IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Miscellaneous Action No.

UNITED STATES DEPARTMENT OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION,

Petitioner,

v.

STATE OF COLORADO BOARD OF PHARMACY,
PATTY SALAZAR, EXECUTIVE DIRECTOR OF THE COLORADO DEPARTMENT OF REGULATORY AGENCIES, and
APPRISS, INC.,

Respondents.

PETITION FOR EXPEDITED ORDER
ENFORCING ADMINISTRATIVE SUBPOENAS

The United States Department of Justice, Drug Enforcement Administration ("DEA"), through the United States Attorney for the District of Colorado, petitions this Court to issue, on an expedited basis, an order directing Respondents—the Colorado Board of Pharmacy; Patty Salazar, Executive Director of the Colorado Department of Regulatory Agencies; and Appriss, Inc.—to comply with two DEA administrative subpoenas seeking data regarding the controlled substances dispensed by two pharmacies under investigation.

The DEA, in coordination with the United States Attorney's Office, is investigating the two pharmacies at issue to determine whether each complied (and is complying) with the law when dispensing controlled substances to patients. To advance those investigations, the DEA issued two subpoenas under the Comprehensive Drug Abuse Prevention and Control Act of 1970

("Controlled Substance Act" or "CSA"), 21 U.S.C. §§ 801–904. The DEA seeks data collected by the Colorado Prescription Drug Monitoring Program ("PDMP") because that data is highly relevant to the investigations. The DEA has been informed that Respondents will not produce all of the dispensing information, as further explained below. The Court has jurisdiction to enforce the subpoenas under 28 U.S.C. §§ 1331 and 1345 and under 21 U.S.C. § 876, which provides that the Attorney General may "invoke the aid of any court of the United States" to compel compliance with the subpoena. 21 U.S.C. § 876(c).

The DEA requests that the Court promptly issue an order, in an expedited manner as authorized by Fed. R. Civ. P. 81(a)(5),[1] that (1) directs Respondents to file a prompt response to this petition, (2) permits a prompt reply by the DEA, and (3) sets a hearing (if the Court deems it necessary) on the petition. The DEA seeks an expedited ruling because the dispensing conduct in which the pharmacies may be engaging has the potential to cause serious public harm.

Three Respondents are named in this petition. First, the Colorado Board of Pharmacy ("Pharmacy Board") is the entity that, by statute, was charged with developing or procuring the Colorado PDMP. *See* Colo. Rev. Stat. § 12-280-403(1). In a prior enforcement action involving PDMP data, the Colorado Attorney General's Office did not object to the Pharmacy Board being

[1] The Court has authority to issue an order setting an expedited briefing schedule to facilitate the issuance of a summary determination on the petition. In a proceeding where a federal agency seeks a summary determination to compel production of documents in response to an administrative subpoena, district courts may issue orders that deviate from the ordinary procedures set forth in the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 81(a)(5) ("These rules apply to proceedings to compel testimony or the production of documents through a subpoena issued by a United States officer or agency under a federal statute, *except as otherwise provided* by statute, by local rule, or *by court order in the proceedings*.") (emphasis added); 1946 Adv. Comm. Notes to Fed. R. Civ. P. 81 (observing that this provision "allows full recognition of the fact that the rigid application of the rules in the proceedings may conflict with the summary determination desired").

named as the respondent. *See U.S. Dep't of Justice v. Colorado Bd. of Pharmacy*, No. 10-cv-01116-WYD-MEH, 2010 WL 3547896 (D. Colo. Sept. 3, 2010) (directing the Pharmacy Board to comply with a DEA administrative subpoena). Second, Executive Director Salazar is an individual with authority to release the subpoenaed information. Third, Appriss, Inc., a private corporation, is the entity that collects, maintains, and processes the Colorado PDMP data in response to requests, as it has been designated by Colorado as the "private agency or organization" tasked with "carrying out the data collection and processing duties" under the PDMP statute. *See* Colo. Rev. Stat. § 12-280-403(5). The petition names all three Respondents to avoid any unnecessary complications as to who a proper Respondent should be; Petitioner is willing to stipulate to dismiss any unnecessary respondents.

BACKGROUND

As explained in detail below, the administrative subpoenas were issued as part of the DEA's investigations of two pharmacies that dispense controlled substances. The DEA issued the subpoenas seeking data that was reported to the PDMP by those two pharmacies showing their dispensing of controlled substances. The Colorado Department of Regulatory Agencies, through its counsel at the Colorado Attorney General's office, has indicated that the Pharmacy Board will not disclose any data identifying the patients to whom the pharmacy dispensed the controlled substances. The DEA seeks a full production, including the patient-identifying data, because that data is highly relevant to the DEA's ongoing investigations of the pharmacies. That data, once produced to the DEA, would be subject to a variety of federal protections against public disclosure.

I. The DEA is investigating the dispensing practices of the two pharmacies to determine whether they have complied with the Controlled Substances Act.

The two Colorado pharmacies under investigation are registered by the DEA to dispense controlled substances.[2] The investigations are assessing whether those pharmacies, in their dispensing of controlled substances to patients, complied with the CSA. The DEA has concerns about the dispensing practices at each pharmacy. *See* Ex. A. (Declaration of Diversion Program Manager Kerry R. Hamilton) at ¶¶ 7-14.

The DEA's authority to conduct these investigations is provided by the CSA. In the CSA, Congress identified a category of potentially dangerous drugs, designated as "controlled substances," that have the potential for abuse and that are subject to strict federal monitoring and regulation. *See Gonzales v. Raich*, 545 U.S. 1, 13-14 (2005). The CSA creates a "closed" system for regulating and monitoring controlled substances, under which it is unlawful to distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. *Id.* at 13.

