

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

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WALMART INC.,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 4:20-cv-00817-SDJ
	)	
U.S. DRUG ENFORCEMENT ADMINISTRATION;	)	
ACTING ADMINISTRATOR TIMOTHY J. SHEA;	)	
U.S. DEPARTMENT OF JUSTICE;	)	
ATTORNEY GENERAL WILLIAM P. BARR,	)	
	)	
Defendants.	)	

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**BRIEF OF *AMICUS CURIAE* ASSOCIATION OF AMERICAN PHYSICIANS &  
SURGEONS IN SUPPORT OF PLAINTIFF AND IN SUPPORT OF ITS MOTION FOR  
PARTIAL SUMMARY JUDGMENT**

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## IDENTITY, INTEREST AND AUTHORITY TO FILE<sup>1</sup>

*Amicus curiae* Association of American Physicians & Surgeons (“AAPS”) is a non-profit association of physicians founded in 1943, whose motto is “omnia pro aegroto” (meaning “all for the patient”). AAPS defends the patient-physician relationship against interference in the private practice of ethical medicine.

Over its 77-year history, AAPS has brought several precedent-setting lawsuits, including *AAPS v. Hillary Clinton*, 997 F.2d 898 (D.C. Cir. 1993), and *AAPS v. Weinberger*, 395 F. Supp. 125 (N.D. Ill.), *aff’d sub nom.*, *AAPS v. Mathews*, 423 U.S. 975 (1975), and amicus briefs by AAPS have been cited by Supreme Court Justices and multiple U.S. Courts of Appeals. *See, e.g.*, *Stenberg v. Carhart*, 530 U.S. 914, 933 (2000); *id.* at 959, 963 (Kennedy, J., dissenting); *District of Columbia v. Heller*, 554 U.S. 570, 704 (2008) (Breyer, J., dissenting); *Texas v. United States*, 945 F.3d 355, 369 (5th Cir. 2019); *Springer v. Henry*, 435 F.3d 268, 271 (3d Cir. 2006).

More than a year ago, on March 25, 2019, our then-President Marilyn Singleton, M.D., J.D., submitted comments to the U.S. Department of Health and Human Services (“HHS”) which objected to “robotic, top-down policies” that harm patients by interfering with prescriptions for the treatment of pain. Letter by Dr. Singleton to Vanila M. Singh, MD, MACM Chief Medical Officer Office of the Assistant Secretary for Health in HHS (“Letter by Dr. Singleton”).<sup>2</sup> About two months later, reflecting the deep commitment by AAPS to this issue on behalf of our physician members and their patients, our then-President-Elect Kristin Held, M.D., delivered

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<sup>1</sup> *Amicus* files this brief with the consent of Plaintiff Walmart, and without opposition by Defendants. Consistent with FED. R. APP. P. 29(c)(5), the undersigned counsel certifies that: counsel for the *amicus* authored this brief in whole; no counsel for a party authored this brief in any respect; and no person or entity – other than *amicus*, its members, and its counsel – contributed monetarily to this brief’s preparation or submission.

<sup>2</sup> <https://beta.regulations.gov/comment/HHS-OS-2018-0027-3426> (viewed 12/4/20).

similar comments to the federal Pain Management Best Practices Inter-Agency Task Force, in response to its Final Report during the “Roundtable Discussion on Dissemination Activities with External Stakeholders” in Washington, D.C.<sup>3</sup> AAPS has extensive experience concerning the patient-physician relationship and the need for pharmacists to fill individualized prescriptions by physicians without interference caused by profiling, “red flag,” or top-down federal agency programs. Simply put, *amicus* AAPS has many physician members who depend on the timely, affordable filling of their prescriptions by Walmart and other pharmacies.

*Amicus* AAPS therefore has a valid stake in opposing “red flag” interference by the Defendants, the Drug Enforcement Administration and the Department of Justice, with pharmacy compliance on individualized prescriptions for approved medications. AAPS thereby has direct and vital interests in the issues presented here, and submits its amicus brief on this basis.

