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November 24, 2020

Timothy J. Shea, Acting Administrator
Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152

Re: ***Rulemaking Petition To Clarify Obligations Of Opioid Dispensers Under The Controlled Substances Act***

Dear Mr. Shea:

Pursuant to section 553(e) of Title 5 of the U.S. Code, Walmart Inc. petitions the Drug Enforcement Administration for rulemaking regarding any legal duties that the Controlled Substances Act imposes on prescribing physicians, pharmacists, and pharmacy owners beyond those delineated in the Act and existing regulations. The company's petition is attached. All notices to be sent regarding this petition should be addressed to undersigned counsel for Walmart, whose address is included herein.

Thank you for your consideration.

Sincerely,

Pratik A. Shah
Counsel for Walmart Inc.

PETITION FOR AGENCY RULEMAKING

SUBMITTED TO
THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION
NOVEMBER 24, 2020

To:

Timothy J. Shea, Acting Administrator
Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, VA 22152

Submitted on behalf of Petitioner Walmart Inc. by:

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I. Overview

Amidst an unprecedented opioid crisis touching millions of lives, most pharmacists and pharmacy owners are doing their best to comply with legal obligations under the Controlled Substances Act ("CSA"), while respecting their obligations to patients, federal and state regulators, law enforcement agencies, and other actors. On November 2, 2020, the U.S. Drug Enforcement Administration ("DEA") published a notice of proposed rulemaking ("NPRM") setting forth the responsibilities of controlled-substance *distributors*. Statements and actions of DEA and Justice Department enforcement officials demonstrate the urgent need for DEA also to promulgate clear regulations—informed by broad public and expert input—setting forth the specific responsibilities of controlled-substance *prescribers* and the corresponding responsibilities of *dispensers*. Accordingly, Walmart Inc. files this petition for rulemaking.

Pharmacists have a professional duty to fill valid prescriptions. The CSA and existing regulations create two (and only two) circumstances in which pharmacists violate the CSA when filling facially valid prescriptions for controlled substances: (1) if they "knowingly fill[]" a prescription that was not issued by a doctor "in the usual course of professional treatment," 21 C.F.R. § 1306.04(a), and (2) if they fill a prescription outside the "usual course of" pharmacy practice, *id.* § 1306.06. The CSA regulations charge "prescribing practitioner[s]" registered with DEA with the primary "responsibility" for proper dispensing of controlled substances, while conferring on pharmacists a "corresponding" duty that depends on their case-by-case judgment in filling individual prescriptions (without the benefit of a medical license, examining the patient, or access to medical records). *Id.* § 1306.04(a). The role a pharmacist plays thus necessarily depends on the conduct and responsibilities of other actors in the system, including the prescribing physicians (in exercising their own sound medical judgment); state medical boards (in licensing

physicians and approving or prohibiting medical practices); and DEA itself (in registering physicians and revoking the credentials of problematic prescribers).

Despite the seemingly clear-cut allocations of responsibilities in those CSA regulations, pharmacists and pharmacy owners are buffeted by demands and threats of DOJ and DEA, on the one hand, and state medical licensing boards, medical associations, and individual litigants, on the other. The demands DOJ and DEA now seek to impose on pharmacists and pharmacies find no support in the text of the CSA or its regulations; instead, the agencies are seeking to enforce sub-regulatory expectations that pharmacists and pharmacies interfere in the doctor-patient relationship to a degree not contemplated by the CSA. For example, in an atmosphere of increased DOJ and DEA pressure, Walmart took a number of voluntary steps to address certain opioid prescription practices. As a result, Walmart was met with state investigations and lawsuits for interfering with medical practice—that is, for going *too far* in refusing to fill opioid prescriptions. At the same time, DOJ and DEA have threatened to sue Walmart for not going *far enough* in refusing to fill opioid prescriptions—including for continuing to fill opioid prescriptions of licensed physicians still authorized by DEA to prescribe opioids to this day. Indeed, DOJ and DEA enforcement and threatened enforcement of sub-regulatory expectations are contributing to a variety of significant and ongoing legal and policy conflicts among federal agencies, and between federal and state regulators, about the proper role of pharmacists and pharmacies in dispensing controlled substances prescriptions.