Congress tasked the Attorney General with regulating this closed system and gave the Attorney General tools to regulate and track controlled substances all the way from the manufacturer to the patient.[3] One tool the DEA uses is registration: anyone who seeks to

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[2] The two pharmacies under investigation have not been informed by the DEA that they are under investigation. To protect the integrity of the investigations and avoid any unfair publicity that may be associated with publicly revealing the subjects of an ongoing government investigation, the identities of the two pharmacies are not identified by name here and have been redacted from the subpoenas attached to this petition. *See* Ex. A at ¶ 9. Petitioner believes that resolution of the dispute presented here does not require disclosure of the identities of the two pharmacies at issue, but should the Court request, Petitioner can provide such information *in camera*.

[3] The Attorney General has in turn delegated his functions under the CSA to the DEA Administrator. 28 C.F.R. § 0.100(b); *see also* 21 U.S.C. § 871(a).

manufacture, distribute, prescribe, dispense, or administer a controlled substance must maintain a federal registration. *See* 21 U.S.C. §§ 822-823, 841. Congress also gave the Attorney General broad authority to enforce the law and to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions" under the CSA. *Id.* § 871(b); *see also id.* § 821 (providing authority to "promulgate rules and regulations … relating to the regulation and control of manufacture, distribution and dispensing of controlled substances").

Here, the DEA is seeking to enforce the law in its investigations of two pharmacies. These investigation focus, in part, on whether those pharmacies have complied (and are complying) with the rules that govern how pharmacies may dispense controlled substances to patients. *See* Ex. A at ¶¶ 3-7; *see also* 21 C.F.R. Part 1306 (establishing rules for dispensing by pharmacies). For example, just as medical practitioners who prescribe controlled substances have obligations to do so for legitimate medical purposes, pharmacists, too, have a "corresponding responsibility" to ensure each prescription for a controlled substance has been "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). A pharmacist also may violate the law by filling a prescription for a controlled substance in a manner outside "the usual course of his professional practice." 21 C.F.R. § 1306.06. Violations of such regulations may lead to penalties or loss of a registration. *See, e.g.*, *United States v. Lovern*, 590 F.3d 1095, 1099-1103 (10th Cir. 2009) (upholding the conviction of a pharmacist who violated his corresponding responsibility under 21 C.F.R. § 1306.04(a)).

II. The DEA seeks the information these two pharmacies reported to the PDMP.

When the DEA investigates pharmacies, a key source of information is the state PDMP, which electronically collects and maintains information that pharmacies report about the controlled substances they dispense. Colo. Rev. Stat. §§ 12-280-401 to -406. Here, in furtherance of its investigations of the two pharmacies, the DEA issued administrative subpoenas seeking data that those pharmacies reported to the Colorado PDMP. One subpoena was issued on August 2, 2019, and the second on August 20, 2019. Each subpoena sought information that the pharmacy had reported to the PDMP about the controlled substances dispensed from the pharmacy at issue. *See* Ex. A at ¶¶ 32-33 & Attach. 1, 2. In submitting the subpoenas to the PDMP, the DEA followed the procedures for law enforcement requests for pharmacy data found on the Colorado Department of Regulatory Agencies' website and using the forms provided. *See id.* ¶ 34. As explained below, the DEA has a critical need for this PDMP information.

A. Colorado law requires pharmacies to report their dispensing of controlled substances and allows the disclosure of that data to law enforcement.

Every day, pharmacies in Colorado are required by state law to report to the PDMP data showing each time they dispensed a controlled substance to a patient. Colo. Rev. Stat. § 12-280-403. This reporting requirement does not cover all prescription drugs they dispense, just controlled substances. *Id.* § 12-280-402(1) (defining the controlled substances covered by the PDMP statute). Most states have enacted similar statutes.[4]

[4] Ex. A at ¶ 17. States vary in how they operate their PDMPs. In California, for example, pharmacies report the prescription information directly to the California Department of Justice. *See* Cal. Health & Safety Code § 11165(a).

In Colorado's statute, the Colorado General Assembly directed the Pharmacy Board to "develop or procure a prescription controlled substance electronic program to track information regarding prescriptions for controlled substances dispensed in Colorado." Colo. Rev. Stat. § 12-280-403(1). The statute permits Colorado to task a "private agency or organization" with "carrying out the data collection and processing duties" under the PDMP statute. *See id.* § 12-280-403(5). Colorado has designated Appriss, Inc., a private corporation headquartered in Kentucky, to carry out those duties. Ex. A at ¶ 35.

Every Colorado pharmacy must report data to the PDMP including certain important details for each instance in which it dispensed a controlled substance to a patient. The statute requires each pharmacy to report, for prescriptions for controlled substances, the "name of the patient and the practitioner," along with "other data elements necessary to determine whether a patient is visiting multiple practitioners or pharmacies, or both, to receive the same or similar medication." Colo. Rev. Stat. § 12-280-403(1). The reported data includes details such as the date the controlled substance was dispensed, the name and amount of the controlled substance, the dispensing pharmacy, and the method of payment. *Id.*; *see also* Colorado State Board of Pharmacy Rules, 3 Colo. Code Reg. 719-1, § 23.00.40 (explaining the data that must be provided in the required data submission format).

In enacting the PDMP, the Colorado General Assembly observed that a central purpose of the PDMP was to identify instances of diversion, such as where a patient may seek to obtain a controlled substance and then divert it to an improper use. The General Assembly found that "[p]rescription drug misuse occurs at times due to the deception of the authorized practitioners where patients seek controlled substances for treatment and the practitioner is unaware of the

patient's other medical providers and treatments[.]" Colo. Rev. Stat. § 12-280-401(1)(b). The General Assembly directed the Pharmacy Board to analyze the PDMP data to identify indicators of potential abuse or diversion of controlled substances. *Id.* § 12-280-404(8) ("The board shall develop criteria for indicators of misuse, abuse, and diversion of controlled substances and, based on those criteria, provide unsolicited reports of dispensed controlled substances to prescribing practitioners and dispensing pharmacies for purposes of education and intervention to prevent and reduce occurrences of controlled substance misuse, abuse, and diversion.").

