Agency suggests that the malicious mental state of one agent cannot generally be combined with the harmful action of another agent to hold the principal liable." 562 U.S. 411, 418 (2011); *see also* Restatement (Second) of Agency § 275,

<sup>&</sup>lt;sup>3</sup> See, e.g., Chaney v. Dreyfus Serv. Corp., 595 F.3d 219, 241 (5th Cir. 2010) ("as a general rule, where 'an essentially subjective state of mind is an element of a cause of action' we have declined to allow this element to be met by a corporation's collective knowledge, instead requiring that the state of mind 'actually exist' in at least one individual and not be imputed on the basis of general principles of agency."); United States v. Philip Morris USA Inc., 566 F.3d 1095, 1122 (D.C. Cir. 2009) (distinguishing "collective knowledge" from "collective intent" and questioning the latter's "legal soundness"); United States v. Sci. Applications Int'l Corp., 626 F.3d 2357, 1274 (D.C. Cir. 2010) ("collective knowledge provides an inappropriate basis for proof of scienter") (quotation omitted); Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1254 (11th Cir. 2008) (looking to mental states of individual officials); Woodmont, Inc. v. Daniels, 274 F.2d 132, 137 (10th Cir. 1959) (rejecting "composite knowledge" where state of mind was "essential").

cmt.b (1958) ("*Knowledge distinguished from reason to know*. If knowledge, as distinguished from reason to know, is the important element in a transaction, and the agent who has the knowledge is not one acting for the principal in the transaction, the principal is not affected by the fact that the agent has the knowledge.").<sup>4</sup>

Thus, even cases that allow for "corporate knowledge of certain facts [to be] accumulated from the knowledge of various individuals" acknowledge that "proscribed intent (willfulness) depend[s] on the wrongful intent of specific employees." *Saba v. Compagnie Nationale Air France*, 78 F.3d 664, 670 n.6 (D.C. Cir. 1996) (emphasis added). This Court should not permit DOJ to proceed on a theory that sidesteps the requirement that it properly allege and prove scienter by making general allegations about the information known to a corporate compliance department rather than specific employees who filled the allegedly irregular prescriptions.

# 3. These core principles have been applied in numerous contexts to reject a "collective" approach to scienter.

The burden to establish scienter in a particular person has been vindicated across many statutes and regulatory programs. Like the Third Circuit's decision in *In re Alpharma Securities Litigation*, courts have rejected imputed scienter in the

<sup>&</sup>lt;sup>4</sup> "In many situations, in order for one to be responsible, it is necessary that the act should be done with knowledge in a subjective sense, and it is not sufficient that one has means of information." Restatement (Second) of Agency § 275, cmt.b.

context of securities and corporate fraud. As the Ninth Circuit explained, a "corporation is deemed to have the requisite scienter for fraud only if the individual corporate officer making the statement has the requisite level of scienter at the time that he or she makes the statement." *In re Apple Computers, Inc.*, 127 F. App'x 296, 303 (9th Cir. 2005) (citing *Nordstrom, Inc. v. Chubb & Son, Inc.*, 54 F.3d 1424, 1435-36 (9th Cir. 1995)). Thus, to survive a motion to dismiss, securities plaintiffs must allege that a specific individual acted with knowledge and bad intent.<sup>5</sup>

Similarly, "under the [False Claims Act], 'collective knowledge' provides an inappropriate basis for proof of scienter." *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010). Thus, a False Claims Act plaintiff may not "prove scienter by piecing together scraps of 'innocent' knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government

<sup>&</sup>lt;sup>5</sup> See, e.g., Suez Equity Invest., L.P. v. Toronto-Dominion Bank, 250 F.3d 87, 100 (2d Cir. 2001) (dismissing claims where "[n]othing in the complaint suggests that [a named officer] or anyone else at [the parent corporation] knew the contents of the [report]."); Southland Sec. Corp. v. Inspire Ins. Solutions, Inc., 365 F.3d 353, 366-67 (5th Cir. 2004) ("It is appropriate to look to the state of mind of the individual corporate official or officials who make or issue the statement."); Kushner v. Beverly Enterprise, Inc., 317 F.3d 820, 827–30 (8th Cir. 2003); Garfield v. NDC Health Corp., 466 F.3d 1255, 1263-67 (11th Cir. 2006); Ezra Charitable Trust v. Tyco Int'l Ltd., 466 F.3d 1, 5-11 (1st Cir. 2006); Nolte v. Capital One Fin. Corp., 390 F.3d 311, 313–16 (4th Cir. 2004).

funds." U.S. ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 918, n.9 (4th Cir. 2003).

Even in the different context of defamation, plaintiffs must show the publisher's knowledge and scienter (there, actual malice) and cannot just aggregate knowledge and intent. For example, the "mere presence of the stories in the files [of the New York Times] does not, of course, establish that the Times 'knew' the advertisement was false, since the state of mind required for actual malice would have to be brought home to the persons in the Times' organization having responsibility for the publication of the advertisement." *New York Times Co. v. Sullivan*, 376 U.S. 254, 287 (1964).

