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

WALMART INC., Plaintiff, v. U.S. DEPARTMENT OF JUSTICE; ATTORNEY GENERAL WILLIAM P. BARR; U.S. DRUG ENFORCEMENT ADMINISTRATION; ACTING ADMINISTRATOR TIMOTHY J. SHEA, Defendants.	CIVIL ACTION NO.: **COMPLAINT FOR DECLARATORY RELIEF**

Walmart Inc. (Walmart) seeks a judicial declaration to resolve a dispute with the U.S. Department of Justice (DOJ) and the U.S. Drug Enforcement Administration (DEA) about the obligations of pharmacists and pharmacies under the Controlled Substances Act (CSA).

DOJ and DEA are placing pharmacists and pharmacies in an untenable position by threatening to hold them liable for violating DOJ's unwritten expectations for handling opioid prescriptions—expectations that are directly at odds with state pharmacy and medical practice laws, the expert judgment of federal health agencies, and even DEA's own public statements. When a patient presents a pharmacist with an opioid prescription written by a doctor who is licensed by a state medical board and credentialed by DEA to prescribe controlled substances, the pharmacist must make a difficult decision. The pharmacist can accept the doctor's medical judgment and fill the opioid prescription, or second-guess the doctor's judgment and refuse to fill it—a decision the pharmacist must make without the benefit of a medical license, examining the patient, or having access to medical records.

Either decision puts the pharmacist and pharmacy at great risk. On the one hand, a pharmacist who fills a facially valid opioid prescription risks federal investigation, civil liability, or even criminal prosecution should DOJ and DEA claim in hindsight that a prescription the pharmacist believed was valid should not have been filled. On the other hand, a pharmacist who refuses to fill such a prescription risks having her license stripped for the unauthorized practice of medicine, not to mention the potential harm to patients in need of their medicine.

These risks are not hypothetical. Walmart pharmacists have refused to fill hundreds of thousands of problematic opioid prescriptions, and Walmart has blocked thousands of concerning doctors from having their opioid prescriptions filled at any Walmart pharmacy. Because of this, Walmart and its pharmacists face state investigations and lawsuits for interfering in medical practice—that is, for going *too far* by refusing to fill opioid prescriptions. And DOJ now has stated it will sue Walmart *for not going far enough* by continuing to fill opioid prescriptions of certain licensed doctors—many of whom are still authorized by DEA to prescribe opioids *to this day.*

DOJ's legal contentions about the duties of pharmacists and pharmacies cannot be found anywhere in the text of the CSA or in any DEA regulation. At most, DOJ has stitched this untested position together from scattered and informal letters and PowerPoint presentations by DEA officials. But these documents are not law, as DOJ has recently reaffirmed in rules and other public statements. In any event, DEA's opioid "guidance" is often inconsistent or even irreconcilable with other DEA statements, with the expert judgment of federal health agencies, and with state practice of medicine and pharmacy laws.

Congress entrusted DEA—not pharmacists and pharmacies—with the responsibility, tools, and legal authority to strip unscrupulous doctors of their prescribing privileges. But DOJ's own Inspector General has described DEA's significant and repeated failures to vet doctors before

letting them prescribe opioids or to revoke the credentials of suspicious doctors. DOJ and DEA should not be allowed to outsource to pharmacists and pharmacies the job DEA has failed to do. The agencies' insistence on doing so continues to expose pharmacists and pharmacies to liability for improperly interfering with the doctor-patient relationship.

To resolve this untenable dilemma, declaratory relief is appropriate and necessary.

INTRODUCTION

1. The United States is in the throes of a public health crisis arising from the abuse of opioids. Opioids are addictive, prone to abuse, and readily available in illegal forms, such as heroin and synthetic fentanyl. At the same time, the federal government's Health and Human Services Pain Management Best Practices Inter-Agency Task Force has determined that tens of millions of Americans rely on legal prescription opioids to treat acute or severe chronic pain, including pain arising from cancer as well as terminal or degenerative illnesses. The Food and Drug Administration (FDA) long ago approved opioid medications for these purposes, and doctors throughout the country lawfully prescribe them.

2. Congress tasked DOJ and its sub-agency DEA with primary responsibility for preventing drug abuse. With respect to illegal opioids—the chief cause of opioid overdose deaths—DEA's and DOJ's duty is to keep those drugs off the streets and to find and punish the criminals who push them.

3. Through the CSA, Congress similarly entrusted DEA with the responsibility for regulating legal opioids. DEA is responsible for enforcing the CSA in a way that preserves legitimate patients' access to pain-relief medications prescribed by their doctors while preventing diversion, misuse, and abuse. As such, Congress has charged DEA with regulating every step in the opioid supply chain:

- DEA must set production quotas to limit the quantity of legal opioids that enter the supply chain each year.

- DEA must approve and renew—or reject and revoke—manufacturers' registrations to *produce* opioids.

- DEA must approve and renew—or reject and revoke—distributors' registrations before they may *distribute* opioids to licensed pharmacies and health care providers.

- DEA must approve—or reject—doctors' initial registrations before they may *prescribe* opioids, and renew—or decline to renew—their registrations upon application every three years. DEA must also revoke registrations when appropriate in the public interest.

- DEA must approve and renew—or reject and revoke—pharmacies' registrations before their pharmacists may *dispense* opioids to patients.

In carrying out these regulatory tasks, DEA must consider whether a given registration advances "the public interest." And if DEA determines, at any time, that continued registration would not be or is no longer in the public interest, it may—and should—deny or revoke the registration or decline its renewal.

4. DEA requires as a condition of registration that each registrant play a role in ensuring the integrity of the opioid supply chain. Manufacturers and distributors must report to DEA any "suspicious orders" they identify. Doctors must exercise professional care to prescribe opioids only for a legitimate medical purpose. And pharmacists must refuse to fill prescriptions they know to be forged, altered, or not written for a legitimate medical need. The system is set up so that DEA can protect the public by robustly enforcing the CSA against any improper conduct anywhere along the supply chain, including by revoking or declining to renew the registrations of bad actors. Every registrant necessarily relies on DEA's endorsement when it interacts with other DEA-registered entities in the supply chain. For example, in deciding whether to fill an opioid

prescription, pharmacists confirm whether the doctor is registered by DEA to prescribe controlled substances.

5. Watchdog agencies have meticulously catalogued, however, myriad ways in which DEA has failed to safeguard the public from improper diversion of prescription opioids. Even as the abuse of legal opioids climbed over the last decade, DEA authorized manufacturers to produce ever-increasing quantities of the drugs, and largely abandoned its most potent enforcement tools against bad actors. Most egregiously, despite years of complaints about the conduct of certain doctors, DEA not only allowed those doctors to continue prescribing opioids, but in many instances renewed their registrations. DEA also refused to provide any clear rules to distributors on how they should detect and report "suspicious orders" from their customers. And DOJ's own Inspector General concluded that when suspicious orders *were* reported, DEA had ignored and discarded the reports with no investigation or follow-up.

6. In the shadow of their own profound failures, DOJ and DEA now seek to retroactively impose on pharmacists and pharmacies unworkable requirements that are not found in any law and go beyond what pharmacists are trained and licensed to perform. And because these new, unsupported expectations directly conflict with the requirements of state regulators who oversee the practice of pharmacy and medicine, pharmacists are left between the proverbial "rock and a hard place."

7. By law, pharmacists presented with an opioid prescription cannot interfere with the doctor-patient relationship by usurping the doctor's professional judgment—and understandably so, because they are not doctors, do not examine or diagnose patients for purposes of dispensing opioid medications, and do not have access to patients' medical records. Pharmacists accordingly lack the tools needed to second-guess doctors' judgments about questions that remain vigorously

debated in the medical field (and even within the government's law enforcement and health agencies), such as the appropriate dosing for particular patients or the necessity of particular combinations of medicines.

8. In fact, when they *refuse* to fill opioid prescriptions, pharmacists and pharmacies have been reprimanded, investigated, and even sued by state boards of pharmacy and medicine, national medical associations, doctors, and patients. State regulators, in particular, contend that state laws regulating the practices of pharmacy and medicine prohibit pharmacists from second-guessing doctors, and particularly from doing so on a categorical rather than prescription-by-prescription basis. Meanwhile, physician organizations such as the American Medical Association maintain that doctors' judgments should be paramount.

9. Nevertheless, Defendants assert that the CSA and its regulations *require* pharmacists—and pharmacies' corporate headquarters—to insert themselves into the doctor-patient relationship. DOJ and DEA now contend that it is not enough for a pharmacist to refuse to fill prescriptions he or she knows to be illegitimate—even though the laws they rely on impose liability *only* based on what is within a pharmacist's knowledge. Instead, Defendants' position would require that every time a patient presents a facially valid prescription for an opioid medication—a prescription written by a DEA-registered doctor who has examined the patient and knows the patient's medical history—the pharmacist must second-guess the doctor's medical judgment.

10. Defendants' position also would effectively impose liability if a pharmacy's corporate headquarters does not override its pharmacists' judgments whether to fill prescriptions (and the judgments of the doctors who write them) by blocking all prescriptions written by particular doctors across the whole pharmacy chain.

11. Defendants' position is an attempt to effectively shift to *pharmacists* duties that Congress has assigned to *DEA* and that state law assigns to *state medical boards*. DEA is charged with revoking or refusing to renew doctors' registrations to prescribe controlled substances if they write medically unnecessary prescriptions. DEA has the legal authority to conduct investigations and even revoke credentials on an emergency basis. And state medical boards police standards of medicine and may suspend or revoke doctors' licenses if they violate their professional obligations. Under Defendants' view, however, pharmacists must reexamine every doctor's diagnosis to confirm that the prescription written by the doctor was medically proper for the patient in question, and then categorically block those doctors that pharmacists deem suspect.

12. These supposed duties find no basis in the text of DEA's own regulations, much less the statutes that Congress enacted. On the contrary, Defendants can piece them together only from scattered letters, PowerPoint presentations, and other materials that are—at best—informal "guidance." Under its own rules, however, DOJ is not permitted to use guidance like this as the basis for enforcement actions. And DOJ has likewise forsworn lawsuits that seek to impose penalties for violating "rules" announced only after the conduct at issue. DEA could have promulgated regulations dictating how pharmacists and pharmacies should evaluate opioid prescriptions, and pharmacists and pharmacies would have complied. But DEA never did. Defendants' threatened suit based on sub-regulatory guidance and *post hoc* asserted obligations cannot be squared with DOJ's formal renunciations of just such unlawful tactics.