The state statute expressly permits the PDMP data to be disclosed to a variety of recipients. The recipients may include medical practitioners and pharmacists, state regulatory boards, and the state department of public health and environment. *See id.* § 12-280-404(3).

In particular, the statute allows PDMP data to be disclosed in response to subpoenas from law enforcement. The General Assembly found that "[e]lectronic monitoring of prescriptions for controlled substances provides a mechanism for law enforcement officials and regulatory boards to efficiently investigate practitioner behavior that is potentially harmful to the public." *Id.* § 12-280-401(d). As relevant here, the statute provides that PDMP data relating to a specific pharmacy may be disclosed when law enforcement provides an official subpoena as part of an investigation of that pharmacy. *See id.* § 12-280-404(3)(g) (providing that PDMP data may be provided to law enforcement so long as "the request for information is accompanied by an official court order or subpoena" and "the information released is specific to an individual patient, pharmacy, or practitioner").

The General Assembly enacted requirements to ensure that patients in Colorado are advised that data on the controlled substances they obtain from a pharmacy will be reported to

the PDMP and may be further disclosed to others. In fact, the statute mandates that each patient be informed twice—by their prescriber, and then by their pharmacy—that their prescription information for controlled substances will be provided to the PDMP and then may be further disclosed to others as permitted by the state statute. The statute provides, "Each practitioner and each dispensing pharmacy shall disclose to a patient receiving a controlled substance that his or her identifying prescription information will be entered into the program database and may be accessed for limited purposes by specified individuals." *Id.* § 12-280-403(3).[5]

B. The PDMP data would advance the ongoing DEA pharmacy investigations.

The DEA determined that its investigations of the two pharmacies would be substantially aided by obtaining the data those pharmacies reported to the Colorado PDMP. That data would aid the investigations for several reasons.

The PDMP data is useful evidence about a pharmacy's dispensing of controlled substances. That data is limited to the drugs the DEA regulates—controlled substances—and thus does not include all the other prescription and non-prescription medications the pharmacies may sell. The PDMP data also usefully reflects representations by the pharmacies: it shows what the pharmacies themselves reported that they had dispensed to patients, and thus shows their own knowledge about those patients and their prescriptions. Also, because pharmacies are required by regulation to retain such data only for two years, PDMP data can be the only source

[5] In addition, on its website, the Pharmacy Board advises the public that it works with the DEA, among others. *See* https://www.colorado.gov/pacific/dora/Pharmacy_Program_Info (explaining that the Board "works in conjunction with the Federal Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), Colorado Pharmacists Society, RxPlus Pharmacies, and the Colorado Retail Council").

of information showing what controlled substances the pharmacy dispensed. *See* Ex. A at ¶¶ 18-19.

The PDMP data is particularly useful because it helps to shed light on whether a pharmacy complied with the rules for dispensing controlled substances. In particular, the data can show "red flags"—factors that could have been identified by the pharmacy when it dispensed the controlled substance to a patient. The data can point to red flags in many different ways. *See generally* Ex. A at ¶¶ 22-23. For example, the data includes the quantity, volume, strength, and nature of controlled substances dispensed to a patient; this data enables the DEA to identify high-volume and high-strength prescribing to a patient.[6] *Id.* at ¶ 22. The data also shows whether a pharmacy has refilled a prescription for a patient with unusual frequency. It shows whether the pharmacy dispensed suspect combinations of controlled substances to the patient around the same time, which is significant because there are multiple combinations of different types of controlled substances—opioids and other medications—that, if used by the same patient, may point to potential abuse, and could cause substantial harm, including death. *Id*. at ¶ 23. The data shows what a pharmacist likely would have seen, upon checking the PDMP, about that pharmacy's prior dispensing history to a patient. It also shows how many prescriptions the pharmacies filled for particular practitioners. It also shows payment information, such as whether the prescription was paid for by the federal government, by private insurance, or in cash. *Id.* at ¶ 22.

[6] For example, all opioids have a conversion factor, which allows a comparison of, in essence, the drug's total strength or opioid effect. Ex. A at ¶ 22 n.1.

C. The PDMP's patient-identifying information is of critical importance to the two pharmacy investigations.

The PDMP data includes the name of the patient to whom a pharmacy dispensed a controlled substances, along with other patient-identifying information (such as addresses and birthdates). Ex. A at ¶ 25. In the DEA's investigations of pharmacies, this patient-identifying information is of critical importance, for several reasons.

First, the DEA uses patient-specific information to "connect the dots" with other information or investigative leads already in the DEA's possession. For example, the DEA can examine patient names to determine whether patients who obtained their controlled substances at a pharmacy are known to have suffered from or died from an overdose. It can examine whether the pharmacy's patients are known to have engaged in criminal activity by unlawfully reselling the medications, or are under investigation. The DEA can use patient names to determine whether patients who filled their prescriptions at that pharmacy are patients of a prescriber who the DEA is investigating. Ex. A at ¶¶ 26-27.

Second, the patient-identifying information sheds light on the pharmacy's controls on improper dispensing. For example, the DEA can use the patient-identifying information to determine whether the pharmacy dispensed to multiple patients who report living at the same address. The patient-identifying information can show whether a patient lived an unusual distance from a pharmacy or prescriber. It may reveal patients who obtained similar prescriptions close in time, or patients who used variations on the same name, or other indications that may have suggested the patient was using a false identity or sharing controlled substances with other patients. The patient-identifying information also may reveal patients who are employees of the pharmacy or of other organizations of concern. *Id*. at ¶ 28.

Third, the patient-identifying information enables the DEA to investigate a pharmacy efficiently and follow up on leads quickly. For example, obtaining the names of both the patients and their prescribers enables the DEA to determine which individuals it may wish to interview. The DEA can use a patient interview to determine whether the patient actually received a prescription from a prescriber, or whether the patient did in fact visit the pharmacy and receive the medication shown in the PDMP data. *Id.* at ¶ 29.