Rather than enforce shifting sub-regulatory expectations that contradict the expert guidance of federal and state health regulators, DEA should initiate notice-and-comment rulemaking to provide prescribers, pharmacists, and pharmacies with the advance notice and clarity they need to comply with any CSA obligations. By involving the public and health experts to help clarify the

obligations of these actors, a rulemaking would result in a better informed and more effective approach to managing the opioid epidemic. Not only pharmacists but all actors in the chain of prescription administration—as well as federal and state regulators, patients, and the general public—would benefit from the clarity a rule would provide. DEA should grant this petition for rulemaking.

II. Statement of Interest

Although Walmart is not principally a pharmacy, the company operates more than 5,000 in-store pharmacies nationwide. Walmart's pharmacies help serve the needs of a diverse array of local communities and—as a component of Walmart stores—offer one-stop shopping for customers. Walmart's pharmacy operations also 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). Nearly half of the prescriptions filled at Walmart pharmacies are paid for by one of these programs.

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. Walmart has long encouraged its pharmacists to exercise their professional judgment and to refuse to fill opioid prescriptions that they do not believe to be valid. 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. Despite these efforts, DOJ has stated it will file a civil complaint against Walmart for filling prescriptions with certain "red flags," not categorically refusing to fill certain prescriptions, and not altogether blocking prescriptions from certain doctors (even hundreds still licensed by the DEA). At the same time,

Walmart has been met with inquiries, lawsuits, threats, and investigations from doctors, patients, legislators, and state boards of medicine and pharmacy on the ground that Walmart's actions in blocking dispensing of prescription opioids interfere with the doctor-patient relationship. *See* Eric Felten, *Walmart an Opioid Villain? The Curious Case of a Deep-Pocketed Defendant*, REALCLEAR INVESTIGATIONS (Oct. 23, 2020), *available at* https://www.realclearinvestigations.com/articles/2020/10/23/a_big_culprit_in_opioids_legal_reckoning_is__wait__walmart_125734.html.

The irreconcilable demands faced by Walmart, the thousands of pharmacists it employs, and other pharmacies and pharmacists demonstrate the need to promulgate rules setting forth the specific legal responsibilities of physicians, pharmacists, and pharmacy owners as they relate to prescriptions for opioids and other controlled substances. Walmart believes that initiating a notice-and-comment rulemaking proceeding is both appropriate and necessary in the midst of ongoing uncertainty during an unprecedented nationwide opioid crisis.

III. Under Existing Law, Prescribers Have The Primary Duty To Ensure The Proper Administration of Controlled Substances By Writing Valid Prescriptions, While Pharmacists Owe A Corresponding Duty Not To Knowingly Fill Invalid Prescriptions

Under the statutory and regulatory framework governing the dispensing of controlled substances, the duty is on prescribers—*i.e.*, physicians—to ensure the proper administration of controlled substances through the writing of valid prescriptions. The duty of pharmacists is secondary: they may not *knowingly* fill *invalid* prescriptions written by physicians.

The CSA prohibits "any person . . . who is subject to the requirements of part C to . . . dispense a controlled substance in violation of section 829 of this title." 21 U.S.C. § 842(a)(1). Section 829, in turn, provides that no controlled substance "may be dispensed without the written prescription of a practitioner," *id.* § 829(a)—a requirement that "ensures patients use controlled substances under the supervision of a doctor." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006). The CSA is thus concerned with ensuring that a properly licensed and registered doctor has

authorized the use of the controlled substance through a written prescription. Nothing in the statute restricts a duly registered and licensed pharmacist from dispensing controlled substances under a facially valid prescription.

DEA has promulgated regulations related to the prescribing and dispensing of prescriptions for controlled substances by prescribers and pharmacists. Many of these requirements are technical—*e.g.*, a licensed and registered practitioner must write the prescription, *see* 21 C.F.R. § 1306.03(a); it must "be dated as of, and signed on, the day when issued"; and it must include certain information, such as "the drug name, strength, dosage form, quantity prescribed, [and] directions for use," *id.* § 1306.05(a). Under some circumstances, however, a physician's prescription that meets these technical specifications may still be invalid, in which case it "is not a prescription at all for purposes of the statute." *United States v. Hayes*, 595 F.2d 258, 260-261 (5th Cir. 1979). Two regulations outline those circumstances.