13. DOJ's and DEA's current position is also impossible to square with DEA's own prior positions and those of other expert federal agencies. DEA has emphasized that the decision to fill a prescription depends on the prescription-by-prescription judgment of licensed medical professionals. DEA, The Pharmacist's Manual 42 (2020); DEA, *Dispensing Controlled*

Substances for the Treatment of Pain, 71 Fed. Reg. 52716, 52716–23 (Sept. 6, 2006) (*Dispensing Controlled Substances*). That position comports with the views of medical experts at the Department of Health and Human Services ("HHS"), Centers for Disease Control and Prevention ("CDC"), and Centers for Medicare & Medicaid Services ("CMS"). *See, e.g.*, HHS, *Draft Report on Pain Management Best Practices* (2019), *available at* https://www.hhs.gov/ash/advisory-committees/pain/reports/2018-12-draft-report-on-updates-gaps-inconsistencies-recommendations/index.html; CDC, *CDC Advises Against Misapplication of the* Guideline for Prescribing Opioids for Chronic Pain (Apr. 24, 2019), https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html (highlighting the need for "individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient"). But DOJ and DEA are now attempting to invent *post hoc* rules—not found in the CSA or its regulations—that would outlaw certain *categories* of prescriptions and essentially impose strict liability based on the government's Monday-morning quarterbacking.

14. Unfortunately, Defendants' attempt to rewrite the CSA and restructure the practice of medicine has placed pharmacists and pharmacies—including Walmart and its pharmacists—in a very difficult position.

15. Walmart is a retailer that serves a diverse array of communities. As a relatively small part of its business—but in keeping with its mission to provide its customers with a one-stop shopping experience—Walmart operates more than 5,000 in-store pharmacies in the United States.

16. Walmart has always encouraged its pharmacists to exercise their professional judgment and refuse to fill opioid prescriptions that they do not believe to be legitimate. In fact, Walmart pharmacists have refused to fill *hundreds of thousands of* opioid prescriptions. Walmart

also has adopted innovative opioid-stewardship programs and partnered with law enforcement agencies, including DEA, to help root out corrupt doctors and put them behind bars.

17. In an atmosphere of government pressure, including DOJ's unethical threats of criminal sanctions meant to leverage a huge civil settlement, Walmart accelerated its implementation of doctor-blocking policies. But Walmart's good-faith efforts have not satisfied Defendants, and at the same time have been met with inquiries, lawsuits, threats, and investigations from doctors, patients, legislators, and state boards of medicine and pharmacy, who believe Walmart's actions go *too far* in blocking dispensing of prescription opioids.

18. Despite these efforts, DOJ and DEA have stated they will file a civil complaint against Walmart for not going far enough in blocking doctors by refusing to fill their prescriptions. This threat is based on legal theories that have no basis in statute or regulation. DOJ will seek civil penalties against Walmart for its licensed pharmacists' filling of prescriptions for pain medications approved by the FDA, written by licensed and registered doctors, presented by individual patients as medically necessary, and filled by pharmacists in their exercise of their professional judgment on a case-by-case basis. There is no allegation that these prescriptions were forged or altered, or that pharmacists were taking kickbacks or had inappropriate relationships with patients or doctors. Defendants' threatened action would be unprecedented.

19. Defendants' effort to regulate through litigation only compounds the untenable dilemma faced by pharmacists across the United States. On the one hand, a pharmacist who fills a facially valid opioid prescription is at risk of federal investigation, civil liability, or even criminal prosecution. On the other hand, a pharmacist who *refuses* to fill such a prescription is at risk of having her license stripped for the unauthorized practice of medicine, not to mention the potential harm to patients in need of their medicine. Those risks become particularly acute where the

pharmacist (or a chain of pharmacies), in accord with Defendants' demands, blocks a given doctor's prescriptions entirely.

20. DOJ's threatened lawsuit also underscores the extent to which Defendants seek to make up for their own regulatory shortcomings by imposing liability on Walmart and its pharmacists. For example, of the hundreds of specific doctors that DOJ has identified to Walmart as having written problematic prescriptions that Walmart's pharmacists allegedly should not have filled, nearly 70% continue to have active DEA registrations to this day. In other words, Defendants want to blame Walmart for continuing to fill purportedly bad prescriptions written by doctors that DEA and state regulators enabled to write those prescriptions in the first place *and continue to stand by today*.

21. Neither Walmart nor its pharmacists caused the opioid crisis. Walmart and its pharmacists never marketed opioids, nor did they mislead the public and the medical community (including pharmacists) about the dangers of opioids. Walmart never shipped opioid medications to any rogue independent or internet pharmacies; it distributed only to itself. Unlike DEA, DOJ, and state medical boards, Walmart and its pharmacists had no say in determining whether opioids should be approved as safe and effective, what conditions they should be approved as treatment for, the quantity of opioids produced in this country, or the circumstances in which they are prescribed. Nor have Walmart or its pharmacists had a role in credentialing doctors or approving and renewing their state licenses or DEA registrations. And of course, Walmart pharmacies and pharmacists never wrote opioid prescriptions at all.

22. Even though Walmart and its pharmacists did not cause the opioid crisis, they remain devoted to trying to combat it while serving their customers' legitimate medical needs. But Walmart and its pharmacists should not be held responsible for the government's failures to

address the opioid crisis, and should not be subject to Defendants' threats to enforce unwritten laws and regulations, conflicting duties, and contradictory guidance.

23. To end the unacceptable uncertainty caused by Defendants' conduct, Walmart reluctantly files this action to obtain a declaration resolving its disputes of law with Defendants and clarifying its legal rights and duties under the CSA and its implementing regulations.

JURISDICTION AND VENUE

24. This Court has jurisdiction over the subject matter of this civil action under 28 U.S.C. §§ 1331 and 2201 because the claims arise under the laws of the United States.

25. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States and a substantial part of the events giving rise to the claims occurred in this judicial district. Specifically, the U.S. Attorney's Office for this judicial district initially led the investigation into Walmart, and that investigation focused primarily on conduct within this judicial district.

THE PARTIES

26. Plaintiff Walmart Inc. (Walmart) is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

27. Defendant U.S. Department of Justice (DOJ) is an executive department of the United States federal government.

28. Defendant William Barr is the Attorney General of the United States, the principal officer of DOJ. He is sued in his official capacity.

29. Defendant U.S. Drug Enforcement Administration (DEA) is a component law enforcement agency under DOJ.

30. Defendant Timothy Shea is the Acting Administrator of DEA, the principal officer of that agency. He is sued in his official capacity.

FACTUAL ALLEGATIONS

I. OPIOIDS, THEIR SUPPLY CHAIN, AND THEIR REGULATORY SCHEME.

31. Opioids are chemical substances, including morphine, hydrocodone, and oxycodone, that provide pain relief. Many opioids have long been approved by the FDA as safe and effective for medical use and are regulated under the CSA. Illegal forms of certain opioids exist, such as heroin and illegally imported synthetic fentanyl.

32. The prescription opioid supply chain includes manufacturers, distributors, doctors, and dispensers (pharmacies and other entities who ultimately provide the medications to patients with prescriptions written by licensed medical professionals). Public agencies, including FDA and DEA, are tasked by law with tightly controlling every aspect of the supply chain, including by limiting manufacture of prescription opioids and registering and regulating the doctors, distributors, and dispensers. Regulatory oversight occurs at every step in the chain.

33. The CSA, 21 U.S.C. § 801 *et seq*., provides the primary framework governing the manufacture, distribution, and dispensing of controlled substances. It establishes registration requirements for participants in the opioid supply chain, *id.* § 822, and sets forth unlawful acts that may give rise to civil or criminal liability, *id*. § 842. DEA has issued regulations interpreting the CSA.

34. Manufacturers make, market, and sell opioids. Production is limited, however, by DEA, which (in consultation with FDA and other interested parties like the manufacturers themselves) sets annual aggregate production quotas ("APQs") that determine the amount of controlled substances that may be produced each year. 21 C.F.R § 1303.11. In setting APQs, DEA is charged with limiting production of controlled substances, including prescription opioids, to the amount necessary for the "estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of

reserve stocks." *Id.* § 1303.11(a). Opioids cannot legally be produced without DEA approval; DEA therefore establishes the total quantity of prescription opioids available in any given year. DEA has been widely criticized for failing to impose proper limits on the national supply of opioids.

35. Some manufacturers are alleged to have aggressively promoted prescription opioids directly to doctors as a safe, non-addictive method for treating pain. These marketing efforts are alleged to have had an effect on prescribing practices, but for many years DEA did little or nothing to stop them. *See, e.g.*, Nat'l Inst. of Health, *Opioid Overdose Crisis* (May 28, 2020), https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis (describing misleading claims about addictiveness); HHS, *About the Epidemic* (Sept. 4, 2019), https://www.hhs.gov/opioids/about-the-epidemic/index.html (same).

36. Manufacturers do not, however, ship their products directly to doctors or pharmacies. Instead, they rely on distributors who ship pharmaceuticals, including prescription opioids, to dispensers. Wholesale distributors ship opioids to all kinds of pharmacies, including to those located in hospitals, independent and internet pharmacies, and certain medical practices.

37. To prevent diversion through distribution channels, distributors are expected to "know their customers" to ensure that those customers are legitimate pharmacies. Distributors are therefore required, as a condition of CSA registration, to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and "inform" local DEA officials of "suspicious orders when discovered." 21 C.F.R. § 1301.74(b). Federal investigations have shown that for many years, however, DEA did not use or maintain suspicious order reports submitted by distributors. DOJ, Office of the Inspector Gen., *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* (Sept. 2019), at 31.

38. For a period of time, Walmart, like other national chain pharmacies, self-distributed controlled substances, including opioids, by buying them from manufacturers and shipping them to its own pharmacies—and *only* to its own pharmacies. Walmart and a number of other national chain pharmacies no longer self-distribute prescription opioids, but instead rely on third-party distributors.

39. Doctors play the central role in the prescription opioid supply chain. Doctors conduct medical exams, review medical histories, and directly interact with their patients before prescribing controlled substances. Their integrity is essential to the regulatory scheme. Doctors are registered by DEA (to whom they must reapply for renewal every three years) and licensed by the relevant state medical boards to prescribe controlled substances.