Fourth, the patient-specific information enables the DEA to obtain a full picture of a pharmacy's overall dispensing practices. For example, the DEA conducts automated analyses of data to detect unusual patterns, and the patient-identifying information is necessary to make these analyses comprehensive and effective. These automated analyses are aided by the fact that the PDMP data is electronic, whereas a pharmacy may maintain its own records in hard copy format. *Id.* at ¶ 30.

The DEA has historically found Colorado PDMP data, including the patient-identifying data, to be highly useful in advancing its investigations of pharmacies. The DEA has repeatedly subpoenaed Colorado PDMP data in support of its investigations of pharmacies and has obtained that data and relied on it to advance those investigations. *See* Ex. A at ¶¶ 17-18, 26. Until recently, the Pharmacy Board had not raised an objection about producing, in response to DEA subpoenas relating to a pharmacy, the PDMP data that includes patient-identifying information. *Id.* at ¶ 31. In fact, earlier this year, as part of the investigation of one of the subject pharmacies, the Pharmacy Board complied without objection to a prior subpoena for two years of pharmacy data, including all patient-identifying information. *Id.* The DEA has been able to use that data to advance its investigation. *Id.*

The DEA recognizes that information about prescriptions for controlled substances is sensitive. Such sensitive information, when obtained by the DEA, is subject to various protections against public disclosure. *Id.* at ¶¶ 39-42. The DEA is limited by law in when it can release information that it has obtained through an administrative subpoena. 28 C.F.R. § 0.103(a)(1), (2) (permitting disclosure of such information only to state licensing boards and to certain officials engaged in the enforcement of laws relating to controlled substances). Various federal statutes also prohibit federal employees from wrongfully disclosing information. *See, e.g.*, 18 U.S.C. § 1905. If there were public requests for such information, the Freedom of Information Act provides barriers to the release of personal information about individuals. *See* 5 U.S.C. § 552(b)(6), (7)(D). And the DEA and other Department of Justice officials are also subject to Department of Justice policies against the unauthorized disclosure of sensitive personal information. Ex. A at ¶ 42.

III. The Pharmacy Board refused to comply with the two subpoenas.

The Colorado Department of Regulatory Agencies, through its counsel at the Colorado Attorney General's Office, has informed counsel for the DEA that the subpoenas will not be complied with to the extent that the subpoenas require the production of patient-identifying data that those pharmacies had reported to the PDMP. The Pharmacy Board appears to take the position that all patient-identifying information must be omitted from any production because: (a) the patient-identifying information is not sufficiently relevant to the DEA's investigations of those pharmacies, and (b) Fourth Amendment privacy concerns prohibit the disclosure of that information to the DEA. Counsel at the Colorado Attorney General's Office indicated the same

position would be taken as to any future DEA subpoenas seeking the PDMP data for a pharmacy. After discussions, the issue could not be resolved.

ARGUMENT

The Court should issue an order directing Respondents to comply with the subpoenas. First, the subpoenas meet the well-established controlling legal standards that apply to such subpoenas. Second, it would not violate the Fourth Amendment for Respondents to disclose the data. Third, the state statute provides for disclosure of the data in response to the subpoenas.

I. The subpoenas at issue meet the controlling legal standards.

The Supreme Court has held that an administrative subpoena "is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950); *accord McLane v. EEOC*, 137 S. Ct. 1159, 1165 (2017) (holding that if the information sought by an administrative subpoena is relevant, "the district court should enforce the subpoena" unless the subpoena "is 'too indefinite,' has been issued for an 'illegitimate purpose,' or is unduly burdensome"). Under those standards: (a) the DEA's issuance of the subpoenas, which seek information on controlled substances dispensing, was "within the authority of the agency"; (b) the demand for the PMDP data reported by the two pharmacies was specific and thus "not too indefinite"; and (c) the information sought is "reasonably relevant" to the investigations of dispensing by the two pharmacies under investigation. *Morton Salt*, 338 U.S. at 652.

A. The DEA had authority to issue the administrative subpoenas.

The first element of the *Morton Salt* test is met because issuing the subpoenas was "within the authority of the agency." *Morton Salt*, 338 U.S. at 652. In the CSA, Congress

granted the Attorney General broad authority to regulate and monitor controlled substances in a closed system. One tool Congress provided to the Attorney General was the authority to issue administrative subpoenas to obtain records that the "Attorney General finds relevant or material" to an investigation under the CSA. 21 U.S.C. § 876(a) ("In any investigation relating to his functions under this subchapter with respect to controlled substances … the Attorney General may … require the production of any records (including books, papers, documents and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation….").[7]

An agency like the DEA, armed with administrative subpoena authority, is authorized to undertake an investigation and gather information to shed light on the threshold question of whether—or not—certain actors are violating the CSA. *Cf. Okla. Press Pub. Co. v. Walling*, 327 U.S. 186, 198-99, 208-09 (1946) (where the statute permitted the Department of Labor to "investigate such … matters as he may deem appropriate to determine whether any person has violated any provision of the Act," it was "not necessary … that a specific charge or complaint of violation of law be pending or that the order be made pursuant to one. It is enough that the investigation be for a lawfully authorized purpose, within the power of Congress to command.").

Here, the DEA is using its subpoena power under § 876(a) in furtherance of its investigations of the two pharmacies. The Pharmacy Board has not objected that these investigations fall outside the scope of what the DEA's statute authorizes it to seek by administrative subpoena under 21 U.S.C. § 876.

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[7] The Attorney General's authority to issue such subpoenas has been redelegated to certain field officials, including DEA Diversion Program Managers. *See* 28 C.F.R. Part O, Subpart R, Appendix § 4. Here, the two subpoenas were issued by a DEA Diversion Program Manager.