### SUMMARY OF ARGUMENT

The practice of private, ethical medicine depends heavily on the prompt filling of physicians’ prescriptions by pharmacists without second-guessing, delays, or bureaucratic red tape. The practices of medicine and pharmacy are fields that are traditionally within the exclusive jurisdiction of the States, and one-size-fits-all or “top-down” interference by federal agencies in medical care is neither beneficial nor authorized by Congress. A complicated system of “red flag” burdens which, for example, impedes filling a prescription for a patient seeking to pay cash for it is a recipe for disaster for many physicians and patients alike. Physicians and particularly their patients would be the ones harmed most if Defendants succeed in interfering

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<sup>3</sup> Letter by Kristin Story Held, M.D., to Vanila M. Singh, MD, MACM Chief Medical Officer Office of the Assistant Secretary for Health U.S. Department of Health and Human Services (May 10, 2019), <https://aapsonline.org/aaps-supports-emphasis-on-individualized-patient-care-in-report-of-pain-management-task-force/> (viewed 12/4/20).

with the filling of prescriptions based on a profiling-like “red flag” approach as sought by distant regulators located in Washington, D.C., who are unfamiliar with the practice of rural medicine. Access to affordable medical care requires that pharmacists be free of suffocating federal burdens which were never authorized by Congress, such as a requiring a laundry list of cross-checking before filling a prescription.

In essence, Defendants’ monitoring program circumvents important due process safeguards by forcing pharmacists to blacklist physicians and refuse to fill prescriptions based on arbitrary criteria such as payment by cash or geographic distance. This interferes with rights of patients and physicians, but they receive no notice of it and are given no opportunity to object. Defendants thereby cut off the air supply of patients and physicians, who may not even have legal standing to challenge this harm to them. If prosecutors were to prevent the accused from using certain licensed defense attorneys, the resultant unconstitutional infringement on rights would be self-evident. Likewise, Defendants’ back-door attempt to cut off the lifeblood of the practice of medicine – by coercing pharmacists not to fill prescriptions – would have the effect of depriving patients and physicians of basic rights without due process. Congress has not and would not confer such authority on Defendants to shake down Walmart by imposing draconian penalties without proof of knowledge of any wrongdoing, and Defendants unjustifiably grab for themselves power to punish without demonstrating scienter.

The facts in this case exemplify the administrative state running amok and trammeling traditional rights within the exclusive jurisdiction of the States. Defendants seek to federalize violations of state law, such that a violation of an unworkable state law which may never be enforced somehow becomes a federal law violation to justify levying draconian federal fines.

This Court should flatly reject Defendants' unauthorized, costly encroachment on a field within the exclusive domain of Texas and other States.

## ARGUMENT

### I. Defendants' "Red Flag," One-Size-Fits-All Approach Violates Due Process Rights of Physicians and Patients to their Detriment, and Penalties Should Not Be Imposed Without Proof of Scienter.

*Amicus* AAPS has a membership that includes physicians in small, often rural, practices. These physicians have particularly strong relationships with their patients, and greater experience than non-physicians to understand the patients' medical needs. Physicians are in a far better position to decide the proper medication for a patient, without second-guessing by pharmacists as caused by their fear of being subjected to fines by Defendants. Pharmacists do not examine patients. Nor do they spend equivalent time evaluating the needs of a patient who seeks to fill a valid prescription. Defendants should not be insisting that pharmacies be penalized unless they profile patients in some kind of one-size-fits-all approach to medical care.

As Marilyn Singleton, M.D., J.D., submitted as President of AAPS in comments to HHS in March 2019:

[T]oo often the unintended consequences created by past robotic, top-down policies resulted in harm to patients. Past policies incentivized the use of opioids even when they might not be in the best interest of patients. Now, the current shift to deterrence is improperly punishing pain patients and those trying to care for them.

Letter by Dr. Singleton, *supra*, at 1. AAPS supported the view taken then by HHS that "individualized, patient-centered care is vital to addressing the public health pain crisis." *Id.* But that is not the approach taken by Defendants now as they pursue through litigation their "robotic, top-down" policy that AAPS and others have properly criticized. Patients are individuals with individual needs, and it is a mistake to subject them to collectivist-style profiling in order to obstruct the filling of their prescriptions. In purely legal terms, it is a denial of patients' due



process rights and those of their physicians for Defendants to deny access to medication in this roundabout way of targeting honest pharmacies rather than wrongdoers.