40. DEA has stated that "the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes." DEA, *Dispensing Controlled Substances*, 71 Fed. Reg. at 52719.

41. Of course, as in any field, there are bad actors—doctors who do not undertake appropriate medical scrutiny before providing a prescription. Both DEA and state medical boards retain oversight of these doctors and have the authority and responsibility to revoke their ability to prescribe controlled substances. *See*, *e.g.*, 21 C.F.R. § 1301.36. Federal law empowers DEA with regulatory tools such as subpoenas, investigatory resources, and the legal authority to suspend on an emergency basis or revoke a doctor's registration. *See*, *e.g.*, 21 C.F.R. §§ 1301.31–46, 1316.41–68. But DEA has failed in its responsibility to deny prescribing privileges to doctors who abuse them, even allowing a multitude of doctors that DOJ and DEA now contend should not have had any of their prescriptions filled to maintain their DEA registrations and continue writing opioid prescriptions.

II. PHARMACISTS' ROLE IN THE OPIOID SUPPLY CHAIN.

42. The role of the pharmacist in this regulatory framework is an important but limited one. Pharmacists do not prescribe opioids, and they cannot dispense them to anyone other than patients with prescriptions written by state-licensed and DEA-registered doctors. They apply their own professional judgment to the facts before them in light of their training, education, and experience.

43. The rules governing the dispensing of controlled substances, including prescription opioids, are set out in part in 21 C.F.R. § 1306.04(a). That section provides:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

44. As that regulation makes clear, it is the "prescribing practitioner" (the doctor) who bears primary responsibility for ensuring that controlled substances are properly prescribed ("for a legitimate medical purpose" and "in the usual course" of a practitioner's professional practice).

45. That allocation of responsibility makes sense. The patient's doctor is the one who has been licensed by the state medical board to practice medicine, has been authorized by DEA to prescribe controlled substances, has the capacity to examine the patient and access her complete medical history, and is best positioned by virtue of the doctor-patient relationship to accurately assess the patient's treatment needs and any accompanying risks.

46. By contrast, pharmacists are not doctors. Pharmacists cannot examine or diagnose a patient who has received a prescription for opioid medication. They cannot obtain or review the

patient's full medical file. Nor can they access the patient's full prescription history at other pharmacies. Instead, a pharmacist's knowledge of the situation is generally limited to the four corners of the prescription, the patient's history at that particular pharmacy, any of the patient's information available to the pharmacist in the state Prescription Drug Management Program, a brief interaction with the patient, and any follow-up or inquiry that the pharmacist may conduct by contacting the prescribing doctor's office. Indeed, pharmacists are not permitted to practice medicine and would be disciplined for doing so.

47. Nevertheless, pharmacists have an important role to play when filling prescriptions. As the DEA regulation proceeds to explain, pharmacists have a "corresponding responsibility" and may not "knowingly" fill a prescription that was not "issued for a legitimate medical purpose by a [prescriber] acting in the usual course of his professional practice." *Id.* A subsequent regulatory provision adds that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." *Id.* § 1306.06.

48. Under these regulations, a pharmacist cannot, for example, fill a prescription if the doctor lacks an active DEA registration, if the pharmacist recognizes the doctor's signature as forged, if the prescription has been photocopied or tampered with, or if it is lacking basic requirements like the patient's date of birth.

49. When a patient presents a facially valid prescription from an actively licensed and DEA-registered doctor, refusing to fill the prescription raises special concerns because it is overriding a licensed medical provider's professional judgment about the care and treatment of that medical provider's particular patient. Patient advocates, medical and pharmaceutical boards, and even government agencies have cautioned pharmacists against disrupting the normal course of medical care in this manner. That holds true for prescription opioids, which "should not [be]

abruptly discontinue[d] … in a patient who is physically dependent." FDA, FDA Drug Safety Communication (Apr. 9, 2019), *available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.

50. The DEA regulations provide no categorical rules and little practical advice on how or when a pharmacist should go about making these decisions. Neither § 1306.04(a) nor the CSA mentions any specific indicators that a prescription is or may not be valid. Nor do they specify when such indicators (or any combination of them) would prohibit a pharmacist from filling the prescription or suggest that a pharmacist is supposed to investigate or resolve questions about the prescription before proceeding.

51. Regulators have exacerbated this uncertainty by providing contradictory guidance to pharmacists. DEA has recently advised pharmacists *not* to fill prescriptions that are "doubtful, questionable, or suspicious." DEA, The Pharmacist's Manual 42 (2020). But state regulators and others in the medical community—those who are supposed to have the final say on which prescriptions are legitimate—object to *any* interference in the doctor-patient relationship. State boards of medicine and pharmacy—which have the power to revoke pharmacists' licenses and to take legal action against pharmacies—have condemned pharmacists and pharmacies for taking medical decisions into their own hands by refusing to fill prescriptions from actively licensed doctors.

52. For example, the Executive Director of the Tennessee Pharmacy Board has stated that pharmacists should dispense medication whenever the prescribing doctor maintains a valid DEA registration and an unencumbered medical license, even if the pharmacist views the prescription as suspicious. Members of the Idaho Board of Pharmacy have agreed; in their view,

even a doctor's arrest on suspicion of narcotics trafficking should not cause pharmacists to decline *all* of the doctor's prescriptions. Such a blanket judgment, the Idaho Board has said, precludes the professional judgment required to discharge a pharmacist's duties. These state regulators recognize that doctors, not pharmacists, are responsible for the decision to prescribe.

53. Pharmacists are also investigated by state attorneys general and consumer protection officials if patients file complaints with the state after the pharmacist refuses a prescription. Doctors have also launched defamation lawsuits against pharmacies for refusing to fill their prescriptions and thus implying that the doctor has engaged in professional malfeasance. *See, e.g.*, *Yarus v. Walgreen Co.*, 738 F. App'x 94 (3d Cir. 2018); *Goulmamine v. CVS Pharmacy, Inc.*, No. 3:15-cv-00370 (E.D. Va. June 19, 2015); *Richardson v. CVS Caremark Corp.*, No. 1:18 CV 1308, 2018 WL 4189522 (N.D. Ohio Aug. 31, 2018); *Kahn v. Ariz. CVS Stores LLC*, No. 1 CA-CV 16-0333, 2017 WL 586398 (Ariz. Ct. App. Feb. 14, 2017).

54. Patients themselves have sued pharmacists and pharmacies for refusing to fill facially valid prescriptions, both in individual suits and in class action lawsuits under the Americans with Disabilities Act and analogous state laws. *See, e.g.*, *Smith v. Walgreens Boots All., Inc.*, No. 3:20-cv-05451-JD (N.D. Cal. Aug. 6, 2020) (putative class action alleging "corporate wide discriminatory practices in refusing to fill, without a legitimate basis, valid and legal prescriptions for opioid medication"); *Fuog v. CVS Pharmacy, Inc.*, No. 1:20-cv-00337-WES-LDA (D.R.I. Aug. 6, 2020) (similar).

55. Finally, doctors have complained to medical boards that pharmacists are "intrud[ing] on [the] practice of medicine" by calling and asking them questions such as "what other medications [they have] tried" before prescribing certain medications for patients. *AMA Meeting: Pharmacists Warned on Intruding into Prescribing Decisions*, AMERICAN MEDICAL

NEWS (July 1, 2013). In response, the American Medical Association ("AMA") adopted a resolution rejecting "inappropriate inquiries from pharmacies to verify the medical rationale behind prescriptions" as "interference with the practice of medicine." AMA Resolution 218 (2013). As suggested above, these doctors' complaints are not just idle talk; they have led to investigations by state authorities for the supposed unlawful practice of medicine by pharmacists simply trying to decide whether to fill a prescription. *See, e.g.*, Sherif Zaafran, MD (@szaafran), Twitter (Sept. 29, 2018, 11:29 pm), https://twitter.com/szaafran/status/1046240520786378752 (President of the Texas Medical Board).

56. This regulatory landscape puts pharmacists in an untenable dilemma. A pharmacist who follows the dictates of the professional licensing board and defers to the medical judgment of the prescribing, validly licensed, actively DEA-registered doctor risks civil or even criminal liability at the hands of the federal government if some of the prescriptions written by that doctor are later determined by DEA to be invalid. But a pharmacist who refuses to fill a prescription—and especially a pharmacist who refuses to fill *every* prescription from a certain doctor—risks other serious professional and personal consequences: investigation by the state medical board, a lawsuit from the doctor, and more. And patients with medical needs are caught in the middle.

57. On information and belief, DOJ intends to sue Walmart for filling prescriptions when there were what DEA calls "red flags"—factors (discussed more below) that, according to DEA, might raise questions about whether the prescription serves a legitimate medical purpose. But threatening to impose liability based on the mere presence of a red flag makes the pharmacists' legal dilemma far worse.

58. A red flag does not necessarily mean a prescription is illegitimate; it only raises a question. There may be an acceptable explanation for any such indicator. For example, one such

factor is a patient who presents a prescription far from his home, on the theory that the patient might be pharmacy-shopping. But legitimate patients might *live* far from the pharmacy but *work* near it, or might need to fill a prescription while on vacation or business travel. So too for any other potential "flag." Some patients may refill their prescriptions early because they will be traveling or anticipating surgery. Some patients pay cash because they lack insurance, or their insurance does not cover the medications they need. Some doctors write more opioid prescriptions than the average doctor because they practice in pain management or because they treat cancer patients.

59. DEA could have promulgated regulations invalidating such prescriptions, prohibiting pharmacists from filling them, or requiring pharmacists to take particular steps when presented with them. That regulatory process would have allowed the agency to seek input from stakeholders and balance their various concerns, including those related to patients' medical needs. But DEA has never done so. Absent specific rules set by DEA, pharmacists and pharmacies should not be subjected to categorical determinations punishing them for decisions they made in the exercise of their professional judgment in such fact-intensive circumstances.

60. Combination prescriptions, including so-called "trinity" prescriptions that combine an opioid (for pain), a benzodiazepine (for anxiety), and a muscle relaxer—further illustrate DOJ's attempt to create a *per se* prohibition on entire categories of prescriptions through a *post-hoc* enforcement proceeding rather than notice-and-comment rulemaking. In a criminal complaint recently filed by DOJ in a neighboring district, the Department declared that "[t]here is no medical basis for the simultaneous prescription of any version of the three 'trinity' drugs." Compl., *United States v. Rodriguez*, No. 19-cv-1055 (N.D. Tex. May 2, 2019).

