United States Court of Appeals
For the First Circuit

No. 19-1243

UNITED STATES DEPARTMENT OF JUSTICE,

Petitioner - Appellee,

v.

MICHELLE RICCO JONAS,

Respondent - Appellant.

ORDER OF COURT

Entered: May 3, 2022

Upon consideration of appellant Michelle Ricco Jonas' motion to stay mandate, the appellee having stated no objection, appellant's motion to stay mandate pending the timely filing of a petition for certiorari in the Supreme Court is granted. The issuance of the mandate is hereby stayed for 90 days, and if within that period a timely petition for certiorari is filed, the stay of mandate shall continue until final disposition by the United States Supreme Court. If the petition for certiorari is denied, mandate shall issue forthwith. Counsel for appellant is directed to promptly notify the Clerk of this Court both of the filing of any such petition for certiorari and the disposition.

By the Court:

Maria R. Hamilton, Clerk

cc:
Gilles R. Bissonnette
Robert Barney Mann
Seth R. Aframe
Zachary Heiden
Laura E. B. Lombardi
William Ramirez-Hernandez
Lawrence M. Edelman
Matthew R Segal
Jessie J. Rossman
Anthony J. Galdieri
Henry R. Klementowicz
Emma Bond
Nathan Wessler
Brett Max Kaufman
Jennifer Stisa Granick

United States Court of Appeals
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No. 19-1243

UNITED STATES DEPARTMENT OF JUSTICE,

Petitioner, Appellee,

v.

MICHELLE RICCO JONAS,

Respondent, Appellant.

APPEAL FROM THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

[Hon. Landya B. McCafferty, U.S. District Judge]

Before

Howard, Chief Judge,
and Thompson,* Circuit Judge.

ORDER OF COURT

Entered: May 3, 2022

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* Judge Torruella heard oral argument in this matter and participated in the semble, but he did not participate in the issuance of the panel's opinion. The remaining two panelists therefore issued the opinion pursuant to 28 U.S.C. § 46(d).

Anthony J. Galdieri, Senior Assistant Attorney General, with whom Gordon J. MacDonald, Attorney General, and Lawrence M. Edelman, Assistant Attorney General, were on brief, for Appellant.

Seth R. Aframe, Assistant United States Attorney, with whom Scott W. Murray, United States Attorney, was on brief, for Appellee.

Nathan Freed Wessler, with whom Brett Max Kaufman and Jennifer Stisa Granick were on brief, for American Civil Liberties Union Foundation, amicus curiae.

Gilles R. Bissonnette and Henry Klementowicz, on brief for ACLU of New Hampshire Foundation, amicus curiae.

Zachary L. Heiden and Emma E. Bond, on brief for American Civil Liberties Union of Maine, amicus curiae.

Matthew R. Segal and Jessie J. Rossman, on brief for American Civil Liberties Union Foundation of Massachusetts, Inc., amicus curiae.

William Ramírez, on brief for American Civil Liberties Union of Puerto Rico, amicus curiae.

Robert B. Mann and Robert B. Mann Law Office, on brief for ACLU of Rhode Island, amicus curiae.

January 27, 2022

HOWARD, Chief Judge. Respondent-appellant Michelle Ricco Jonas ("Ricco Jonas"), the Program Manager for New Hampshire's Prescription Drug Monitoring Program (the "PDMP"), appeals from a district court judgment ordering compliance with an administrative subpoena issued to her by the United States Drug Enforcement Administration ("DEA") pursuant to 21 U.S.C. § 876, to produce the PDMP-kept prescription drug records of an individual.[1] On appeal, Ricco Jonas contends that the subpoena is unenforceable because, although it was issued to her and 21 U.S.C. § 876(c) authorizes the enforcement of a "subp[o]ena issued to any person," in her view, the subpoena really targeted the State of New Hampshire and states are not "person[s]" within the meaning of 21 U.S.C. § 876(c) against whom administrative subpoenas may be issued and enforced. Additionally, she argues that, even if 21 U.S.C. § 876(c) generally authorizes the enforcement of administrative subpoenas against a state, the Fourth Amendment still poses a bar to compliance because the subpoena-specified individual has a reasonable expectation of privacy in his prescription drug records, thereby allowing disclosure only after a finding of probable cause by a court. After careful consideration, we reject both of Ricco Jonas's contentions and affirm the district court judgment.

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[1] During the pendency of this appeal, Ricco Jonas informed us that she is no longer the PDMP program manager. Nevertheless, neither party has suggested that the appeal is moot.