Unless Walmart prevails on its motion for partial summary judgment, Defendants will prevent pharmacists from filling prescriptions by physicians based on the blacklisting of certain physicians and the use of cash by patients, without due process to physicians and patients. Defendants should not be allowed to do an end run through litigation to evade such due process.

**A. The Unauthorized “Red Flag” Program by Defendants Violates Due Process.**

A physician has due process rights against revocation of his medical license, and patients have a due process right against arbitrary interference by the government with access to ethical medical care. Yet Defendants’ approach bypasses these due process safeguards by litigating against pharmacies, without providing any opportunity to physicians and patients to defend their rights. A medical license loses value if pharmacies refuse to fill the physician’s prescriptions based on litigation against the pharmacies by Defendants. Similarly, cash as property of an individual loses value if he cannot use the cash to purchase medication to alleviate his suffering.

Patients of AAPS physicians include uninsured, underinsured, and insured who sometimes prefer to pay cash. Privacy is one obvious reason to pay cash. Avoiding the time-consuming red tape of insurance, and simply being in a hurry or forgetting one’s insurance card are additional reasons. Not all insurance plans pay for prescriptions filled at all pharmacies, and it may be more efficient simply to pay cash than to try to find out what is covered and what is not, and where. Regulations under the Hitech Act even require most entities to accept cash if requested. Philip Eskew, “Exercising Patient Rights under the HITECH Act,” 24 *Journal of American Physicians and Surgeons* 50, 52 (2019).<sup>4</sup> Paying cash may be less than a “co-pay”.

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<sup>4</sup> <https://jpands.org/vol24no2/eskew.pdf> (viewed 12/6/20).

In an infringement on basic rights, Defendants would punish pharmacies that accept cash from patients for medication which might be covered by insurance. *See* Walmart’s Motion for Partial Summary Judgment (“Walmart Mot.”) at 5; Complaint ¶ 41, *United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207-FL (E.D.N.C.) (filed Oct. 30, 2020, “Seashore Complaint”) (“Red Flag No. 8: Cash Payments”). Pharmacies have no way of knowing whether the insurance plan which a patient has may or may not pay for a particular medication, or whether the patient is current in his premium payments to that insurance plan, or whether the patient has legitimate reasons such as privacy or convenience for paying cash. Many pharmacies might simply refuse to accept cash from *any* patient rather than run the risk of taking cash and being investigated and fined by Defendants for doing so. In Washington, D.C., restaurants and retailers increasingly refused to accept cash until the D.C. Council recently passed an ordinance prohibiting “no cash” policies, because no-cash policies harm many people. Fenit Nirappil, “D.C. Council votes to outlaw cashless stores, allow some prisoners to seek early release,” *THE WASHINGTON POST* (Dec. 2, 2020) (“San Francisco, New York City and Philadelphia have [also] recently started requiring retailers to take cash payments, as do the states of New Jersey and Massachusetts”).<sup>5</sup>

The interference by Defendants, based in D.C., with cash payments for medications outside of the Beltway is both ironic and lacking in due process for those wanting to pay or receive cash for legitimate transactions. *See* Lawrence H. White, “The Curse of the War on Cash,” *CATO JOURNAL* (Spring/Summer 2018) (“Coercive efforts to suppress cash deprive honest people of the ability to use their preferred method of payment.”).<sup>6</sup> It is pure fiction that banning or disfavoring cash transactions for medications would reduce overall crime, as the use

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<sup>5</sup> <https://www.msn.com/en-us/news/us/d-c-council-votes-to-outlaw-cashless-stores-allow-some-prisoners-to-seek-early-release/ar-BB1bxrOI> (viewed 12/5/20).