B. The DEA's demand is not too indefinite.

The second element of the *Morton Salt* test is met because the DEA's subpoenas are specific and thus not "too indefinite." *Morton Salt*, 338 U.S. at 652.

Each subpoena here requests a specific set of data, for a specific timeframe, reflecting what each pharmacy reported to the PDMP. Because the request is clear and specific, it does not burden the Pharmacy Board by requiring it review the materials to evaluate their responsiveness. The Board has not argued that the subpoenas are too indefinite. It appears that Respondent Appriss can manage the request and that the data could be produced quickly. Ex. A. at ¶¶ 35-36.

C. The information sought is reasonably relevant to the investigation.

Finally, the third element of the *Morton Salt* test is met because, as explained above, the data sought is "reasonably relevant" to the ongoing investigation. *Morton Salt*, 338 U.S. at 652.

The Supreme Court has recognized that the administrative subpoena authority of a federal agency is broad because the purpose of an administrative subpoena is not adjudicative, but is instead a power "to inquire." *United States v. Clarke*, 573 U.S. 248, 254 (2014) (explaining that the purpose of an IRS summons "is 'not to accuse,' much less to adjudicate, but only 'to inquire'"); *United States v. Powell*, 379 U.S. 48, 57 (1964) (discussing other agencies' administrative subpoena powers as a "power of inquisition") (quoting *Morton Salt*, 338 U.S. at 642-43).

Given this regulatory function, the scope of information that may be sought by an administrative subpoena is much broader than the subpoena authority available during a judicial process. The Supreme Court made this point in *Morton Salt*, where a corporation challenged the authority of the Federal Trade Commission to issue administrative subpoenas. The corporation

argued that the FTC's subpoena was too broad because it was "engaged in a mere 'fishing expedition' to see if it can turn up evidence of guilt." 338 U.S. at 641. In rejecting this argument, the Court criticized prior courts that had rejected administrative subpoenas by "engraft[ing] judicial limitations upon the administrative process." *Id*. at 642; *see also id.* ("This case illustrates the difference between the judicial function and the function the [FTC] is attempting to perform."). The *Morton Salt* Court explained that an agency exercising its administrative subpoena authority "has a power of inquisition … which is not derived from the judicial function. It is more analogous to the Grand Jury, which … can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *Id*. at 642-43. The Court explained that administrative subpoenas can properly be based on "official curiosity" about whether a party has complied with the law. *See id.* at 652 ("Even if one were to regard the request for information in this case as caused by nothing other than official curiosity, nevertheless law-enforcing agencies have a legitimate right to satisfy themselves that corporate behavior is consistent with the law and the public interest."); *see also Phillips Petroleum v. Lujan*, 951 F.2d 257, 260 (10th Cir. 1991) (citing *Morton Salt* for the proposition that an agency "could compel the production of information *even if action was a 'fishing expedition'*") (emphasis added).

Accordingly, where an agency has the authority to issue an administrative subpoena to investigate a matter, "relevance" must be given a broad meaning. The Supreme Court recognized this principle in *United States v. Arthur Young & Co.*, 465 U.S. 805 (1984), where it explained that where a statute permitted the IRS to "'examine any books, papers, records or other data which may be relevant or material' to a particular tax inquiry," the inquiry was "not to be

judged by the relevance standards used in deciding whether to admit evidence in federal court," and that the IRS "should not be required to establish that the documents it seeks are actually relevant in any technical, evidentiary sense." *Id.* at 813-14; *see also id*. at 815 ("Records that illuminate any aspect of the return … are therefore highly relevant to legitimate IRS inquiry."). The Tenth Circuit has similarly held that the reasonable relevance test establishes only "minimal" requirements. In *Becker v. Kroll*, 494 F.3d 904 (10th Cir. 2007), the State of Utah, in an investigation of a doctor, issued administrative subpoenas for the billing records of forty-seven randomly-selected patients over a three-year period. The Tenth Circuit held that the subpoena met the "minimal requirements" for the reasonableness of the subpoena because the records sought were relevant to the state's investigation of potential fraud. *Id.* at 916-17.

Here, the DEA's subpoenas meet these "minimal requirements" for reasonable relevance because the data sought would shed light on the pharmacies' dispensing practices. *Id*. As explained in detail above, the data will aid the DEA, among other things, to assess whether those pharmacies complied with the law when they dispensed controlled substances to patients, to compare the PDMP data with other information gathered in the investigations, and to assess the scope and extent of any violation of law.

In sum, the subpoenas are proper, as they meet all elements of the *Morton Salt* test.

II. Producing the data would not violate the Fourth Amendment.

The Pharmacy Board has suggested, through counsel, that Fourth Amendment privacy concerns may bar the disclosure of the patient-identifying PDMP data in response to the DEA's subpoenas. This argument lacks merit. First, the Supreme Court has set forth the general constitutional standards that apply to such subpoenas, and these subpoenas meet those standards.

Second, the subpoenas are also proper under the standards the Supreme Court and Tenth Circuit have set in cases involving records of prescriptions for controlled substances.

A. The subpoenas comply with the general constitutional standards that the Supreme Court has held apply to administrative subpoenas.

The Supreme Court has held that the "constitutional requirements for administrative subpoenas" are that "'that the subpoena be sufficiently limited in scope, relevant in purpose, and specific in directive so that compliance will not be unreasonably burdensome.'" *Donovan v. Lone Steer, Inc.*, 464 U.S. 408, 415 (1984) (quoting *See v. City of Seattle*, 387 U.S. 541, 544 (1967)); *see also Becker*, 494 F.3d at 916 (explaining that "[t]he Fourth Amendment requires only that an [administrative] subpoena" meet these standards).