The principal regulation defining a valid "prescription" and (to a limited extent) setting forth the duties of prescribers and pharmacists, 21 C.F.R. § 1306.04(a), 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 . . . is not a prescription within the meaning and intent of [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.

The first sentence of this regulation defines a valid prescription: The doctor must issue it for "a legitimate medical purpose" "in the usual course" of his practice. *Id.* The second allocates responsibility for ensuring adherence to that rule: The primary duty falls "upon the prescribing practitioner," but the pharmacist also holds a "corresponding responsibility." *Id.* The third

sentence spells out how those responsibilities operate in practice and their implications: A "purported prescription" issued outside "the usual course of professional treatment" is not a prescription under 21 U.S.C. § 829, and "the person issuing it" (the doctor) and "the person *knowingly* filling" it (the pharmacist) are both "subject to the penalties provided for violations" of the CSA. *Id.* (emphasis added). Thus, a pharmacist violates the CSA based on this regulation only if (1) the prescriber did not issue prescriptions "for a legitimate medical purpose," and (2) the pharmacist filled them "knowing that the prescriptions were invalid." *United States v. Veal*, 23 F.3d 985, 988 (6th Cir. 1994).

The second regulation, 21 C.F.R. § 1306.06, states that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." The Supreme Court has explained that acting outside "the usual course" of one's profession means abandoning all professional norms to the point of no longer acting in a professional capacity, such as when a doctor "did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded." *United States v. Moore*, 423 U.S. 122, 143 (1975). In that case, the doctor also "did not charge for medical services rendered, but graduated his fee according to the number of tablets desired." *Id*. Because "[i]n practical effect, he acted as a large-scale 'pusher' not as a physician," his activities "f[e]ll outside the usual course of professional practice" and subjected him to CSA liability. *Id*. at 124, 143. The meager case law applying section 1306.06 is in accord. *See 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 . . . and that the bulk of them had not been issued in the course of legitimate medical practice"); *United States v. Barbacoff*, 416 F. Supp. 606, 609 (D.D.C. 1976) (pharmacist filled prescriptions "knowing that the signatures thereon were mechanically reproduced").

DEA has promulgated no other regulations regarding the obligations of pharmacists when dispensing controlled substances like opioids. Current law therefore forbids a pharmacist from knowingly filling a prescription issued by a prescribing physician outside the ordinary course of medical practice, or from dispensing outside the usual course of pharmacy practice—nothing more, nothing less. As DEA has itself emphasized, the decision to fill a particular prescription thus depends on the case-by-case judgment of licensed medical professionals. *See* DEA, The Pharmacist's Manual 42 (2020).

IV. DOJ Has Threatened Enforcement Based On Purported Duties Found Nowhere In The CSA Or Its Regulations, In Conflict With Other Federal Guidance And State Standards

Although the CSA and its implementing regulations place only limited legal obligations on pharmacists—do not knowingly fill an invalid prescription or abandon all professional norms—DOJ and DEA are threatening legal action based on a much broader set of supposed duties found nowhere in the CSA or any regulation:

- *First*, DOJ and DEA have stated that pharmacists must take special (but unspecified) actions regarding prescriptions that raise what DEA calls "red flags"—factors that, according to DEA, might prompt questions about whether the prescription serves a legitimate medical purpose. DOJ has asserted not only that pharmacists and pharmacies must proactively identify such red flags and resolve them before filling a prescription, but also that they must document that resolution.

- *Second*, DOJ and DEA claim that large categories of prescriptions raise "unresolvable" red flags and simply cannot be filled by a pharmacist in any circumstance. For instance, DOJ and DEA have suggested that any prescription presented by a patient a certain number of days before the next regularly scheduled refill constitutes a red flag that can never be resolved, and that so-called "trinity" combinations of drugs—prescriptions that combine an opioid (for pain), a benzodiazepine (for anxiety), and a muscle relaxer—may also constitute unresolvable red flags.