61. But many medical experts—including within the federal government—disagree with DOJ's position. No statute or regulation declares "trinity" prescriptions to be categorically illegal, and several agencies have said that they are *permissible* in certain circumstances.

62. Commercial health plans and government programs like Medicare and Medicaid have the ability to prevent prescriptions from being filled by refusing to cover medications, refills, dosages, strengths, or combinations of medications they believe are not appropriate for individual patients or are not generally prescribed for a legitimate medical purpose. But these health plans and government programs continue to cover the types of prescriptions DOJ now argues are *per se* invalid. For instance, CMS considered whether to continue paying for "trinity" prescriptions under Medicare and decided to continue doing so with an "additional safety review" during the dispensing process for certain combinations. *See, e.g.*, CMS, Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Apr. 4, 2016); CMS, Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Apr. 2, 2018).

63. Indeed, even DEA appears to disagree with DOJ's inflexible position on this issue. After DOJ filed the complaint in *Rodriguez*, the National Association of Chain Drug Stores asked DEA whether it believed that all "trinity" prescriptions were invalid. In response, DEA refused to categorically condemn these prescriptions; instead, it disclaimed any authority "to issue guidelines that constitute advice relating to the general practice of medicine" and asserted that "[f]ederal law and DEA regulations do not impose a specific quantitative minimum or maximum limit on the amount of medication that may be prescribed on a single prescription, or the duration of treatment

intended with the prescribed controlled substance." Letter from Deputy Assistant Administrator Prevoznik to Kevin N. Nicholson (Nov. 4, 2019).

64. In short, a pharmacist confronted with any facially valid opioid prescription, whether for a so-called "trinity" prescription or one featuring some other factor DOJ or DEA might deem a "red flag," risks censure whether she fills it or not. These are not hypothetical scenarios. Pharmacies and their pharmacists face these realities every day.

III. WALMART AND ITS PHARMACISTS PROTECT PATIENTS.

65. Sam Walton opened a discount general store in Rogers, Arkansas, in 1962. Today, Walmart employs more than 1.5 million people in more than 5,000 stores across the United States. Walmart stores often form the commercial backbone of their communities.

66. Although Walmart is not principally a pharmacy, the company's pharmacy operations help serve the needs of its local communities and offer one-stop shopping for customers. More broadly, Walmart's pharmacies disproportionately help those with limited financial resources. Each year, Walmart fills prescriptions for millions of customers on Medicare, Medicaid, and TRICARE (the insurance system for military personnel, veterans, and their families). In fact, nearly half of the prescriptions filled at Walmart pharmacies are paid for by one of these programs.

A. Walmart's Pharmacists Are Empowered to Exercise Their Judgment.

67. Walmart's pharmacy dispensing policies have always complied with the letter and spirit of the CSA. Above all, Walmart has consistently supported its pharmacists in the discharge of their duties. To this end, Walmart has always reinforced for its pharmacists their duty to exercise their professional judgment and to refuse to fill any prescription that they determine to be illegitimate—an obligation that Walmart pharmacists have executed hundreds of thousands of times with respect to opioid prescriptions.

68. For example, Walmart's Pharmacy Operations Manual ("POM") has long instructed pharmacists to refuse to fill a prescription if the pharmacist does not reasonably believe that a valid doctor-patient relationship exists. Walmart's POM has also instructed pharmacists to refuse to fill a prescription if the pharmacist knows that it was not written for a legitimate medical purpose, and it provides a number of factors for pharmacists to consider in determining whether to fill any given prescription.

69. From 2011 to 2015, Walmart shared information reflecting its pharmacists' individual decisions to refuse to fill with local DEA officials, pursuant to an agreement the company entered with the agency, so that DEA—using data from other pharmacies as well as additional sources—could investigate suspicious doctors and take appropriate enforcement action.

70. During this period, Walmart did not dictate refusals-to-fill from its corporate headquarters or otherwise interfere with how its pharmacists carried out their CSA duties. For example, Walmart advised its pharmacists to exercise their professional judgment on every individual prescription written by licensed, active doctors, and not to categorically block certain prescriptions. Walmart also did not impose central blocks prohibiting all of its pharmacies from filling prescriptions from particular doctors.

71. Rather, decisions about whether to fill individual prescriptions were made by Walmart's licensed pharmacists, exercising their discretion and professional judgment, with direction to perform their duties as required by law.

72. Walmart's pharmacist-determined, prescription-by-prescription approach complied with federal law. As DEA has admitted, "each patient's situation is unique and the nature and degree of physician oversight should be tailored accordingly, based on the physician's sound

medical judgment and consistent with established medical standards." DEA, *Dispensing Controlled Substances,* 71 Fed. Reg. at 52723.

73. In keeping with this background of widespread compliance through professional judgment, no published DEA guidance—let alone any statutory provision or final agency rule—has ever indicated that a pharmacy or pharmacist must categorically reject all prescriptions or even certain types of prescriptions from a doctor who has a valid, active DEA registration without individualized consideration of a given prescription. After all, it is DEA's responsibility under the CSA to determine whether a particular doctor should retain the ability to prescribe controlled substances. *See, e.g.*, 21 U.S.C. § 824(a) (allowing DEA to "suspend[]" or "revoke[]" a registration if the prescriber's registration becomes "inconsistent with the public interest" due to his conduct).

74. Walmart's approach also complied with state law. Indeed, several states take the position that it is *illegal* for companies to mandate refusals-to-fill at the corporate level, because (they maintain) doing so interferes with the pharmacist's ability to evaluate each prescription based on the circumstances of each patient. *See, e.g.*, 225 Ill. Comp. Stat. Ann. 85/30(a)(23) (pharmacy's license may be revoked if it "[i]nterfer[es] with the professional judgment of a pharmacist"); Tenn. Food, Drugs, and Cosmetics Code § 53-10-112 ("It shall be a Class A misdemeanor … for the owner … or operator of a pharmacy to knowingly restrict or interfere with, or knowingly require a protocol or procedure that restricts or interferes with … the exercise of [a] pharmacist's professional judgment as to whether it is appropriate to dispense a legend drug to a patient."); Fla. Admin. Code R. 64b16-27.831(2)(a) (forbidding any "person" or "licensee" from "interfer[ing] with the exercise of the pharmacist's independent professional judgment"); Tex. Occ. Code

§ 551.006 (reiterating that "whether or not to dispense a drug" falls within the "exclusive authority" of the "pharmacist").

75. Finally, Walmart's prior policy comported with the consensus view of the medical profession. Medical authorities have noted that blanket and corporate refusal-to-fill policies might harm the very people that they are intended to benefit. Cutting off access to prescription medication might cause life-threatening withdrawal. And blanket and corporate refusals-to-fill, like any other "barrier[] to obtaining properly prescribed pain medications," might result in "limiting access to optimal pain care. Without such access, many patients face significant medical complications, prolonged suffering, and increased risk of psychiatric conditions." HHS, *Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations* (May 9, 2019), at 62–63.

76. But Walmart has adopted certain doctor-blocking policies, as explained below. It has done so in part as a response to Defendants' unsupported legal positions, even though federal law does not require them and some states may prohibit them.

B. Walmart's Opioid Stewardship Practices Aid the Fight Against Opioid Abuse.

77. Walmart has always complied carefully and faithfully with its CSA obligations. Walmart's more recent Opioid Stewardship Initiative has gone even further, adopting a host of practices—none of which the CSA requires—that help fight opioid abuse.

78. Walmart's comprehensive stewardship efforts are designed to reduce the volume of opioids dispensed; provide pharmacists with the best available training and information to make decisions about opioid prescriptions; give patients safe opioid disposal solutions; educate patients, employees, and the public about the risks of opioids; and save lives by making anti-overdose medications readily available. Walmart has taken steps at every point in its handling of opioids and opioid prescriptions to reduce the risk that opioids are diverted or abused.

79. For example, based on CDC guidance that high-dose initial prescriptions for non-chronic conditions pose a heightened risk for abuse, *see* CDC, Guideline for Prescribing Opioids for Chronic Pain (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm, Walmart instituted a nationwide policy restricting initial acute opioid prescriptions in most circumstances to no more than a seven-day supply of up to 50 MME for patients.

80. Walmart also accelerated—in part due to the current environment of DEA and DOJ pressure, and despite serious disagreement from medical professionals—its implementation of policies allowing blanket refusals-to-fill and corporate refusals-to-fill. If a pharmacist has concerns about a doctor's controlled-substance prescribing practices, the pharmacist may refuse to fill all prescriptions from that doctor. And Walmart may institute a corporate refusal-to-fill that blocks *every* Walmart pharmacy from filling controlled-substance prescriptions from that doctor. These practices—which satisfy DOJ's demands but are not required under the CSA—have led to significant pushback against Walmart and its pharmacists from regulators, medical associations, and individual doctors, as described below.

81. Walmart has devoted enormous resources to enhance its ability to identify and block problematic doctors. Walmart built an Investigative Risk Operations Center ("IROC") to house a team of data analysts and scientists with backgrounds in pharmacy operations, financial services, crime analytics, and software platforms. That team develops and uses cutting-edge statistical analysis to identify potentially problematic doctors so that Walmart's expert investigators—teams of former law enforcement officers stationed across the country—can investigate further. The results of the investigation are then used when determining whether the doctor's prescriptions should be blocked across all of the company's pharmacies through a corporate refusal-to-fill.

82. Walmart shares information it identifies about potentially problematic doctors with law enforcement as appropriate. Walmart has relied on information developed in the IROC to provide in-depth assistance to law enforcement, helping to secure search warrants and to provide compelling evidence leading juries to convict bad doctors. Walmart has also met with officials from DEA and other state and federal agencies to demonstrate IROC's capabilities and to increase collaboration between Walmart and law enforcement.

C. Walmart Faces Pushback from Doctors, Patients, and State Regulators.

83. Predictably, Walmart's stewardship policies have faced sustained resistance from state regulators, medical associations, and individual doctors—resistance that often finds support in the federal government's own contradictory positions on these issues.