These longstanding governing standards[8] are met here because compliance with the subpoenas would not be unreasonably burdensome. The Board has not objected that producing the data relating to these pharmacies is insufficiently specific or that gathering the data would impose an unreasonable burden. The subpoenas are specific and defined. They are limited to the

[8] These constitutional standards for administrative subpoenas were not altered by the Supreme Court's decision in *Carpenter v. United States*, 138 S. Ct. 2206 (2018), where the Court held that an individual maintains a reasonable expectation of privacy in the precise and constant cell-site location information ("CSLI") maintained by a wireless carrier. In that case, the Court repeatedly made clear that its holding was focused on the special surveillance characteristics of CSLI, *id*. at 2218, because CSLI is different from most other business records. *Id*. at 2222 (observing that "CSLI is an entirely different species of business record"); *id.* at 2220 (explaining that "[o]ur decision today is a narrow one"). The Court observed that because CSLI amounted to "tireless and absolute surveillance," the government was required to obtain a warrant before seeking such CSLI records from a wireless carrier. *Id*. at 2218. The Court did not suggest that it was abandoning its extensive prior precedent setting the constitutional standards for administrative subpoenas for other types of information; on the contrary, the Court went out of its way to observe that its holding was limited to CSLI and that "[t]he Government will be able to use subpoenas to acquire records in the overwhelming majority of investigations." *Id*. at 2222.

PDMP data from the two pharmacies. The Board can readily produce this PDMP data; indeed, it previously produced to the DEA some of the PDMP data—including patient-identifying data—for one of the pharmacies.

B. Courts have recognized that while controlled substance prescription records are sensitive, disclosure of such records remains constitutionally permissible.

The Board has objected that privacy concerns prevent it from disclosing the patient-identifying information that the pharmacies reported about the controlled substances they dispensed. Even accepting that controlled substance prescription records are sensitive, the subpoenas remain constitutionally permissible under the applicable standards.

1. The Supreme Court has recognized that while prescription drug records are sensitive, the government may obtain them.

The Supreme Court has long recognized that while prescription records for controlled substances may contain sensitive information, the government still may obtain such records. In *Whalen v. Roe*, 429 U.S. 589 (1977), the Supreme Court rejected a privacy-based constitutional challenge to a New York statute requiring doctors to provide the state with a copy of every prescription for certain controlled substances. In rejecting the privacy-based challenge,[9] the Court in *Whalen* appeared to rely on three separate principles.

First, the Court observed that even if controlled substance prescription records are sensitive, the government has a "vital interest in controlling the distribution of dangerous drugs." *Id*. at 598. The Court observed that collecting these prescription records would aid investigations relating to controlled substances, explaining that the reporting requirement "could reasonably be

[9] The challengers in *Whalen* rested primarily on an asserted privacy interest based on the Fourteenth Amendment, but the Court noted that the privacy challenge also appeared to be based in part on the Fourth Amendment. 429 U.S. at 603-04 & n.32.

expected to have a deterrent effect on potential violators as well as to aid in the detection or investigation of specific instances of apparent abuse." *Id.* at 598.

Second, the Court observed that patients recognize and expect that many health care records—though admittedly sensitive—are routinely and necessarily provided to the government for valid purposes.[10] The Court observed that the required disclosures of controlled substance prescriptions to the State of New York were not "meaningfully distinguishable from a host of other unpleasant invasions of privacy that are associated with many facts of health care," and that "disclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient." *Id.* at 601.

Third, the Court recognized that privacy concerns associated with the government's collection of personal prescription information were diminished because there remained legal protections against the government's public disclosure of that sensitive information. The Court took note that the New York statute created protections against public disclosure of the prescription records. The Court recognized that notwithstanding those protections, public disclosure of those records still might occur because "[a] patient or a doctor may be accused of a violation and the stored data may be offered in evidence in a judicial proceeding." *Id.* at 600. But the Court observed that in any such judicial proceeding, a court could order protections against the disclosure of sensitive information. *Id*. at 601-02 (refusing to invalidate the

[10] Shortly before *Whalen*, the Supreme Court had affirmed (without opinion) a lower court's decision rejecting a privacy-based challenge to the federal government's collection of patient information to assess the propriety of medical services paid for by the Medicare and Medicaid programs. *See Ass'n of Am. Physicians & Surgeons v. Weinberger*, 395 F. Supp. 125, 135-38 (N.D. Ill. 1975) (decision of three-judge panel), *aff'd*, 423 U.S. 975 (1975).

prescription-reporting requirement based on "the remote possibility that judicial supervision of the evidentiary use of particular items of stored information will provide inadequate protections against unwarranted disclosures").

2. The three principles identified in *Whalen* have been reaffirmed.

All three reasons that the Court in *Whalen* relied on in rejecting the privacy-based challenge—that (1) even though prescription records for controlled substances are private, the government has a vital interest in obtaining them; (2) patients recognize that sensitive health records may be disclosed to the government; and (3) privacy concerns are diminished when there are protections against public disclosures—have been reaffirmed in later decisions from the Supreme Court or Tenth Circuit.

First, for example, the Tenth Circuit has recognized that even if there is a privacy interest in prescription drug records for controlled substances, such records still can be collected by the government as part of its regulation of controlled substances. *See Pyle v. Woods*, 874 F.3d 1257, 1264 (10th Cir. 2017) (in rejecting a constitutional claim against a detective based on his access of a state prescription drug database, observing that "any right to privacy in prescription drug records 'is not absolute … as it is well settled that the State has broad police powers in regulating the administration of drugs by the health professions'") (quoting *Douglas v. Dobbs*, 419 F.3d 1097, 1102 n.3 (10th Cir. 2005)); *cf. Douglas*, 419 F.3d at 1102 & n.3 (noting that there is some privacy interest in prescription drug records but that "state law can operate to diminish the privacy expectation" where state law permits disclosure of the records to law enforcement)

Second, the Tenth Circuit has recognized that patients already expect that their medical information may, in some situations, be reported to the government. *See Kerns v. Bader*, 663

F.3d 1173, 1185 (10th Cir. 2011) (in rejecting a constitutional claim against a sheriff who obtained an arrestee's medical records, observing that the Supreme Court has acknowledged that in some situations "a patient might well 'expect that members of the hospital staff might turn over evidence' without his or her consent") (quoting *Ferguson v. City of Charleston*, 532 U.S. 67, 78 n.13 (2001)).