<sup>6</sup> <https://www.cato.org/cato-journal/springsummer-2018/curse-war-cash> (viewed 11/26/20).

of cash thwarts other types of crimes such as stolen accounts and identity theft. Cash transactions are therefore preferred by many people to protect their privacy and security:

Although advocates of a cashless society laud crime prevention as one of the significant benefits, the increase in cashless transactions in recent years has also ushered in increased levels of identity theft and cybercrime. In 2017 alone, more than 1,500 data breaches occurred compromising more than 170 million records, including approximately 14 million credit card numbers. As recently as November 2018, Marriott International disclosed that a guest reservation database had been breached, affecting as many as 500 million guests. In September 2018, Facebook announced that roughly 90 million user accounts had been compromised by hackers. In December 2017, online auction platform eBay announced that a privacy leak resulted in personal information of many customers being made publicly available – in some cases customers’ real names were listed alongside their sensitive purchases such as pregnancy, drug, and HIV testing kits.

Tamara Kurtzman, “Cashing Out,” 42 Los Angeles Lawyer 22, 26 (March 2019).

Similarly, traveling long distances for goods or services is common in rural America, and AAPS member physicians have patients who travel substantial distances both to obtain medical care and purchase medication. In rural and western parts of the United States there is nothing suspicious about a patient to driving a long distance for preferred medical care or medication from a favored pharmacy. Colorado’s third congressional district, for example, is the size of the entire state of Pennsylvania,<sup>7</sup> and political campaigners would inevitably purchase legitimate medication far from home in that district. Categorizing geographical distance as a red flag, as Defendants attempt to do, would improperly chill and deter many legitimate, beneficial prescriptions. *See* Seashore Complaint ¶ 33.

Defendants’ attempt to have pharmacies blacklist physicians such that *all* their controlled substance prescriptions are rejected, not merely suspect ones, is likewise improper and a violation of the physicians’ due process rights. *See* Walmart’s Mot. at 19. Many physicians

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<sup>7</sup> <https://nsjonline.com/article/2020/11/republican-lauren-boebert-wins-bitter-colorado-house-race/> (viewed 12/5/20).

would be destroyed, and their patients denied medical care, if the physicians were blacklisted by pharmacies such that *none* of their controlled substance prescriptions are filled. It is unclear what, if any, legal recourse such physicians would have against such a blacklisting. State medical boards regulate medicine, and due process protects physicians against unfair actions taken by the State against their license. But physicians have no due process means to protect themselves and their patients against pharmacies refusing to fill their prescriptions out of fear of Defendants suing the pharmacies.

Pharmacies, like any business, strive out of necessity to keep their costs low in order to stay open, and Defendants' demand for complicated monitoring would result in many pharmacies simply refusing to fill legitimate prescriptions by good physicians rather than incur the substantial costs and risks associated with Defendants' monitoring program. Defendants have not sought or obtained input by groups such as AAPS before imposing red flags, which lack the protections of notice-and-comment style regulation. Defendants should limit themselves to instances of actual knowledge of wrongdoing, as required by traditional scienter.

**B. This Court Should Reject Defendants' Attempt to Bypass Scienter.**

The requirement of scienter is fundamental to our legal system, as centuries of Anglo-American jurisprudence confirm the need to prove real *mens rea* before depriving someone of his liberty or property. Imposing penalties without a finding of scienter, as Defendants seek to do, is improper except in very limited circumstances absent here.

More than a half-century ago, the Supreme Court held that the requirement of *mens rea* in criminal prosecutions is "universal and persistent in mature systems of law":

The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil.

*Morrisette v. United States*, 342 U.S. 246, 250 (1952).

In *Staples v. United States*, the Supreme Court rejected a lower standard for criminal intent that was urged by the government. 511 U.S. 600, 604 (1994). Proof of intent to do something is not enough; there must also be proof of intent to do something criminal. *Mens rea* “require[s] that the defendant know the facts that make his conduct illegal.” *Id.* at 605. Moreover, even where there is not an express requirement of proof of an intent of wrongdoing, such a requirement should be inferred in order to avoid constitutional infirmities. *See, e.g., United States v. United States Gypsum Co.*, 438 U.S. 422, 446 (1978) (rejecting an interpretation of a statute that “would effectively eliminate intent as an ingredient of the offense”) (inner quotations omitted). *See also Nat’l Fed’n of Indep. Bus v. Sebelius*, 567 U.S. 519, 668 (2012) (Scalia, Kennedy, Thomas, and Alito, JJ., dissenting) (“[W]here a statute is silent as to scienter, we traditionally presume a *mens rea* requirement if the statute imposes a ‘severe penalty.’”) (quoting *Staples*, 511 U.S. at 618).