These principles governing agency and scienter are universal and apply here. The Court should reject DOJ's novel collective knowledge theory.

## B. DOJ's Collective Scienter Theory Threatens to Harm American Business and the Public

DOJ's novel approach seeks to sidestep the scienter requirement by aggregating the knowledge and intent of all company employees. However righteous its goals may seem in a particular case, this theory risks causing serious harm to American business and to the public.

*First*, it will undermine the use of compliance programs that are of critical importance to employees, vendors, and customers. It is unquestionably desirable for companies to comply with their obligations under the law. It may be desirable for

companies to go beyond legal obligations; hence the trend toward proactive compliance and some companies' decisions to implement varied Environmental, Social, and Governance (ESG) programs. Compliance can be particularly complex for large multinationals that want to oversee and respond to the activities of hundreds of thousands of employees; they may deploy innovative tools, flexible databases, and machine learning to identify trends, problem areas, and new challenges.<sup>6</sup> Information aggregation across large organizations can be a huge benefit, but DOJ's collective knowledge and scienter approach would turn those programs into treasure troves of evidence, observations, or data that could be used against the organization.

DOJ's approach may reduce incentives to invest in compliance and information gathering efforts. By turning organizations' robust compliance programs against them, DOJ punishes companies who acted without any intent to violate the law instead of promoting creative and aggressive compliance programs.

In the modern administrative state, voluntary compliance is an important objective. 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.* 

<sup>6</sup> See, e.g., Price Waterhouse Coopers, Machine learning: what every risk and compliance professional needs to know, <u>https://www.pwc.com/us/en/services/consulting/cybersecurity-privacy-forensics/library/machine-learning-risk-compliance.html</u> (last visited Mar. 3, 2021); David Ackerman, AI Compliance Oversight is Here... and So Are Next-Gen Compliance Officers (November 24, 2020), <u>https://www.corporatecomplianceinsights.com/ai-compliance-oversight-next-gen-compliance-officers/</u>(last visited Mar. 3, 2021).

*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 allow agencies 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,"<sup>7</sup> though it is impossible to provide a full accounting.

Given the high stakes of the enforcement environment and the complexities of the various enforcement regimes, companies voluntarily make substantial investments to build robust compliance programs just to keep pace. *See* Clyde Wayne Crews, Jr., CEI, Ten Thousand Commandments at 3 (2018) (stating that some estimate annual regulatory compliance costs at nearly \$2 trillion).<sup>8</sup> Indeed, Federal Register public notices "normally exceed 24,000 annually, including uncounted guidance documents and other proclamations with potential regulatory effect," *id.* at 5, making the tracking of obligations is a herculean task. *See PDR* 

<sup>&</sup>lt;sup>7</sup> *Heritage Explains: Overcriminalization*, Heritage Foundation, <u>https://www.heritage.org/crime-and-justice/heritage-explains/overcriminalization</u> (last visited March 3, 2021).

<sup>&</sup>lt;sup>8</sup> Available at <u>https://cei.org/sites/default/files/Ten\_Thousand\_Commandments\_2018.pdf</u>.

*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 Register.") (quoting Adamo Wrecking Co. v. United States, 434 U.S. 275, 290 (1978) (Powell, J., concurring)). And importantly, most regulators offer credit to companies for such voluntary programs. *See* U.S. Department of Justice, Criminal Division, *Evaluation of Corporate Compliance Programs* at 6, 15 (June 2020) (stating that credit can be awarded for proactive compliance programs).<sup>9</sup>

But proactive compliance programs may be frustrated if DOJ can turn them into weapons against companies that voluntarily establish them. Under DOJ's approach, bits of knowledge from across a large organization that may be reported to a corporate compliance department can be stitched together with perfect hindsight to try to show corporate knowledge and intent. Here, DOJ's theory is that a prescription can be "knowingly" filled in violation of the CSA without a single individual behaving dishonestly, so long as another employee flagged a concern to corporate compliance. This runs contrary to the traditional rule that a "corporation

<sup>&</sup>lt;sup>9</sup>Available at https://www.justice.gov/criminal-fraud/page/file/937501/download.

can be held to have a particular state of mind only when that state of mind is possessed by a single individual." *First Equity Corp.*, 690 F. Supp. at 260.

DOJ's theory thus exposes companies to staggering liability—even where no one, identifiable employee knowingly engaged in any wrongdoing. This massive shift in liability risk all but destroys the incentive to invest in proactive compliance programs. If compliance department logs of reported information trigger strict liability for regulatory violations related to the reported information, encouraging broad reporting and investing in proactive compliance will become tantamount to creating potential evidence against the company. The court should not depart from the traditional rule rejecting collective scienter.