Third, the Supreme Court has reaffirmed the principle that privacy concerns about the government's collection of personal information are allayed where there are protections against the *public* disclosure of that information. In *NASA v. Nelson*, 562 U.S. 134 (2011), the Court found that the federal government did not violate the privacy interests of contract employees by requiring them to answer a questionnaire that asked about illegal drug use. In so ruling, the Court observed that even if "government accumulation of personal information for public purposes may pose a threat to privacy," the Court had recognized in *Whalen* that "a statutory or regulatory duty to avoid unwarranted disclosures generally allays these privacy concerns." *Id.* at 155 (internal quotation marks omitted); *see id*. at 156 (citing federal statutory protections for the information at issue). The Court in *Nelson* explained that even if the government's protections against public disclosure may be imperfect, it had *not* previously held in *Whalen* that "an ironclad disclosure bar is needed to satisfy privacy interests that may be 'root[ed] in the Constitution.'" *Nelson*, 562 U.S. at 157 (quoting *Whalen*, 429 U.S. at 605); *see also Nelson*, 562 U.S. at 158 ("As the Court recognized in *Whalen*, the mere possibility that security measures will fail provides no 'proper ground' for a broad-based attack on government information-collection practices.").

The Tenth Circuit, too, has recognized that privacy concerns about information collected by the government are diminished where the information the government obtains is protected against public disclosure. For example, in *Kerns*, a case rejecting a constitutional claim against a law enforcement officer who sought an arrestee's hospital records, the Tenth Circuit observed that the Supreme Court had held (1) in *Whalen,* that "access by the government without a concomitant public disclosure does not automatically amount to an impermissible invasion of privacy," and (2) in *Nelson,* that the government's collection of information "didn't violate an assumed privacy interest when the information was sufficiently protected against public disclosure." 663 F.3d at 1186 (internal quotation marks omitted).

3. Under the principles identified in *Whalen*, the subpoenas are proper.

Each of these three principles show that constitutional privacy concerns do not prevent Respondents from producing the data sought by the DEA's administrative subpoenas.

a. The DEA has a vital interest in obtaining these controlled substances records. The DEA has a clear interest in obtaining records on controlled substance dispensing to aid it in carrying out its statutory mandate to monitor the closed system of controlled substances. Indeed, in enacting the PDMP, the Colorado General Assembly recognized that one purpose of the PDMP was to "provide[] a mechanism for law enforcement officials and regulatory boards to efficiently investigate practitioner behavior that is potentially harmful to the public." Colo. Rev. Stat. § 12-280-401(d). As explained in detail above, obtaining the controlled substances records at issue is critical to the DEA's ability to investigate the dispensing of controlled substances by the two pharmacies under investigation.

b. Patients are advised that their controlled substances records may be disclosed. As a district court within the Tenth Circuit explained in upholding a DEA administrative subpoena for PDMP records in Utah, "the expectation created by the CSA is that the prescription and use of controlled substances will happen under the watchful eye of the federal government." *U.S. Dep't of Justice v. Utah Dep't of Commerce*, Case No. 2:16-cv-611-DN-DBP, 2017 WL 3189868, at *8 (D. Utah July 27, 2017).

In addition, patients in Colorado are on notice that records on the controlled substances they receive from a pharmacy will be reported by the pharmacy to the PDMP and may then be further provided by the PDMP to law enforcement. The statute creating the PDMP made clear that patient information would be provided to the PDMP and could be further disclosed. The statute not only permits disclosure of PDMP records to law enforcement officials in response to a subpoena, but also directs the Pharmacy Board itself to analyze the data itself to identify potential abuse. Colo. Rev. Stat. §§ 12-280-404(3)(g), (8).

Moreover, Colorado law mandates that patients be warned—by both their prescribing practitioner and their pharmacy—that records of their prescriptions for controlled substances are being reported to the state and could be provided to other individuals. *Id.* § 12-280-403(3).[11]

c. There are protections against public disclosure of these records. Concerns about the sensitivity of the information sought here are allayed because there are regulatory and

[11] The privacy concerns here are further diminished because the DEA's investigations are of the pharmacies. In *Tiffany Fine Arts, Inc. v. United States*, 469 U.S. 310 (1985), the Supreme Court observed that if an IRS summons were issued to a company under investigation where the records sought could shed light on other taxpayers, "any incidental effect on the privacy rights of unnamed taxpayers is justified by the IRS's interest in enforcing the tax laws." *Id.* at 321. Here, similarly, disclosure of the patients to whom the pharmacies dispensed controlled substances is incidental to the DEA's investigation of the two pharmacies' dispensing practices.

statutory protections against public disclosure of the information the DEA gathers. The DEA routinely obtains and protects sensitive information and takes data protection seriously. As explained above, information the DEA obtains through administrative subpoenas can be released only under limited circumstances—"to Federal, State, and local officials engaged in the enforcement of laws related to controlled substances" and to prosecutors and state licensing boards. 28 C.F.R. § 0.103(a)(1), (2). Various other federal statutes and policies also provide protections against release. *See* Ex. A at ¶¶ 40-42.

In sum, all three principles from *Whalen* support a ruling here that disclosure to the DEA of the information that the two pharmacies under investigation reported to the PDMP would not violate the Fourth Amendment.[12]

III. The state statute provides for disclosure of the data.

Another basis for ordering the disclosure of the data sought here is that the Colorado statute provides that the PDMP data "is available for query" by "Law enforcement officials" who are investigating a pharmacy and provide a subpoena seeking the PDMP data for that pharmacy. Colo. Rev. Stat. §§ 12-280-404(3)(g). The Board seeks to redact any patient-identifying data.