Despite these well-established requirements of due process, Defendants attempt to impose draconian fines while bypassing scienter requirements. This has the effect of depriving due process rights of patients too, who are left unable to purchase medication on legitimate prescriptions, based on the collectivist-style profiling demanded by Defendants of pharmacies.

**C. As AAPS Has Previously Stated to HHS, Defendants’ Top-Down Approach is Misguided.**

As AAPS has emphasized in its comments to HHS, “Blaming doctors and pain patients for the surge in opioid deaths is misplaced and diverts resources from addressing the true culprits complicit in the increased deaths.” Letter by Dr. Singleton, *supra*, at 1. Instead, as AAPS has stated to HHS:

The needs of individual patients need to remain at the center of patient care decisions and ... actions by third parties interfering in the patient-physician relationship need to be minimized and even eliminated.

*Id.* at 3.

It is improper for Defendants, without complying with the safeguards of notice-and-comment rulemaking, to create incentives for pharmacies to interfere with the medical judgment of physicians who are treating patients according to their individualized needs. Defendants' monitoring program distorts the independent medical and pharmacist decision-making which is essential to attaining optimal medical care for each patient. Defendants would subject pharmacists to fear for filling legitimate prescriptions, and burden physicians with phone calls or rejections by pharmacists who refuse to provide medication which physicians have already determined to be necessary for patients.

Defendants' approach of impeding access by the law-abiding public to a good which may be misused by some has been resoundingly rejected in other areas of law, such as gun control. Compelling gun shops to refuse to sell guns to those who pay cash or travel a long distance would hardly pass muster. In our society the law-abiding public is not to be held hostage to miscreants and criminals. Law-abiding patients and their physicians should not lose their liberties because of a few who misbehave. Profiling has been rejected for similar reasons, and yet Defendants try to impose profiling here in a roundabout way with their demands that pharmacies profile patients.

Defendants' red flag program is Orwellian and contrary to fundamental liberty. Physicians and their patients should not have to explain to a pharmacist why something is being paid in cash rather than through insurance or why someone is buying at a distant location, and pharmacists should not be compelled by Defendants to disfavor and block such transactions.

**II. A Majority on the Supreme Court Has Rejected Unauthorized Regulation by the DOJ which Is Analogous to What It Attempts Here.**

Fully half of an eight-member Supreme Court cast doubt on a statutory delegation by Congress to Defendant DOJ to establish requirements for registration by sex offenders, which is arguably a more compelling context for deferring to the DOJ than the issue at bar here. *Gundy v. United States*, 139 S. Ct. 2116 (2019). Three justices sharply criticized and rejected a congressional delegation to Defendant DOJ to promulgate a rule on whether sex offenders convicted prior to the enactment of a certain law would be required to register pursuant to that law. *Id.* at 2131-48 (Gorsuch, Thomas, and Roberts, JJ., dissenting). A fourth justice was critical also, but joined the affirmance of the congressional delegation because he did not yet see a majority on the Court to invalidate in that case an unconstitutional delegation of power to the executive branch. Thus the view of fully half of the then eight-member Court – all of the more textualist side of the Court – was that broad or vague lawmaking should not be delegated by Congress to the executive branch.<sup>8</sup>

Under the foregoing approach, even if Congress had delegated to Defendants the authority to require detailed monitoring by pharmacists, the Constitution would not allow such a sweeping delegation of lawmaking by Congress to the executive branch. In fact, Congress did not even delegate such authority to Defendants, so Defendants' legal position is far weaker here than its tenuous position in *Gundy*.