84. For example, the AMA wrote to Walmart to criticize its restrictions on initial acute opioid prescriptions, claiming that these restrictions have blocked access for patients "with acute, palliative, cancer-related, chronic pain and other medical conditions requiring amounts or doses greater than [Walmart's] corporate policy." Letter from James L. Madara, M.D., to Thomas Van Gilder (Sept. 24, 2019). The AMA similarly criticized Walmart's new blanket refusal-to-fill and corporate refusal-to-fill policies. In the same letter, it complained that Walmart's policy had "disrupted legitimate medical practices that receive form letters telling them their prescribing rights under state law will be superseded by a Walmart-created algorithm that deems a physician unfit to prescribe." In its view, Walmart was "interfering in the practice of medicine and pharmacy" by assuming the "licensing oversight" that is supposed to be maintained by "medical [and] pharmacy board[s]." *Id.*; *see also* Report 22-A-19 of the AMA Board of Trustees, https://www.ama-assn.org/system/files/2019-05/a19-refcomm-b-addendum.pdf (criticizing Walmart's "blacklist" letters).

85. In pressing these views, the AMA and others in the medical community have often thrown the federal government's inconsistent statements back at Walmart. Medical associations cite HHS's statement that prescribers and patients—not pharmacists—should be the ones making the decisions. *See* HHS, *Pain Management Best Practices Inter-Agency Task Force Report*, at 54 (noting that pharmacists must not use Prescription Drug Monitoring Programs "as tools to stop dispensing medications appropriately to those in need"); *see also, e.g.*, *id.* (noting that "the conclusion of inappropriate multiple provider use" must be made "only after the pharmacist has communicated directly with the prescribing clinician" because "doctors often work as teams"). They also cite the CDC's reluctance to let its guidelines shape pharmacy policies, such as Walmart's restriction on initial acute opioid prescriptions in most circumstances to no more than a seven-day supply of up to 50 MME. In this vein, the authors of the CDC's guidelines criticized the "inflexible application of recommended dosage and duration thresholds" as well as "policies that encourage harm limits and abrupt tapering of drug dosages." Deborah Dowell et al., *No Shortcuts to Safer Opioid Prescribing*, 308 NEW ENG. J. MED. 2285, 2285 (June 13, 2019).

86. Many state regulators continue to contend that state law prohibits corporate headquarters from interfering with an individual pharmacist's dispensing decisions, and that pharmacists who carefully scrutinize the judgments of a licensed doctor have intruded into the practice of medicine.

87. The Tennessee Board of Pharmacy has investigated whether Walmart's refusals to fill prescriptions violate state law and has complained about interference by corporate headquarters with the professional judgment of pharmacists. When Walmart refused to abandon its new policies, the Board conducted a host of inspections of Walmart pharmacies.

88. Wisconsin's Board of Pharmacy has threatened disciplinary action, issuing an Administrative Warning to a Walmart pharmacy in East Green Bay because it "informed a local clinic that the Pharmacy would no longer fill controlled substance prescriptions from that clinic due to concerns of overprescribing." Wisconsin Pharmacy Examining Board, Administrative Warning, Division of Legal Services and Compliance Case Number 17 PHM 095 (Dec. 6, 2018). In the Board's view, "[t]he broad prohibition … deterred pharmacists at the Pharmacy from exercising their independent clinical judgment regarding dispensing controlled substances pursuant to a prescription order." *Id.* It warned that "any subsequent similar violation may result in disciplinary action." *Id.*

89. The President of the Texas Medical Board threatened to issue "cease and desist orders" against those who he believed practiced medicine without a license, such as pharmacists who "change amounts of opioids prescribed" or "override" a physician's judgment. Sherif Zaafran, MD (@szaafran), Twitter (Sept. 29, 2018, 11:29 pm), https://twitter.com/szaafran/status/1046240520786378752. The Texas Medical Board then met with Walmart in April 2019 and expressed concerns that Walmart's pharmacists were overstepping their bounds and engaging in the unauthorized practice of medicine. Oversight of prescriber decisions should be done by the Texas Medical Board alone, it claimed, not by pharmacists. In the Board's view, pharmacists should be limited to identifying indicators of fraud or forgery, but not inquiring into the medical legitimacy of prescriptions issued by licensed and accredited doctors.

90. Complaints against Walmart and its pharmacists for refusing to fill opioid prescriptions have also been filed with, or pursued by, numerous Boards of Pharmacy, including those in Alaska, Arkansas, Colorado, Idaho, Kansas, Maryland, Missouri, New Hampshire, Ohio,

Oregon, Pennsylvania, Tennessee, West Virginia, and Wisconsin. The Idaho Board, for example, has taken the position that any blanket refusals would improperly preclude the pharmacist from exercising professional judgment.

91. This problematic list is far from comprehensive. State attorneys general and other health oversight entities have joined in as well, subjecting Walmart and its pharmacists to additional investigations and proceedings because of Walmart's recent efforts to conform its policies to DEA's expectations.

92. Individual doctors have also fought against Walmart's policies. Some of those subject to Walmart's block policies have filed defamation suits against the company and its individual pharmacists, accusing them of tarnishing the doctors' professional reputations. *See, e.g.*, *Lambertus v. Onken*, No. 83CO-1811-CT-000015 (Ind. Cir. Ct. Nov. 28, 2018) (suing Walmart pharmacist for defamation because pharmacist allegedly told patients that the prescriber was "too loose with her scripts" when refusing to fill them); *Reasor v. Walmart, Inc.*, No. 3:19-cv-27 (W.D. Ky. Jan. 10, 2019) (alleging that a pharmacist stated Walmart pharmacies were "no longer allowed to" fill the prescriber's prescriptions and that the prescriber was "under investigation"). Patients who were unable to fill prescriptions at Walmart have filed lawsuits, too. *See, e.g.*, *Bruno v. Walmart Stores, Inc.*, No. 2019CV000053 (Wis. Cir. Ct. May 3, 2019); *Thomas v. Walmart Inc.*, No. 19CY-CV02460 (Mo. Cir. Ct. Mar. 8, 2019).

93. In short, Walmart and its pharmacists find themselves in an untenable position. Under Defendants' sweeping view, Walmart and its pharmacists may be held liable—perhaps even criminally—for failing to second-guess DEA-registered doctors and refuse their prescriptions. But if pharmacists do so, they may face the wrath of state medical boards, the medical community at large, individual doctors, and patients.

D. Walmart Appropriately Performed Its Obligations When It Self-Distributed to Its Pharmacies.

94. From 2002 until the spring of 2018, Walmart self-distributed Schedule II opioids to its pharmacies. All Schedule II prescription opioids that Walmart self-distributed were shipped to Walmart's pharmacies from a Walmart distribution center in Rogers, Arkansas. Walmart distributed exclusively to its own pharmacies—never to third parties, such as independent pharmacies.

95. Although its systems evolved and improved over the years, throughout the period that it self-distributed controlled substances, Walmart complied with its obligations as a DEA-registered distributor under the CSA.

96. Walmart no longer self-distributes. Instead, it purchases all controlled substances from third-party distributors.

IV. THE GOVERNMENT'S FAILURE TO ENFORCE THE CSA AND PROTRACTED INVESTIGATION INTO WALMART.

97. The government's own watchdog agencies have concluded that Defendants' response to the opioid crisis has been both inept and inadequate. But rather than addressing the deficiencies in its regulations and oversight, and despite Walmart's opioid stewardship practices, Defendants have spent the last four years searching for a theory to, in DOJ's own words, "embarrass" Walmart with a high-profile indictment or civil complaint that will garner press coverage but do nothing to address the opioid crisis.

A. DEA's Failures in Combating the Opioid Crisis.

98. DEA's comprehensive failures have dramatically exacerbated the opioid crisis over at least the past twenty years.

99. In September 2019, the Office of the U.S. Department of Justice Inspector General ("OIG") issued a report entitled "Review of the Drug Enforcement Administration's Regulatory

and Enforcement Efforts to Control the Diversion of Opioids" ("OIG Report"). The report's conclusions (OIG Report at i) were stark:

> We found that DEA was slow to respond to the significant increase in the use and diversion of opioids since 2000. We also found that DEA did not use its available resources, including its data systems and strongest administrative enforcement tools, to detect and regulate diversion effectively.

100. These failures occurred throughout the prescription opioid supply chain, which is subject to DEA's control, from initial manufacture of such substances to their diversion by crooked doctors.

101. Critically, DEA failed adequately to vet applicants for registrations to prescribe, dispense, or distribute narcotics. *Id.* at 15–17. "DEA did not conduct background checks on all new applicants and relied instead on the good faith of applicants to disclose relevant information, even in cases in which the applicant had previously engaged in criminal activity." *Id.* at 15.

102. As to manufacturing, the OIG report noted that while the rate of opioid overdose deaths grew by 8% per year on average between 1999 and 2013—and 71% per year between 2013 and 2017—DEA continued to "authorize[] manufacturers to produce substantial amounts of opioids." *Id.* at 13.

103. The "concerning trend" of *increases* in opioid production quotas between 2010 and 2016 was also explored in a 2020 report by the West Virginia Attorney General. *See* W. Va. Att'y Gen., *DEA's Failure to Combat Diversion Cost Lives: Results from the West Virginia Attorney General's Investigation into the DEA's Catastrophic Failure to Manage the National Drug Quota System From 2010-2016* (June 4, 2020), at ES1–3.

104. Enforcement efforts also failed on the back end. DEA imposed rigid work plans on field divisions, which "le[ft] little room for quickly responding to new information [by] targeting local registrants suspected of prescribing or dispensing opioids outside the scope of

legitimate medical practice." OIG Report at 20. As part of this failure, DEA neglected to act on the tens of thousands of leads Walmart provided to it in the form of refusal-to-fill notifications.

105. OIG also found that DEA rarely used its most potent tool: Immediate Suspension Orders ("ISOs"), which "immediately deprive[] the registrant of the right to manufacture, distribute, prescribe, or dispense controlled substances." *Id.* at 21. In fact, DEA issued only eight ISOs in 2014, five in 2015, 10 in 2016, and six in 2017—for *all* DEA registrants. *Id.* at 22. By contrast, Walmart has blocked all controlled substance prescriptions by thousands of doctors nationwide since it implemented its corporate-block policy.

106. Remarkably, DOJ alleges that pharmacists should be liable for filling facially valid prescriptions from the very doctors DEA registered and, in many cases, continues to register, even after DEA knew about their potentially problematic prescribing practices. But in determining whether to fill an opioid prescription, a critical piece of information on which pharmacists can and must rely is whether the prescribing doctor has been registered by DEA to prescribe controlled substances. Defendants cannot blame pharmacists for relying on registrations that DEA has never revoked.