- *Third*, DOJ and DEA have taken the extraordinary and unprecedented position that "acting in the usual course of pharmacy practice includes compliance with all relevant state laws and regulations"—no matter its nature. Compl. ¶ 21, *United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207 (E.D.N.C. filed Oct. 30,

2020), ECF No. 1; *see also* Compl. ¶ 19, *United States v. Farmville Disc. Drug, Inc.*, No. 4:20-cv-0018 (E.D.N.C. filed Jan. 29, 2020), ECF No. 1. In other words, every state regulatory or administrative violation—which may be subject only to minor penalties, or even no penalties at all, under state law—gives rise to a CSA violation and potentially to a *federal crime*.

- *Finally*, according to DOJ and DEA, pharmacy owners like Walmart are required to 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, the corporation that employs a pharmacist has duties extending far beyond those owed by the individual pharmacist, including obligations to categorically block prescriptions written by particular doctors based on (again unspecified) factors.

Imposing liability on pharmacists or pharmacy owners based on such alleged requirements—far beyond those specified in any statute or regulation—would be unlawful. Congress may authorize agencies to promulgate regulations carrying the force and effect of law, and agencies can then enforce those regulations. But only "[r]ules issued through the notice-and-comment process . . . have the force and effect of law." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) (internal quotation marks omitted). And no such rule imposes the above duties. Current DEA regulations impose no categorical obligations (beyond not "knowingly" filling an invalid prescription) and little practical advice on how a pharmacist should go about deciding when not to fill a facially valid prescription from an actively licensed and DEA-registered doctor. Neither the CSA itself nor section 1306.04(a) mentions any specific indicators that a prescription is or may not be valid. They neither specify when such indicators (or any combination of them) would prohibit a pharmacist from filling the prescription nor suggest that a pharmacist must investigate certain indicators before proceeding. No statute or regulation imports the varied pharmacy laws of every state, let alone with the requisite level of clarity. *See United States v. Turley*, 352 U.S. 407, 411 (1957) ("[I]n the absence of a plain indication of an intent to incorporate diverse state laws into a federal criminal statute, the meaning of the federal statute should not be

dependent on state law."). Nor does the CSA or any regulation require pharmacy owners to document or maintain any information about refusals to fill, much less to analyze or share that information in a particular way. In other words, no legally enforceable provision imposes the above restrictions on pharmacies or pharmacists.

What is more, those extra-legal obligations go beyond what pharmacists are trained and licensed to perform. And they conflict with the requirements of state regulators who oversee the practice of pharmacy and medicine. By law, pharmacists presented with a valid 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. 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 viewed by 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. 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.

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 overrides a licensed and registered doctor's professional judgment about the care and treatment of that doctor's patient. Thus, while DEA has recently advised pharmacists *not* to fill prescriptions that are "doubtful, questionable, or suspicious," DEA, The Pharmacist's Manual 42 (2020), patient

advocates, medical and pharmaceutical boards, and even government agencies have cautioned pharmacists against disrupting the normal course of medical care in that 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.

In fact, when they refuse to fill opioid prescriptions, pharmacists and pharmacy owners have been reprimanded, investigated, and even sued. In one instance, the President of the Texas Medical Board threatened to issue "cease and desist orders" against pharmacists who "change amounts of opioids prescribed" or "override" a physician's judgment, asserting that doing so constitutes practicing medicine without a license. Sherif Zaafran, MD (@szaafran), Twitter (Sept. 29, 2018, 11:29 pm), https://twitter.com/szaafran/status/1046240520786378752. In another, Wisconsin's Board of Pharmacy threatened disciplinary action, issuing an Administrative Warning to a Walmart pharmacy 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). The Wisconsin Board claimed that "[t]he broad prohibition . . . deterred pharmacists at the Pharmacy from exercising their independent clinical judgment regarding dispensing controlled substances pursuant to a prescription order," and warned that "any subsequent similar violation may result in disciplinary action." *Id.* The Tennessee Board of Pharmacy similarly 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. Altogether, complaints against Walmart and its pharmacists

for refusing to fill opioid prescriptions have 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.