Newly confirmed Justice Brett Kavanaugh was unable to participate in the *Gundy* decision. But Justice Kavanaugh subsequently wrote in praise of the dissent that opposed the

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<sup>8</sup> The three justices who rejected DOJ's authority to create a new requirement in *Gundy* were Justices Neil Gorsuch and Clarence Thomas, and Chief Justice John Roberts. Justice Sam Alito expressed his preference to join them in a future case. Newly confirmed Justice Brett Kavanaugh was not able to participate in the *Gundy* case, but praised the dissent in a subsequent opinion.

lawmaking by DOJ, which suggests that there is at least a 5-4 majority on the Court against the unauthorized regulations by Defendants which are at issue in this case:

I agree with the denial of certiorari because this case ultimately raises the same statutory interpretation issue that the Court resolved last Term in *Gundy v. United States*, 588 U. S. \_\_\_, 139 S. Ct. 2116, 204 L. Ed. 2d 522 (2019). I write separately because Justice Gorsuch’s scholarly analysis of the Constitution’s nondelegation doctrine in his *Gundy* dissent may warrant further consideration in future cases. Justice Gorsuch’s opinion built on views expressed by then-Justice Rehnquist some 40 years ago in *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 685-686, 100 S. Ct. 2844, 65 L. Ed. 2d 1010 (1980) (Rehnquist, J., concurring in judgment). In that case, Justice Rehnquist opined that major national policy decisions must be made by Congress and the President in the legislative process, not delegated by Congress to the Executive Branch.

In the wake of Justice Rehnquist’s opinion, the Court has not adopted a nondelegation principle for major questions. But the Court has applied a closely related statutory interpretation doctrine: ***In order for an executive or independent agency to exercise regulatory authority over a major policy question of great economic and political importance, Congress must either: (i) expressly and specifically decide the major policy question itself and delegate to the agency the authority to regulate and enforce; or (ii) expressly and specifically delegate to the agency the authority both to decide the major policy question and to regulate and enforce.*** See, e.g., *Utility Air Regulatory Group v. EPA*, 573 U. S. 302, 134 S. Ct. 2427, 189 L. Ed. 2d 372 (2014); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U. S. 120, 120 S. Ct. 1291, 146 L. Ed. 2d 121 (2000); *MCI Telecommunications Corp. v. American Telephone & Telegraph Co.*, 512 U.S. 218, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994); Breyer, *Judicial Review of Questions of Law and Policy*, 38 Admin. L. Rev. 363, 370 (1986).

*Paul v. United States*, 140 S. Ct. 342, 342 (2019) (Kavanaugh, J., concurring in the denial of a petition for *certiorari*, emphasis added).

The attempt by Defendants to impose red flag monitoring on pharmacies falls far short of the above test. Thus Defendants have acted without authority, and a declaratory judgment should be granted as requested by Walmart. The Fifth Circuit has agreed with the views of the Supreme Court Justices who now comprise a majority. See, e.g., *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 443 (5th Cir. 2020) (“Indeed, ‘[w]e ought not to shy away from our judicial duty to invalidate unconstitutional delegations’; ‘[i]f we are ever to reshoulder the burden of ensuring



that Congress itself make the critical policy decisions, these are surely the cases in which to do it.”) (quoting *Indus. Union Dep’t, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 686-87 (1980) (Rehnquist, J., concurring in the judgment)). It seems likely that the Fifth Circuit and the Supreme Court would view with enormous skepticism any profiling which flags the use of cash or geographic distance as criteria for blocking medication, as sought by Defendants, particularly in the absence of congressional authorization for such a potentially harmful approach.

The vice of a runaway administrative state that makes up its own rules as it goes along has been widely criticized. “[T]he claim that imposing the rule of law on agency behavior could protect Americans from an administrative state run amok, which prior to World War II had been solely the claim of opponents of the New Deal, was increasingly heard across the political spectrum.” Reuel E. Schiller, “Enlarging the Administrative Polity: Administrative Law and the Changing Definition of Pluralism, 1945-1970,” 53 *VAND. L. REV.* 1389, 1405 (Oct. 2000). It is overdue to enjoin the “administrative state run amok,” as presented in this case.