*Second*, the Government's approach inappropriately invites litigants to treat each employee's individual opinions and judgment calls as determinative of an entire company's knowledge and intent. As courts have recognized, however, there are often differences of opinion in a large company. As the Ninth Circuit explained in rejecting corporate scienter based on the doubts of "lower level employees," "in any large corporation there will be differences of opinion expressed." *Lilley v. Charren*, 17 F. App'x 603, 607 (9th Cir. 2001). The Eighth Circuit likewise rejected the theory that sales forecasts were fraudulent because a single regional sales manager had stated that the forecasts were "unattainable." *In re Cerner Corp. Sec. Litig.*, 425 F.3d 1079, 1085-86 (8th Cir. 2005). And the Fourth Circuit likewise refused to entertain liability based on an allegation that corporate management did not believe in the adequacy of financial reserves because one executive had expressed doubts. *Nolte*, 390 F.3d at 315.

In any large company, the collective scienter theory would "allow[] 'a plaintiff to prove scienter by piecing together scraps of 'innocent' knowledge held by various corporate officials," as well as "thousands of ordinary employees." *Sci. Applications Int'l Corp.*, 626 F.3d at 1273–76. Allowing DOJ to proceed on its "collective" approach to scienter would transform internal differences of opinion into a basis for liability where the company diverts from the most cautious or pessimistic employee's opinion—even where the opinion is unjustified.

The implications of DOJ's theory would be profound, from securities disclosures to environmental compliance to ethics to government contracting, and more. Whatever an employee thinks is problematic could be transformed into the company's position, knowledge, and scienter. This not only interferes with a company's supervision and control of its workers; it risks harming the public. Here, for example, if an employee reported so-called "red flags" about a prescriber, but a more experienced pharmacist determined that the prescription was legitimate, it appears not to matter. Under DOJ's approach, the result could be that a patient's legitimate prescription would go unfilled.

Finally, DOJ's novel approach to liability based on information reported to corporate compliance programs should be imposed, if at all, through appropriate regulations that let the agency and stakeholders weigh costs and benefits in particular settings. For example, the Drug Enforcement Administration ("DEA") administers the CSA and has been granted rulemaking authority. See 21 U.S.C. § 821 (granting the Attorney General rulemaking authority under the CSA); 28 C.F.R. § 0.100(b) (delegating the Attorney General's authority to the Administrator of DEA). Thus, if DEA wishes to require registered entities to establish compliance departments to track suspicious prescriptions and then alert all pharmacists within the company to the reported information, it could try to impose that requirement as an exercise of its regulatory power. DEA has created a compliance tracking and reporting requirement for the distribution of controlled substances, but not dispensing them.<sup>10</sup> See 21 C.F.R. § 1301.74(b) (distributors must maintain "system" to identify "suspicious orders" and "inform" DEA).

It is black letter law that "an agency must have clearly communicated its policies before a private party may be sanctioned . . . for violating them." *United States v. Harra*, 985 F.3d 196, 213 (3d Cir. 2021); *FCC v. Fox Television Stations*,

<sup>&</sup>lt;sup>10</sup> The CSA distinguishes between distribution of controlled substances (e.g., shipping large quantities to pharmacies) and dispensing, which is the act of filling a prescription or administering a controlled substance. DEA's reporting and tracking regulations only apply to distribution, not to dispensing.

*Inc.*, 567 U.S. 239, 253 (2012) (citations omitted) ("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."). Where an agency wants to "impose legally binding obligations or prohibitions on regulated parties," the agency must comply with procedural requirements, including the notice and comment requirement of the Administrative Procedures Act. *Nat'l Mining Ass'nv. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). DEA has not subjected any such dispensing compliance programs to public comment.

Businesses that face liability for alleged 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. For these reasons, this Court should reject DOJ's attempt to use a collective approach to corporate scienter and enforce the traditional rule requiring the Government to prove that a specific, identified individual violated the law with knowing intent. Dated: March 3, 2021

Daryl Joseffer Michael B. Schon

U.S. CHAMBER LITIGATION CENTER 1615 H Street, NW Washington, DC 20062 (202) 463-5337

Stephanie A. Martz NATIONAL RETAIL FEDERATION 1101 New York Avenue, NW Suite 1200 Washington, DC 20005

Cory L. Andrews John M. Masslon II WASHINGTON LEGAL FOUNDATION 2009 Massachusetts Avenue, NW Washington, DC 20036 (202) 588-0302 Respectfully submitted,

<u>/s/ Christopher Kelly</u> Christopher Kelly (DE Bar No. 2754) Megan L. Brown Stephen J. Obermeier Wesley E. Weeks

WILEY REIN LLP 1776 K Street, NW Washington, DC 20006 (202) 719-7000 ckelly@wiley.law

Counsel for Amici Curiae

## **CERTIFICATION OF COMPLIANCE**

The undersigned hereby certifies that the foregoing contains 3,781 words in Times New Roman 14-point font, counted using Microsoft Word's word count feature. While the local rules do not address *amicus* briefs, the United States asked *Amici* to agree to limit their brief to half the length of Walmart's brieffiled in support of its motion to dismiss and *Amici* have complied with that limitation.

/s/ Christopher Kelly

Christopher Kelly (DE Bar No. 2754)