Pharmacists also have been investigated by state attorneys general and consumer protection officials when patients file complaints with the state after the pharmacist refuses a prescription. And doctors have launched defamation lawsuits against pharmacy owners 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.*, 138 F. Supp. 3d 652 (E.D. Va. 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). Even patients have sued pharmacists and pharmacy owners 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.*, Compl. ¶ 2, *Smith v. Walgreens Boots All., Inc.*, No. 3:20-cv-05451-JD (N.D. Cal. Aug. 6, 2020), ECF No. 1 (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).

All of this puts pharmacists and pharmacy owners in an untenable position. 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—even where so-called "red flags" are present—risks other serious professional and personal

consequences: investigation by the state medical board, a lawsuit from the doctor, and more. Patients with medical needs are caught in the middle.

V. DEA Should Grant This Petition And Initiate Rulemaking To Specify The Duties That Prescribers, Pharmacists, And Pharmacy Owners Owe Under The Controlled Substances Act

1) The Scope Of Opioid Dispensers' Legal Duties Is A Textbook Example Of An Issue That Would Benefit From Notice-And-Comment Rulemaking

The current predicament faced by pharmacists and pharmacy owners—among others, including doctors and patients—cries out for rulemaking by DEA. As explained above, no existing regulation imposes any of the specific expectations that DOJ and DEA have threatened to enforce against pharmacists and pharmacies. Moreover, the agencies' sub-regulatory expectations frequently conflict with the legal and policy judgments of federal and state health agencies. Notice-and-comment rulemaking will standardize dispensing practices and recordkeeping with respect to controlled substance prescriptions; clarify the respective responsibilities of prescribing physicians, pharmacists, and pharmacy owners; and afford all regulated actors the certainty they need to proceed in this challenging area.

The APA "was designed to promote general fairness and regularity in administrative action." *Pan-Atlantic S.S. Corp. v. Atlantic Coast Line R.R. Co.*, 353 U.S. 436, 442-443 (1957). To that end, it mandates specific "procedural requirements which 'assure fairness and mature consideration of rules of general application.'" *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979) (quoting *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 764 (1969) (plurality op.)); *see MCI Telecommc'ns Corp. v. FCC*, 57 F.3d 1136, 1141 (D.C. Cir. 1995) (APA procedures designed to encourage "public participation and fairness to affected parties"). Those procedural requirements ensure that legislative rules—*i.e.*, ones "affecting individual rights and obligations"—are

promulgated only after "certain procedural requisites" are satisfied. *Chrysler*, 441 U.S. at 301-302.

Chief among these procedural safeguards is the right of the public to notice and participation before an agency enacts legislative rules with binding effect. "In enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment." *Chrysler*, 441 U.S. at 316. That "relatively formal administrative procedure tend[s] to foster the fairness and deliberation that should underlie a pronouncement" with the force of law. *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001); *see Small Refiner Lead Phase-Down Task Force v. U.S.E.P.A.*, 705 F.2d 506, 547 (D.C. Cir. 1983) (observing that "notice and the opportunity to be heard are an essential component of 'fairness to affected parties'"). Unlike adjudications, which "by nature are likely to be specific to individuals or entities," rulemaking scenarios "generally involve broad applications of more general principles." *Neustar, Inc. v. FCC*, 857 F.3d 886, 893, 896 (D.C. Cir. 2017). Although "[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." *Wyman-Gordon Co.*, 394 U.S. at 765-766 (plurality op.) (footnote omitted).

Beyond fairness, notice-and-comment rulemaking has a number of other benefits. For one, it "improves the quality of agency rulemaking by ensuring that agency regulations will be 'tested by exposure to diverse public comment.'" *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 547. By inviting public participation, notice-and-comment requirements "assure that the agency

will have before it the facts and information relevant to a particular administrative problem." *MCI Telecommc'ns Corp.*, 57 F.3d at 1141 (internal quotation marks omitted).