107. OIG also found glaring shortcomings in DEA's tracking of suspicious order reports from manufacturers and distributors. In fact, of the approximately 1,400 manufacturers and distributors required to report suspicious orders to DEA, the DEA database included reports from only the *eight* manufacturers and distributors that had agreements with DEA to send their reports directly to DEA headquarters. *Id.* at ii. And when OIG asked DEA headquarters officials where the remaining suspicious order reports were, it learned that "staff were unaware of the requirement to maintain the reports and could not locate them." *Id.* at 31. That is, DEA appears to have done nothing with any of the suspicious order reports it did receive. And even though the GAO issued

a report to DEA in 2015 criticizing the ambiguity of regulations concerning identification of suspicious orders and how a suspicious order monitoring system should operate, DEA continued to refuse to promulgate any additional rules. GAO, *Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations* (June 22, 2016), at 19.

B. DOJ Spent Years on an Investigation of Walmart Tainted by Ethical Transgressions.

108. The Government's investigation of Walmart began in December 2016 as a misguided criminal investigation conducted by the United States Attorney's Office ("USAO") for the Eastern District of Texas ("EDTX"). Walmart fully cooperated with the government's investigation. In Spring 2018, the USAO advised Walmart that it intended to indict the company. Its unsupported theory was that Walmart allegedly "conspired" with a local doctor to illegally distribute controlled substances simply because Walmart had not directed its pharmacies to block all future prescriptions from that doctor.

109. Although the USAO offered no evidence of criminal wrongdoing by Walmart or any of its pharmacists, EDTX prosecutors declared their intention to "embarrass" Walmart and tried to use the threat of criminal indictment to pressure the company into paying a massive civil penalty.

110. Among the many examples of unethical conduct during the company's discussions with the USAO, the lead federal prosecutor took out her cell phone and read aloud a confidential text message she said she had received earlier in the day from the then-U.S. Attorney for EDTX (who was absent from the meeting), which she said directed her to terminate the meeting, indict Walmart, and settle with the Company after the indictment. This was a clear violation of DOJ policy and professional ethics rules that prohibit using the threat of criminal charges to extract a civil penalty. The USAO also pointed to the company's size—rather than its alleged conduct—as

the reason it should pay an exorbitant sum. One USAO attorney noted Walmart's $1 billion in charitable giving the prior year as evidence of what Walmart could afford to pay.

111. The USAO also stated that if Walmart did not agree to a nationwide settlement for the exorbitant sum suggested, a particular USAO attorney would travel around the country to encourage other districts to bring cases against the company.

112. Walmart quickly elevated the USAO's misconduct and lack of evidence to support a criminal indictment to DOJ leadership in Washington. In August 2018, DOJ leadership recognized that there was no plausible basis for a criminal indictment, and DOJ formally declined to prosecute Walmart.

113. Notwithstanding the declination of the criminal indictment, DOJ continued the investigation of Walmart by creating a civil Working Group of 15 USAOs and attorneys at Main Justice. The Working Group was co-chaired by the same EDTX USAO attorney who had earlier threatened to contact USAOs across the country to generate cases against Walmart if the company refused to comply with EDTX's demand for a massive civil penalty. The enormous dedication of resources and taxpayer funds to this investigation has been out of all proportion to any evidence of wrongdoing, particularly given the investigation's tainted origin in a misguided criminal inquiry that DOJ attorneys transformed into a civil investigation when their attempt to indict the company failed. Yet Walmart continued to cooperate with DOJ's investigation over the past two years.

114. Some DOJ officials even decided to carry out the earlier threat to "embarrass" Walmart by leaking confidential information—including documents Walmart produced in response to DEA subpoenas and the company's confidential letters to DOJ. The officials also confirmed to the media the existence of the Department's non-public criminal and civil investigations of Walmart. These actions were in clear violation of the Justice Manual and the

Rules of Professional Conduct. In response to DOJ's ongoing misconduct in this investigation, Walmart filed an official complaint with the Department's Office of Professional Responsibility.

115. And now, on information and belief, Defendants intend to pursue a civil enforcement action against Walmart based on a number of positions—identified in Part V below—that are wrong as a matter of federal law.

116. Some of Defendants' positions contradict DEA's own previously expressed views. For example, Defendants assert that some categories of prescriptions are *per se* invalid and can never be dispensed by pharmacists. But DEA has denounced any categorical approach to potentially questionable prescriptions. As reports of large retail pharmacies refusing pain medication prescriptions have increased, DEA has expressed concern that "legitimate patients" are sometimes unable to "get their prescription for pain medications filled at large retail pharmacies" because of those refusals. Matt Grant, *Special Report: Pharmacies Denying Legitimate Patients*, WESH 2 NEWS (Jan. 29, 2015); *see also, e.g.*, Rachel Balick, *Your Best Judgment Is Okay with DEA, Agency Official Says*, 24 Pharmacy Today 46 (June 1, 2018) (reporting the Chief of Liaison and Policy for DEA's Diversion Control Division's statement that DEA lacks rules regarding refusals to fill and that "[w]hether or not they fill the prescription is strictly up to the pharmacist"); Comments of DEA Special Agent Susan Langston to the Florida Board of Pharmacy (Aug. 10, 2015) (stating that "[a]ll patients should be assessed individually" in response to concerns about patients having to do a "pharmacy crawl" to obtain valid prescriptions).

117. On information and belief, DOJ intends to seek massive liability based on the prescriptions Walmart's pharmacists filled for doctors whose prescriptions should supposedly have been rejected across the board. But nearly ***70%*** of the doctors whose prescriptions Defendants intend to place at issue maintain their DEA prescription privileges to this day. DEA

in fact rarely revokes the registration of any doctor and regularly renews the registrations of doctors while an investigation is ongoing. In this way, DEA permits a doctor to continue writing controlled-substance prescriptions, while DOJ simultaneously has stated that it will sue Walmart on the ground that no pharmacist should fill an opioid prescription written by that doctor. But by allowing these doctors to keep their registrations, DEA is implicitly representing to pharmacists and the public that these doctors' ability to continue prescribing controlled substances is in the public interest (because if it were not in the public interest, DEA would revoke their registrations). *See* 21 U.S.C. § 824(a).

118. Walmart and its pharmacists are torn between demands from DOJ and DEA on one side and health agencies and regulators on the other, with patients caught in the middle. To resolve this untenable situation, Walmart now seeks relief from this Court in the form of a declaration establishing the obligations of pharmacists and pharmacies under the CSA.

V. THE RIPE LEGAL DISPUTES BETWEEN WALMART AND DEFENDANTS.

119. A fundamental legal dispute exists between Walmart and Defendants about the nature of pharmacists' and pharmacies' legal obligations under the CSA and its implementing regulations. On information and belief, Defendants intend, in a civil complaint against Walmart, to attempt to retroactively transform general duties demanding case-by-case exercise of professional judgment by pharmacists into mechanical and categorical rules—not found in any statute or regulation—that would effectively impose strict liability based on hindsight.

120. A declaration resolving the parties' legal disputes would fully and finally settle the controversy between them, as it would authoritatively determine the obligations of Walmart and its pharmacists under the CSA and its implementing regulations. Without such a declaration, Walmart and its pharmacists face substantial hardship. Walmart and its pharmacists require

certainty, both to clarify that their ongoing conduct is permissible and to remove the cloud of indeterminacy caused by Defendants' threats.

A. The CSA and Its Regulations Impose No Categorical Duties Relating to Identification, Resolution, or Documentation of "Red Flags."

121. The CSA imposes criminal and civil liability on a pharmacist who dispenses controlled substances "without the written prescription of a practitioner." 21 U.S.C. § 829(a); *see id.* §§ 841(a), (c), 842. Beyond that, the statutory text does not define the duties of a pharmacist. As noted above, two regulations further govern the dispensing of controlled substance prescriptions: 21 C.F.R. §§ 1306.04 and 1306.06.

122. 21 C.F.R. § 1306.04(a) states that "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription," and that any person who "knowingly fill[s]" a prescription not issued "in the usual course of professional treatment" shall be subject to penalties under the CSA.

123. 21 C.F.R. § 1306.06 provides that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice" and with appropriate registration.

124. Many of DOJ's objections to Walmart's and its pharmacists' conduct stem from Defendants' unsupported legal positions surrounding "red flags" that a prescription may not be proper. These red flags are factors DEA believes may indicate that a prescription might not have been issued for a legitimate medical purpose. But the CSA and its implementing regulations do not include the concept of red flags, let alone identify any particular factors as a red flag. Nor do they require that pharmacists—who are charged with exercising their professional judgment—respond to such indicators in any particular way.

125. Many of DOJ's "red flags" themselves were identified by DEA in a series of slideshow presentations delivered at industry conferences. Neither these presentations nor their relevant contents were promulgated pursuant to the Administrative Procedure Act's notice-and-comment rulemaking procedures. Indeed, Defendants have never issued any rule or regulation through notice-and-comment rulemaking that imposes obligations with respect to red flags.

126. At most, these presentations are mere "guidance," 28 C.F.R. § 50.26(a)(1), and Defendants are specifically prohibited by regulation from basing a civil enforcement action on noncompliance with a guidance document. *Id.* § 50.27(b)(1).

127. In any event, even under DEA's non-binding explanations, red flags are merely factors that might, depending on the circumstances, cause a pharmacist to question a particular prescription. DEA itself has recognized the importance of "ensur[ing] that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound medical judgment of their physicians," and to that end has instructed pharmacists that "each case must be evaluated based on its own merits in view of the totality of the circumstances particular to the physician and patient." DEA, *Dispensing Controlled Substances*, 71 Fed. Reg. at 52719–20. And as explained, many state medical and pharmacy boards take a similar view, requiring pharmacists to engage in a specific, individualized assessment of each patient and prescription.

128. Indeed, the CSA and its implementing regulations focus on the legitimacy of *each prescription filled*, considered on an individual basis. And with good reason. As explained above, there may be any number of reasons why pharmacists, in the exercise of their professional judgment based on the facts and circumstances before them, may determine that a prescription may be filled. In short, this regulatory regime does not allow DOJ, after the fact, to declare that

particular red flags or combinations of red flags categorically render entire sets of prescriptions improper and thus trigger liability for the dispensing pharmacists or their employer pharmacies.