[12] There is another reason the Fourth Amendment does not prohibit Respondents from disclosing the information to the DEA: the government—here the State—already has access to that information. As explained above, the Pharmacy Board has access to the data, is itself directed by statute to analyze the data to identify diversion, and is permitted by statute to make disclosures to law enforcement. Once the state lawfully obtained access to that information, the Fourth Amendment does not prevent further disclosure of that information to the federal government, because the Fourth Amendment does not prevent governmental review of evidence already disclosed to the government. *See United States v. Jacobsen*, 466 U.S. 109, 117 (1984) (in a case holding that the Fourth Amendment was not violated when federal agents tested a package that employees of a private freight carrier had already examined, explaining that once information is lawfully obtained to the government, "the Fourth Amendment does not prohibit governmental use" of that information).

But the state statute does not provide for redaction in this context, as can be seen in multiple ways.

First, the text of § 12-280-404(3) does not direct that the Board redact patient-identifying information in a disclosure to law enforcement. That provision, in subsection (g), requires that the information to be disclosed must be "specific to an individual patient, pharmacy, or practitioner," but this requirement just ensures that the information released has a direct nexus to an investigation of a patient, pharmacy, or medical practitioner. This provision does not provide that when the data has a specific nexus to a pharmacy, the data then must be redacted to remove any identifying information for all the pharmacy's patients.

Second, if the General Assembly intended redaction in this context, the statute would have needed to make this clear because, as a practical matter, *every* dispensing transaction that a pharmacy submits to the PDMP relates to a specific patient. The PDMP is a "program to track information regarding prescriptions for controlled substances dispensed in Colorado," Colo. Rev. Stat. § 12-280-403(1). The statute requires the pharmacy to report every time it dispenses a controlled substance to a patient, and expressly requires the reporting of patient-identifying information. *Id.* Put another way, the PDMP does not track pharmacy activities in general; it tracks the specific instances where a pharmacy dispenses controlled substances to specific patients.

Third, the rest of § 12-280-404 shows that the General Assembly knew how to provide for redaction—and that it expressly did so in other contexts. In a later subsection of § 12-280-404(3), the General Assembly provided that patient-identifying information may be redacted

from disclosures to the Colorado Department of Public Health and Environment. Subsection (k) provides that the Board may disclose PDMP data to

> [t]he department of public health and environment for purposes of population-level analysis, but any use of program data by the Department is subject to the federal 'Health Insurance Portability and Accountability Act of 1996', Pub. L. 104-191, as amended, and implementing federal regulations, *including the requirement to remove any identifying data unless exempted from the requirement.*

Colo. Rev. Stat. § 12-280-404(3)(k) (emphasis added). A later subsection—subsection (6)—expressly provides for redaction in another context: it permits the Board to "provide data to qualified personnel of a public or private entity for the purpose of bona fide research or education *so long as the data does not identify a recipient of*, a practitioner who prescribed, or a prescription drug outlet that dispensed, *a prescription drug*." *Id.* § 12-280-404(6). Thus, in two specific contexts—providing data to the Colorado Department of Public Health and Environment for population-level analysis, or providing data to another entity for research or education—the General Assembly expressly provided for the redaction of patient-identifying information disclosed by the PDMP. But the General Assembly included no similar limitation for the disclosures to law enforcement covered by subsection (3)(g).

In sum, the state statute itself provides for the disclosure of the information the DEA seeks here. Indeed, it provides another basis for ordering the disclosure.

If the state statute *did* require redaction in response to a DEA subpoena issued under 21 U.S.C. § 876, such a state restriction on disclosure would be preempted by § 876. In cases where a state statute has set a limit on the disclosure of PDMP data that would limit the DEA's ability to obtain information by subpoena under 21 U.S.C. § 876, courts have consistently held such

state limitations on disclosure are preempted by § 876 and have enforced the subpoenas.[13] For example, in a case in 2010 involving a prior version of the Colorado PDMP statute, the district court in Colorado enforced the DEA's administrative subpoena, ruling that the federal statute that gives the DEA administrative subpoena authority, 21 U.S.C. § 876, preempted a provision of the Colorado statute (since amended) that purported to limit what data could obtained by administrative subpoena. *See U.S. Department of Justice v. Colorado Bd. of Pharmacy*, 2010 WL 3547898 (D. Colo. Aug. 13, 2010), *report and recommendation adopted by* 2010 WL 3547896 (D. Colo. Sept. 10, 2010).

CONCLUSION

Because the subpoenas are proper under the applicable standards and the information is needed promptly for the ongoing investigations, the DEA respectfully requests that the Court issue an order expediting these proceedings—giving Respondents an opportunity to be heard by filing a prompt response to the petition, and allowing a prompt reply by Petitioner to the objections raised by Respondents—and then issue an order directing compliance with the subpoenas.

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[13] *See, e.g., Oregon Prescription Monitoring Program v. U.S. DEA*, 860 F.3d 1228, 1236 (9th Cir. 2017) (holding that a provision of Oregon state law that required a court order before the DEA could obtain PDMP data was preempted by § 876); *U.S. Dep't of Justice v. Ricco Jonas*, No. 18-mc-56-LM, 2018 WL 6718579, at *5 (D.N.H. Nov. 1, 2018) (recommending that an § 876 subpoena be enforced notwithstanding a state rule requiring a showing of probable cause, and noting the "[c]onsistent weight of authority" that § 876 preempts state law that would prevent production of prescription drug records), *report and recommendation adopted by* 2019 WL 251246 (D.N.H. Jan. 7, 2019), *appeal docketed* No. 19-1243 (1st Cir.); *U.S. Dep't of Justice v. Utah Dep't of Commerce*, No. 2:16-cv-611-DN-DBP, 2017 WL 3189868, at *6-7 (D. Utah July 27, 2017) (ruling that a Utah law requiring a warrant for law enforcement access to its PDMP conflicted with, and thus was preempted by, § 876).

Respectfully submitted this 5th day of November, 2019.

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