Indeed, the benefits of broad public participation are particularly apparent in a complex situation (like this one) where so many "important interests are in conflict." *Chrysler*, 441 U.S. at 316. The "opioid threat (controlled prescription drugs, synthetic opioids, and heroin) continues at ever-increasing epidemic levels, affecting large portions of the United States." DEA, 2019 National Drug Threat Assessment 4, *available at* https://www.dea.gov/sites/default/files/2020-01/2019-NDTA-final-01-14-2020_Low_Web-DIR-007-20_2019.pdf. DEA rules governing controlled substance prescriptions thus affect the interests of a broad array of parties: pharmacists, pharmacy owners, doctors, nurses, patients, hospitals, clinics, state medical boards, medical associations, and federal, state, and local law enforcement, to name a few. Formal rulemaking with public participation is crucial to ensure that DEA properly "strike[s] a balance" in allocating responsibilities among such a multitude of stakeholders. *Chrysler*, 441 U.S. at 316.

In addition to promoting sound decisionmaking, notice-and-comment rulemaking leads to clear rules for regulated parties and helps avoid retroactivity concerns. Especially when an agency has the power to bring enforcement actions, as here, it "should provide regulated parties 'fair warning of the conduct [a regulation] prohibits or requires.'" *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) (alteration in original) (quoting *Gates & Fox Co. v. Occupational Safety & Health Review Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986)); *see, e.g.*, *Phelps Dodge Corp. v. Federal Mine Safety & Health Review Comm'n*, 681 F.2d 1189, 1192 (9th Cir. 1982) ("[T]he application of a regulation in a particular situation may be challenged on the ground that it does not give fair warning that the allegedly violative conduct was prohibited."); *Kropp Forge Co. v. Secretary of Labor*, 657 F.2d 119, 122 (7th Cir. 1981) (refusing to impose sanctions where

standard the regulated party allegedly violated "d[id] not provide 'fair warning' of what is required or prohibited"); *Diamond Roofing Co. v. Occupational Safety & Health Review Comm'n*, 528 F.2d 645, 649 (5th Cir. 1976) ("[S]tatutes and regulations which allow monetary penalties against those who violate them" must "give an employer fair warning of the conduct [they] prohibit[] or require[.]"). Crafting binding legislative obligations through notice-and-comment rulemaking thus offers advance notice to regulated parties and avoids "unfair surprise." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170-171 (2007); *see Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 158 (1991) (identifying "adequacy of notice to regulated parties" as one factor relevant to the reasonableness of the agency's interpretation).

By contrast, fashioning and enforcing obligations through interpretations of ambiguous statutory or regulatory language found only in sub-regulatory guidance or post hoc, case-by-case adjudication "frustrat[es] the notice and predictability purposes of rulemaking." *Christopher*, 567 U.S. at 158; *see NLRB v. Bell Aerospace Co. Div. of Textron Inc.*, 416 U.S. 267, 295 (1974) (an agency should avoid imposing "new liability . . . on individuals for past actions which were taken in good-faith reliance on [agency] pronouncements" or in a case involving "fines or damages"). As the Supreme Court has observed, "[i]t is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference." *Christopher*, 567 U.S. at 158-159. Indeed, one of the reasons courts defer to an agency's interpretation of its own regulations is that the agency's interpretation "itself never forms the basis for an enforcement action." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) (plurality

op.). "An enforcement action must instead rely on a legislative rule, which (to be valid) must go through notice and comment." *Id.*

All of the foregoing principles should be non-controversial. In fact, DOJ has acknowledged them repeatedly and recently: "Criminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents," which "cannot by themselves create binding requirements that do not already exist by statute or regulation." Justice Manual § 1-20.100 (Dec. 2018); *see* 28 C.F.R. § 50.27 (same). That provision implements an Attorney General directive stating 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. DOJ has since codified that requirement in a binding regulation. *See* Interim Final Rule, Processes and Procedures for Issuance and Use of Guidance Documents, 85 Fed. Reg. 63,200 (Oct. 7, 2020) (to be codified at 28 C.F.R. pt. 50). Under that regulation, DOJ cannot "treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations." 28 C.F.R. § 50.27(b)(1). Rather, "[t]he Department must establish a violation by reference to statutes and regulations." *Id*.