129. Notwithstanding the text of the statute and its implementing regulations and DEA's prior position that the presence of a red flag cannot make a prescription *per se* illegitimate, Defendants now take the position that large categories of prescriptions raise "unresolvable" red flags and therefore simply cannot be filled by a pharmacist properly exercising her corresponding responsibility. For instance, Defendants assert that *any* prescription filled by a patient before the next regularly scheduled refill presents a red flag that can never be resolved, and have indicated that so-called "trinity" combinations of drugs may also present unresolvable red flags. On information and belief, DOJ intends to sue Walmart based on Defendants' position that certain red flags make a prescription *per se* improper.

130. DOJ's categorical position finds no support in the CSA or its implementing regulations. And its insistence that some red flags are categorically unresolvable interferes with pharmacists' ability to consider each patient and prescription in the context of the case's individual circumstances, which both the DEA and state boards have emphasized as an essential assessment.

131. Moreover, even if there were categories of facially unfillable prescriptions, DOJ's leap to liability would still be legally unacceptable. *Mistakenly* filling an invalid prescription does not demonstrate that the pharmacist acted *knowingly*. Nor does it prove that the conduct, mistaken as it might have been, was outside the "usual course" of practice. The CSA regulations require individualized, subjective assessment of the pharmacist's mental state and a determination that, in each instance, the pharmacist knowingly filled a prescription that was improper.

132. In addition to claiming that some facially valid prescriptions are so problematic that they can never be filled, DOJ has incorrectly asserted that the CSA and its implementing

regulations require pharmacists to take certain procedural steps when dealing with red flags. DOJ has asserted not only that Walmart's pharmacists and pharmacies must proactively identify red flags associated with a prescription and resolve those red flags before filling the prescription, but also that they must document the resolution of any red flags. This documentation requirement appears nowhere in the CSA or its implementing regulations.

133. As support, DOJ points to DEA registration revocation proceedings. But these administrative decisions apply an entirely different legal standard, and in any event do not announce rules applicable to Walmart or other pharmacies not party to those proceedings. While "[a]djudicated cases may … serve as vehicles for the formulation of agency policies,… this is far from saying … that commands, decisions, or policies announced in adjudication are 'rules' in the sense that they must, without more, be obeyed by the affected public." *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 765–66 (1969) (plurality op.). Sections 1306.04 and 1306.06 are legislative rules that were promulgated through notice and comment. An agency seeking to modify a rule promulgated through notice and comment must employ those same procedures to do so. Just as Defendants may not impose liability through sub-regulatory guidance, they may not use one-off adjudications to impose new legal obligations beyond the scope of existing regulations that are not otherwise found in the governing statute. Nor may they seek to impose such duties through after-the-fact litigation such as the one Defendants have stated they will file.

134. Even if Defendants were entitled to effectively amend the relevant regulations through adjudicatory proceedings, they would nevertheless be obligated to explain their change in position in a manner detailed enough for a reviewing court to examine under 5 U.S.C. § 706. Defendants have not done so. To the extent that DEA's revocation decisions modify parties' obligations under the CSA's implementing regulations, they are arbitrary and capricious.

135. On information and belief, through application of these unsupported red-flag requirements, DOJ intends to sue Walmart on the theory that many facially valid prescriptions are presumptively invalid and either could not be filled under any circumstances, or could not be filled absent investigation by the pharmacist, requiring intrusion into the doctor-patient relationship and second guessing of the doctor's medical judgment. DOJ asserts that a pharmacist, upon being presented with a duly issued prescription, must refuse to fill it until the pharmacist has taken some subsequent action to verify the medical necessity of the prescription. Thus, according to DOJ, when a supposed red flag exists, the pharmacist is required to conduct a second level of review of medical necessity, or "second guess" the prescription's medical necessity. Because DOJ's enforcement position creates new legal obligations beyond those contained in the existing statutes and regulations, it cannot be imposed without notice-and-comment rulemaking, if it can be imposed at all.

136. Finally, DOJ's last flag-related claim—that pharmacists must *document* their resolution of red flags—is entirely without support. This requirement appears nowhere in the CSA or the relevant regulations and sheds no light at all on whether a pharmacist "knowingly filled" an invalid prescription or acted outside the "usual course" of practice. To hold otherwise would effectively impose a strict liability requirement for failure to document the resolution of red flags—thereby, again, imposing a new "rule" without amending the CSA regulations through notice-and-comment rulemaking.

B. 21 C.F.R. § 1306.06 Provides No Basis for CSA Liability.

137. In DOJ's view, § 1306.06 may be violated whenever a pharmacist acts outside the usual course of professional practice, defined as the failure to abide by professional standards within the jurisdiction. Under this view, and contrary to the statutory language, there need not be a "knowing violation." Rather, a pharmacist acts "outside the usual course of professional

practice," and triggers CSA liability, whenever she departs from the standard of care. Every departure from state-law pharmacy practice standards thereby blossoms into an independent federal *crime* under the CSA. That position has no basis in law.

138. The only two cases finding violations of § 1306.06 involved knowing violations. *United States v. Williams*, 416 F. Supp. 611, 613 (D.D.C. 1976) (pharmacist "must have known that some of the prescriptions had been forged"); *United States v. Barbacoff*, 416 F. Supp. 606, 609 (D.D.C. 1976) (filled prescriptions "knowing that the signatures" were photocopied). Indeed, the Acting DEA Administrator himself recently explained that, "[w]hen pharmacists *knowingly* fail to follow [physician] instructions in filling otherwise valid prescriptions," they violate § 1306.06. *Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7333 (DEA Feb. 20, 2018) (emphasis added).

139. Moreover, conduct that takes a pharmacist outside "the usual course of professional practice" requires far more than the showing of some deviation from professional or state-imposed norms. Instead, the pharmacist must effectively abandon *all* professional norms, so that his conduct could truly be said to be outside the "usual course of professional practice." This view is consistent with the established meaning of that phrase. "A controlled substance is distributed by a practitioner in the usual course of his professional practice if the substance is distributed by him *in good faith in medically treating a patient*." *United States v. Feingold*, 454 F.3d 1001, 1006 (9th Cir. 2006) (emphasis added).

140. For example, the Supreme Court explained in *United States v. Moore* that there was sufficient evidence to find that a physician was acting outside "the course of his professional practice" when, "[i]n practical effect, he acted as a large-scale 'pusher' not as a physician." 423 U.S. 122, 142–43 (1975); *see also United States v. Alerre*, 430 F.3d 681, 691 (4th Cir. 2005) ("[E]vidence that a physician's performance has consistently departed from accepted professional

standards supports the proposition that the physician was not practicing medicine, but was instead cloaking drug deals under the guise of a professional medical practice."). There is no textual basis for imposing a more exacting standard of conduct on pharmacists than on doctors, nor is there any basis to distinguish between the criminal and civil enforcement contexts, as the predicate act under § 1306.06 is exactly the same.

141. Defendants' aggressive reimagining of the CSA's regulatory framework is arbitrary and capricious, and it runs directly contrary to law. Walmart cannot allow its pharmacists, who come to work every day to help patients, to be caught in this untenable dilemma.

C. Walmart's Corporate-Level Dispensing Policies Are Not a Basis for Imposing CSA Liability.

142. On information and belief, Defendants also intend to seek massive retroactive liability on Walmart under the view that its corporate-level policies violated the CSA. Specifically, they intend to assert that Walmart was required to affirmatively analyze and share information, including information about a particular pharmacist's refusal to fill a particular prescription and the prescribing and prescription-filling habits of particular doctors and patients, across all of its stores. Under this theory, DOJ intends to assert that Walmart as a corporation had an obligation to categorically block prescriptions written by particular doctors based on certain factors, such as when a family doctor prescribes opioids to a large number of patients; when a doctor prescribes the same pharmaceutical regimen to multiple patients; or when a customer has an erratic fill history or fills the same type of prescription at multiple pharmacies.

143. The CSA does not and has never imposed any such obligation. No statutory text, no regulation, and no administrative enforcement action requires a corporate pharmacy to maintain information about refusals to fill, or the prescribing or prescription-filling habits or conduct of particular doctors and patients, let alone analyze such data and share it in a particular way.

Although Walmart has chosen *voluntarily* to require some of these practices—maintaining information about refusals to fill, for example—DOJ may not hold Walmart liable for failing to require any such practices sooner or for failing to require any other practices where no law has ever obligated Walmart to do so. Nor may DOJ hold Walmart's voluntary measures against the company as somehow proving any prior wrongdoing.

144. Indeed, the CSA's implementing regulations specifically *exclude* prescription drug dispensers from the requirement that CSA registrants must "design and operate a system" to detect suspicious orders. *Compare* 21 C.F.R. § 1301.74 (maintenance of effective controls against diversion requires manufacturers and distributors to create suspicious order monitoring systems) *with id.* § 1301.76 (maintenance of effective controls against diversion for pharmacies does not include system-level requirements).

D. Defendants Seek to Enforce Non-Existent Distribution Obligations.

145. With respect to distribution, on information and belief, Defendants intend to seek to enforce specific rules that are not required by the statute or any duly promulgated implementing regulations but instead derive from informal guidance that does not have the force and effect of law.

146. Defendants intend to claim that the CSA required Walmart not only to *report* suspicious orders of opioids, but also to investigate and clear them before shipping. This requirement exists nowhere in the text of the CSA or its implementing regulations. Instead, this purported requirement originated in informal agency guidance—which DOJ itself has stated is not a sufficient basis for enforcement. And the requirement makes no sense as applied to a self-distributor, like Walmart, that ships orders *only to itself*—and thus "knows its customer" and has ample additional controls against diversion of the medications in question.

147. Under 21 C.F.R. § 1301.74(b), distributor registrants are required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and "inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." This is the totality of what the CSA and its regulations require with respect to a distributor's suspicious order monitoring ("SOM") program. The regulations do not impose a requirement that orders be investigated and cleared before shipping.

148. Instead of promulgating clear rules for distributors about what a SOM program should look like, DOJ intends to assert that the "duties" outlined in various DEA guidance letters to pharmaceutical distributors have the force of law, including a duty not to ship orders identified as suspicious by the registrant's SOM system until they have been investigated.

149. This purported duty originated in a December 2007 letter from Deputy Assistant DEA Administrator Joseph Rannazzisi stating that "[r]egistrants must conduct an independent analysis of suspicious orders prior to completing a sale." But again, the regulation provides only that registrants must report suspicious orders to the DEA; it nowhere says those orders cannot be shipped or that the distributor has a duty to investigate before shipping them.