### **III. Defendants Overreach Constitutional Limits on Their Jurisdiction.**

Defendants improperly attempt to federalize law which has traditionally been within the exclusive jurisdiction of the States. States, not the federal government, regulate pharmacies. On issues not relevant here, the Food & Drug Administration has some limited authority over the marketing of medications sold in interstate commerce. Defendant Drug Enforcement Administration has some limited authority over medications designated as controlled substances. No federal agency has any authority over the practice of medicine, or any power to federalize state law concerning prescriptions and the practice of medicine.

Yet Defendants are attempting to do exactly that, by searching for a technical violation of state law and treating it as though it were an automatic implied violation of federal law. *See* Walmart’s Mot. at 11-12. This infringes on the dual sovereignties fundamental to our system of

government. State sovereigns are not mere vassals of federal sovereignty, but rather are co-equal authorities having some exclusive domains. Indeed, since the States created the federal government, it is properly understood as an agent of the States, having limited authority.

In the seminal case of *Lopez v. United States*, the Supreme Court invalidated a federal law which criminalized carrying a gun within a school zone. As Justice Kennedy explained in his concurrence in that case:

Though on the surface the idea may seem counter-intuitive, it was the insight of the Framers that freedom was enhanced by the creation of two governments, not one. In the compound republic of America, the power surrendered by the people is first divided between two distinct governments, and then the portion allotted to each subdivided among distinct and separate departments. Hence a double security arises to the rights of the people. The different governments will control each other, at the same time that each will be controlled by itself. ... The Constitution divides authority between federal and state governments for the protection of individuals. State sovereignty is not just an end in itself: Rather, federalism secures to citizens the liberties that derive from the diffusion of sovereign power.

*United States v. Lopez*, 514 U.S. 549, 576 (1995) (Kennedy, J., concurring, inner citations and quotation marks omitted). *See also United States v. Morrison*, 529 U.S. 598, 615-16 (2000) (rejecting as fallacious a failure to recognize constitutional limits on federal intrusions into “traditional state regulation” because “[u]nder our written Constitution ... the limitation of congressional authority is not solely a matter of legislative grace.”).

Here, Congress has not even authorized the red flag monitoring demanded by Defendants. It is as though Defendants attempt to implicitly tax Walmart and other pharmacies with penalties, without any congressional authorization to do so. It does not matter how compelling Defendants may think the need is for such a tax. The executive branch lacks the authority to create new taxes in the absence of congressional authorization. “Taxation is a legislative function, and Congress ... is the sole organ for levying taxes.” *Nat’l Cable Television Ass’n v. United States*, 415 U.S. 336, 340 (1974).

In its *Nat'l Cable Television Ass'n* decision, the Supreme Court declared that:

It would be such a sharp break with our traditions to conclude that Congress had bestowed on a federal agency the taxing power .... The addition of “public policy or interest served, and other pertinent facts,” *if read literally, carries an agency far from its customary orbit and puts it in search of revenue in the manner of an Appropriations Committee of the House.*

*Id.* at 341 (emphasis added).

Yet Defendants’ red flag monitoring program attempts to do what the Supreme Court has held to be within the exclusive province of Congress: impose an assessment on Walmart and other pharmacies purportedly to advance the “public policy or interest served,” which is a legislative function. *Id.* (inner quotations omitted). “Such assessments are in the nature of ‘taxes’ which under our constitutional regime are traditionally levied by Congress.” *Id.*

Defendants’ browbeating of pharmacies disrupts the beneficial functioning of the free market and improperly circumvents Congress. In this case, patients are the economic victims of Defendants’ actions against pharmacies, because when the cost of doing business increases then those costs are shifted to and borne by the customers, who in this case are patients of physicians.

While this case relates to controlled substances, about which there may be some empathy for more regulation, the legal principles at stake extend throughout the medical profession and across all types of economic activity. The energy sector central to the Texas economy, for example, is increasingly a target of politically motivated regulation and bounty-hunting by out-of-state politicians. The protections of the legislative process in Congress are essential, such that the many representatives of Texas on Capitol Hill may defend against shaking down entire industries important to Texas. This Court should reject circumvention by administrative fiat.

### **Conclusion**

The Court should grant Defendants’ motion for partial summary judgment in its entirety.

Dated: December 7, 2020

Respectfully submitted,

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