The necessity of specific regulations for those doctors and pharmacists who administer and dispense controlled substances is underscored by DEA's recent promulgation of guidance for those who *distribute* such substances. Just weeks ago, DEA issued an NPRM regarding regulations for distributors related to "Suspicious Orders and the Opioid Epidemic." *See* Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, 85 Fed. Reg. 69,282 (proposed Nov. 2, 2020) (to be codified at 21 C.F.R. pt. 1301). As most relevant here, DEA

"propos[ed] to amend its regulations to provide registrants with additional clarity regarding the procedures that must be followed upon receiving an order under suspicious circumstances." *Id.* at 69,288. Among other things, DEA proposed to add a number of specific definitions, as well as to identify specific "procedures for identifying and reporting suspicious orders of controlled substances consistent with the due diligence requirement articulated in" various agency adjudications. *Id.* DEA described "numerous non-quantifiable benefits associated with this rule," including to "provide[] clarity and enhance[] understanding of required procedures," "formalize current business practices and create consistency across all registrants," and "standardize reporting procedures." *Id.* at 69,292; *see id.* at 69,285 (describing regulation as "the next step to address suspicious orders and combat the opioid epidemic"). But this proposed rule explicitly "does not apply to controlled substances dispensed or administered within the normal course of professional practice of a practitioner, to include prescriptions filled by a pharmacy." *Id.* at 69,289

This petition for rulemaking thus seeks clarity for the benefit of regulated actors that *prescribe* and *dispense* rather than distribute. That is, the ultimate goal of this petition is a rule that will "standardize" and "enhance[] understanding of required procedures," increase "efficiency," and provide much-needed "clarity regarding the procedures that must be followed" by pharmacists, pharmacy owners, and doctors in the context of prescriptions for controlled substances including opioids. 85 Fed. Reg. at 69,288, 69,292.

2) <u>DEA's Rulemaking Should Address Topics That Will Clarify The Legal Obligations Of Prescribers, Pharmacists, And Pharmacy Owners</u>

Clarity for prescribers, pharmacists, and pharmacies is urgently needed. As noted, existing CSA regulations related to pharmacists and doctors, sections 1306.04(a) and 1306.06, prohibit pharmacists from filling only those prescriptions they "know[]" to be invalid on a prescription-by-prescription basis (not categorically), and impose no specific investigative requirements on

pharmacists or pharmacy owners. To the extent DEA believes that prescribers and pharmacists should have additional duties beyond those delineated in existing regulations, then DEA should grant this petition and initiate a notice-and-comment rulemaking to impose those duties. Indeed, all actors in the chain of prescription administration—as well as patients, hospitals, federal and state regulators, the public at large, and many others—would benefit from such a rulemaking, and deserve to weigh in before DEA takes further action.

In particular, DEA's rulemaking proceeding should address at least the following issues related to doctor, pharmacist, and pharmacy owner responsibilities under the CSA in the context of writing or dispensing opioid prescriptions:

1) The obligations of a pharmacist relative to those of a prescribing physician.

Existing CSA regulations provide that the "[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." 21 C.F.R. 1306.04(a). State regulations provide the same, limiting the pharmacist's role and ability to second-guess a doctor's professional judgment about the care and treatment of the doctor's particular patient. To the extent DEA believes that the "corresponding" duty of a pharmacist should extend beyond refusing to "knowingly" fill invalid prescriptions, *id.*, it can extend that corresponding duty only through a new rulemaking. Any such rulemaking should address the specific nature of the pharmacist's obligations relative to the duty of the "prescribing practitioner." Indeed, because a pharmacist's responsibility is only "corresponding" to the duties of the "prescribing practitioner," any clarification or extension of a pharmacist's "corresponding" duty when *dispensing* controlled substances necessarily depends on first clarifying and extending the scope of the responsibilities

of practitioners when *prescribing* controlled substances. The rulemaking should address issues such as:

- whether and in what specific circumstances a pharmacist has a duty under the CSA to investigate, or refuse to fill, a facially valid prescription issued by a licensed and DEA-registered prescribing practitioner;

- whether and in what specific circumstances a pharmacist is subject to CSA liability when lacking knowledge, or even clear notice, that a prescription was not issued for a legitimate medical purpose by the DEA-registered practitioner; and

- whether and in what specific circumstances a pharmacist has the authority and duty to refuse to fill entire categories of prescriptions, regardless of the individual facts, even when issued by a DEA-registered practitioner in the usual course of professional medical practice.

