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

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