150. Defendants now retroactively rely on this so-called requirement despite agency policy prohibiting enforcement action on the basis of informal guidance. As the *Justice Manual* instructs, enforcement actions "must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents." *Justice Manual* § 1-20.100. That provision implements an Attorney General directive that "guidance may not be used as a substitute for rulemaking." Memorandum of Att'y Gen. Jefferson B. Sessions III, Prohibition on Improper Guidance Documents (Nov. 16, 2017), *available at* https://www.justice.gov/opa/press-release/file/1012271/download. The Department has recently codified this requirement in its

binding regulations. *See* Interim Final Rule, Processes and Procedures for Issuance and Use of Guidance Documents, 85 Fed. Reg. 63200 (effective Oct. 7, 2020) (to be codified at 28 C.F.R. pt. 50).

151. Moreover, any attempt to impose this "no ship" duty faces the additional obstacle that such a duty would represent a dramatic change in agency policy. The Unit Chief of the E-commerce Section at the Office of Diversion Control at the DEA testified "that the DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products, and that practice had been approved by the DEA." *United States v. $463,497.72 in U.S. Currency*, 853 F. Supp. 2d 675, 685 (E.D. Mich. 2012). DEA officials feared the "change in policy" alluded to in the DEA guidance letters would confuse distributors, "since the prior 'report-only' policy had been in place for 35 years." *Id.*

152. An agency cannot change its position without at least acknowledging and explaining the change. DEA has not acknowledged any change here, let alone explained it.

153. Furthermore, even when an agency recognizes and explains a change in position, the new position is still invalid if it conflicts with an existing rule. The "no ship" guidance is inconsistent with the DEA's own regulations—which do not include a prohibition on shipment of suspicious orders—and is therefore invalid.

154. Defendants cannot impose liability based on a legal duty that finds no support in statute or regulation. Because the purported shipping requirement would impose new due diligence and "no shipping" obligations on distributors and is inconsistent with the federal statutory and regulatory scheme, it can be imposed only through legislative rulemaking. At the least, Defendants must acknowledge and explain their change in position. They have failed to do so, and therefore the requirement cannot be enforced.

E. The CSA Does Not Impose Civil Liability Related to Suspicious Order Reporting.

155. Moreover, on information and belief, Defendants intend to seek civil penalties related to Walmart's purported failure to submit suspicious order reports. The CSA provides no basis for Defendants to pursue such penalties. During the period in which Walmart self-distributed opioids to its own pharmacies, the sole remedy for a failure to file suspicious order reports was a registration revocation proceeding. That remedy is obviously unavailable against a party that is no longer registered as a distributor.

156. The penalty provision cited by DOJ, 21 U.S.C. § 842(a)(5), allows the Department to seek civil penalties if a CSA registrant "refuse[s] or negligently fail[s] to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required *under this subchapter or subchapter II*" of the CSA (emphasis added). This language refers to the statute—not to its implementing regulations. Defendants therefore may seek civil penalties based on this provision only if a registrant fails to "make, keep, or furnish" a record required *by statute*.

157. The CSA itself requires registrants to make, keep, or furnish numerous records, reports, or other items that fall within the civil penalty provision. For example, 21 U.S.C. §§ 827–828 provide for the following:

1. Every two years, every registrant must "make a complete and accurate record of all stocks thereof on hand";

2. Any time the Attorney General issues a regulation "controlling a substance that immediately prior to such date was not a controlled substance," every registrant "shall make a complete and accurate record of all stocks thereof on hand";

3. Every registrant must "maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, [or] delivered";

4. Every manufacturer must "make periodic reports ... of every sale, delivery or other disposal by him of any controlled substance";

5. Every distributor must periodically report sales of narcotic controlled substances; and

6. Distributors after filling an order must "preserve such order for a period of two years."

158. During the period in which Walmart self-distributed, the CSA did *not* require distributors to "make, keep, or furnish" suspicious order reports. That requirement instead was imposed by the Department through *regulations*. 21 C.F.R. § 1301.74. Compliance with that regulation—that is, whether the distributor maintained "effective control against diversion," 21 U.S.C. § 823(b)—could be considered as a factor in determining whether to revoke the distributor's registration. *See* 21 C.F.R. § 1301.74.

159. Because suspicious order reports were not required by the statute itself, the sole remedy available to DEA for a failure to file one is registration revocation. Civil penalties are not available for a purported failure to detect and report suspicious orders.

160. Congress has since updated the CSA such that the statute itself now requires registrants to operate a suspicious order monitoring system and report suspicious orders to DEA, 21 U.S.C. § 832(a), but civil penalties cannot be imposed retroactively on Walmart for conduct that occurred before the statute was amended. Indeed, Congress' decision to make this change strongly reinforces that penalties were *not* available under prior law.

161. Defendants' position as to each of these legal disputes harms Walmart now and in the future. Walmart's pharmacists continue to dispense controlled substances and encounter "red flags" in doing so. And Walmart continues to disagree with Defendants about the scope of its corporate-level dispensing policy obligations, distribution obligations, and civil liability under the CSA. Regulatory contradiction and the threat of massive liability inhibit Walmart's and its pharmacists' efforts to fully comply with all applicable laws while serving the public.

CLAIM FOR RELIEF

DECLARATORY JUDGMENT ACT, 28 U.S.C. § 2201

162. Walmart repeats and incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

163. Walmart faces the risk of a civil enforcement action under the CSA.

164. The CSA and its duly promulgated regulations do not set forth the legal standards upon which Defendants purport to base their civil enforcement action against Walmart. For example, contrary to Defendants' statements, no statutory provision, final agency rule, or published guidance has ever indicated that a pharmacist or pharmacy must categorically reject all prescriptions from a doctor with a valid, active DEA registration.

165. Specifically, Defendants may not impose liability under the CSA and its implementing regulations based on (1) purported red flag obligations; (2) anything short of a *knowing* violation by Walmart pharmacists; (3) corporate-level dispensing policies; (4) non-existent distribution duties; or (5) purported failures to submit suspicious order reports.

166. *First*, Defendants have taken the position that certain red flags or combinations of red flags render prescriptions categorically invalid and unfillable, and that pharmacists and pharmacies have an obligation to resolve—and document the resolution of—certain red flags. In doing so, Defendants have effectively sought to confer the force of law on the purported "duties" outlined in DEA informal letters and conference presentations concerning pharmaceutical dispensing. But none of these purported legal requirements is found in the text of the CSA or its implementing regulations. In fact, as noted above, the purported duties on which DEA seeks to base liability are found only in scattered, sub-regulatory, informal "guidance" that DOJ itself has forsworn using as the basis for enforcement actions.

167. Further, Defendants' approach is inconsistent with their prior recognition of the importance of preventing interference with the dispensing of controlled substances to a patient in accordance with the sound judgment of a doctor and their prior instruction to pharmacists that each prescription must be evaluated on a case-by-case basis.

168. *Second*, Defendants assert that Walmart may be liable when its pharmacists make mistakes. Because § 1306.06 requires a *knowing* violation, however, Defendants' interpretation is unsupported by the relevant text.

169. *Third*, no authority requires a corporate pharmacy to maintain, analyze, or share information about refusals to fill or the prescribing or prescription-filling habits or conduct of particular doctors and patients. The CSA reaches, at most, individual pharmacists and registrant pharmacy locations—not a corporate headquarters operating a nationwide chain of pharmacies with individual registrations.

170. *Fourth*, the purported distributor duties that Defendants identify are found only in informal guidance—not in duly promulgated regulations. Such informal guidance does not have the force of law and cannot be enforced against Walmart, particularly in the face of an agency rule *prohibiting* enforcement action on the basis of informal guidance documents.

171. *Fifth*, the CSA does not provide a cause of action for Defendants to pursue penalties for the purported failure to submit suspicious order reports. Rather, for the period in which Walmart self-distributed opioids to its own pharmacies, the only remedy available to Defendants for the failure to file suspicious order reports was a registration revocation proceeding based on regulatory requirements.

172. Defendants' interpretation of the CSA and its regulations is inconsistent with the statutory and regulatory text and purports to obligate Walmart to follow requirements that are unsupported by the relevant statute and regulations.

173. Accordingly, an actual or substantial controversy exists between Walmart and Defendants as to their respective legal rights and duties.

174. This dispute is ripe. As set forth above, on information and belief, Defendants intend to file a civil enforcement action based on alleged violations of the CSA and the False Claims Act, and Walmart disputes the factual and legal basis for such action.

175. A declaration would clarify and settle the parties' legal obligations under the text of the CSA and its implementing regulations.

176. Walmart is thus entitled to declaratory relief as set forth below.

PRAYER FOR RELIEF

For the reasons above, Plaintiff respectfully requests that the Court:

1. Declare that:

   A. Pharmacists may be liable under the CSA and its regulations only when they fill a prescription that they know was not issued for a legitimate medical purpose by a prescriber acting in the usual course of the prescriber's professional practice or when pharmacists knowingly abandon all professional norms;

   B. The CSA does not require pharmacists to second-guess a registered and licensed doctor's decision that a prescription serves a legitimate medical purpose;

   C. The CSA and its regulations do not require pharmacists to refuse to fill entire categories of prescriptions without regard to individual facts and circumstances;

   D. The CSA and its regulations do not require pharmacists to document in writing why filling a prescription was appropriate;

   E. Pharmacies do not have an affirmative obligation under the CSA and its regulations to analyze and share aggregate prescription data across its stores and with line pharmacists;

F. Pharmacies do not have an affirmative obligation under the CSA and its regulations to impose corporation-wide refusals-to-fill for particular doctors;

G. The CSA and its regulations do not require distributors not to ship suspicious orders after reporting them;

H. The CSA and its regulations did not impose monetary penalties for failure to report suspicious orders to DEA during the time Walmart self-distributed; and

I. Defendants must follow their own regulations and may not base any enforceable legal positions on the alleged violation of agency guidance rather than obligations found in a statute or duly promulgated rule or regulation.

2. Award costs and attorneys' fees to Plaintiff; and

3. Grant such other relief as may be just and proper.

Dated: October 22, 2020

Respectfully submitted,

/s/ Karen P. Hewitt

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**Application for admission* pro hac vice *forthcoming.*