2) The obligations of a prescriber or a pharmacist to identify, investigate, document, and otherwise act on "red flags" or other indicia beyond the four corners of a facially valid prescription.

Existing CSA regulations provide that pharmacists shall be liable only for "knowingly filling" a prescription not issued "in the usual course of professional treatment or in legitimate and authorized research." 21 C.F.R. 1306.04(a). Under that regulation, the prescriber bears the responsibility to issue a valid prescription in the first instance, and then the decision to fill a prescription depends on the pharmacist's sound professional judgment as to the validity of the prescription. To the extent DEA believes that pharmacists should have additional duties, it can enforce those new duties only if they are established in a rulemaking and are consistent with the CSA. If DEA believes it should impose such new obligations on pharmacists, it should do so through a rulemaking that addresses the duties of both prescribers and pharmacists with respect to "red flags," including:

- what categories of "red flags" or other indicia, if any, trigger a prescriber's duty under the CSA to refuse to write a prescription, including the weight to ascribe to any particular red flag or combination thereof;

- to what extent, if any, prescribers must document how certain "red flags" or other indicia of potentially problematic prescriptions have been resolved;

- to what extent, if any, prescribers have a duty under the CSA to cooperate with pharmacists seeking to investigate possible "red flags" about prescriptions;

- what duties, if any, pharmacists have under the CSA beyond the existing obligation to refuse to fill prescriptions they "know[]" to be invalid;

- what categories of "red flags" or other indicia, if any, trigger a pharmacist's duty under the CSA to question the validity of a prescription issued by a DEA registrant pursuant to a doctor-patient relationship, including the weight to ascribe to any particular flag or combination thereof;

- what process a pharmacist must follow, if any, including what investigative steps must be taken and what resolution is appropriate after any "red flags" are identified; and

- to what extent, if any, pharmacists must document "red flags" or other indicia, including any resolution of the same.

3) The extent to which violations of state medical or pharmacy licensing rules trigger federal CSA liability.

Existing CSA regulations provide that "[a] prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Moreover, such a prescription "may only be filled by a pharmacist, acting in the usual course of his professional practice." *Id.* § 1306.06. To the extent DEA believes that compliance with "the usual course" of the relevant "professional practice" should turn on the prescriber's or pharmacist's compliance with applicable *state* laws and regulations, the rulemaking should address:

- which state rules, if violated, can form the basis of liability under the CSA;

- how CSA liability is affected by the nature of the predicate violation, including the extent, materiality, and procedural finality of any alleged or adjudicated noncompliance with a state law, regulation, or licensing requirement; and

- whether CSA liability is affected when the non-compliance with state rules is subject to minor, *de minimis,* or no penalties under state law.

4) The obligations of a pharmacy business or owner.

Existing CSA regulations do not identify any independent legal duties of a pharmacy business or owner related to the filling of opioid prescriptions. To the extent DEA believes a pharmacy business or owner should have specific duties beyond the duties owed by an individual pharmacist employee, the rulemaking should address:

- the nature of any specific duties owed by a pharmacy business or owner under the CSA separate and apart from the duties of an individual pharmacist;

- whether and to what extent a pharmacy business or owner is required under the CSA to share a pharmacist's refusal to fill a prescription for a particular doctor with all other pharmacists it employs;

- whether and to what extent a pharmacy business or owner is required under the CSA to collect, aggregate, analyze, and/or retain dispensing data, and, if so, what types of dispensing data;

- whether and to what extent a pharmacy business or owner is required under the CSA to provide particular types of data or data analysis to its pharmacists, and, if so, what types of data or data analysis.

VI. Conclusion

For the foregoing reasons, DEA should grant the petition for rulemaking and publish either a notice of proposed rulemaking or an advanced notice of public rulemaking concerning the issues identified above.