I. STATUTORY BACKGROUND

A. The Controlled Substances Act

In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act (the "Act"), Pub. L. No. 91-513, 84 Stat. 1236, to "consolidate various drug laws on the books into a comprehensive statute, provide meaningful regulation over legitimate sources of drugs to prevent diversion into illegal channels, and strengthen law enforcement tools against the traffic in illicit drugs." Gonzales v. Raich, 545 U.S. 1, 10 (2005). The main objectives of Title II of the Act, the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et seq., are "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances."[2] Raich, 545 U.S. at 12; id. at 12-13 ("Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels."). To achieve these goals, Congress established a "closed regulatory system" that makes it unlawful "to manufacture, distribute, dispense, or possess any controlled substance except as authorized by the CSA." Id. at 13 (citing 21 U.S.C. §§ 841(a)(1), 844(a)). As part of this regulatory system, "[t]he CSA requires manufacturers, physicians, pharmacies, and other handlers of

[2] The CSA categorizes controlled substances into five schedules (I through V), based on the drugs' potential for abuse, accepted medical uses, and likelihood of causing psychological or physical dependency. 21 U.S.C. § 812. Drugs categorized in schedules II through V have "a currently accepted medical use in treatment in the United States" or "a currently accepted medical use with severe restrictions." Id. §§ 812(b)(2)-(5). Schedule I drugs do not have any accepted medical use. Id. § 812(b)(1).

controlled substances to comply with statutory and regulatory provisions mandating registration with the DEA, compliance with specific production quotas, security controls to guard against diversion, recordkeeping and reporting obligations, and prescription requirements." Id. at 27 (citing 21 U.S.C. §§ 821-830; 21 C.F.R. § 1301 et seq. (2004)).

The CSA authorizes the Attorney General to issue administrative subpoenas to investigate suspected illicit drug activity. See 21 U.S.C. § 876. Specifically, § 876(a) of the statute provides in relevant part that,

> In any investigation . . . with respect to controlled substances . . . the Attorney General may subpe[o]na witnesses, compel the attendance and testimony of witnesses, and 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. The attendance of witnesses and the production of records may be required from any place in any State or in any territory or other place subject to the jurisdiction of the United States. . . .

Id. § 876(a). The Attorney General has delegated this authority to the DEA. See id. § 878(a)(2); 28 C.F.R. §§ 0.100, 0.104, Appendix to Subpart R, Section 4.

Section 876(c) of the CSA provides for judicial enforcement of subpoenas issued under § 876(a). It states that,

> In the case of contumacy by or refusal to obey a subp[o]ena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subp[o]enaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subp[o]ena. The court may issue an order requiring the subp[o]enaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

21 U.S.C. § 876(c). The CSA provides that state law is preempted whenever "there is a positive conflict between [a] provision of th[e] [CSA] and [a] State law so that the two cannot consistently stand together." Id. § 903.

B. The PDMP and New Hampshire Law

In 2012, the New Hampshire legislature established the PDMP to "enhanc[e] patient care, curtail[] the misuse and abuse of controlled substances, combat[] illegal trade in and diversion of controlled substances, and enabl[e] access to prescription information by practitioners, dispensers, and other authorized individuals

and agencies."[3] New Hampshire PDMP, https://www.newhampshirepdmp.com/ (last visited Jan. 27, 2022).

The PDMP operates an electronic system that "facilitate[s] the confidential sharing of information relating to the prescribing and dispensing of schedule II-IV controlled substances" within the State. N.H. Rev. Stat. Ann. § 126-A:90. Every dispenser – "a person or entity who is lawfully authorized to deliver a schedule II-IV controlled substance" – must report certain information each time a schedule II-IV drug is dispensed, including: dispenser's DEA registration number; prescriber's DEA registration number; patient's name, address, and date of birth; National Drug Code[4] of drug dispensed; quantity dispensed; date of dispensing; number of refills granted; whether the prescription is new or a refill; and, source of payment, among others. Id. §§ 126-A:89(VI), 126-A:91(VI)(a)-(o). This information is then stored in the PDMP database.[5]

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[3] The PDMP is currently administered by the New Hampshire Department of Health and Human Services. N.H. Rev. Stat. Ann. §§ 126-A:89-:96. The PDMP has been previously administered by the New Hampshire Office of Professional Licensure and Certification and the New Hampshire Board of Pharmacy.

[4] National Drug Codes are unique, three-segment numbers which serve as identifiers for drugs. U.S. Food and Drug Administration, National Drug Code Directory, https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory (last visited Jan. 27, 2022).

[5] The information is deleted from the database three years "after the initial prescription was dispensed." N.H. Rev. Stat. Ann. § 126-A:90(III).

New Hampshire state law provides that all information contained in or obtained from the PDMP "is confidential," and "is not subject to discovery, subpoena, or other means of legal compulsion for release."[6] Id. § 126-A:92(I). Law enforcement may request information from the PDMP "on a case-by-case basis for the purpose of investigation and prosecution of a criminal offense when presented with a court order based on probable cause." Id. § 126-A:93(I)(b)(3). However, "[n]o law enforcement agency or official shall have direct access to query program information." Id.

In addition to the state-kept PDMP database, New Hampshire also requires practitioners – including physicians, pharmacists, and hospitals – to maintain their own, similar records "to show the receipt and disposition of all controlled drugs." Id. § 318-B:12(I). These practitioners' records must "meet the requirements of the department of health and human services and federal laws and regulations," and "shall indicate at least the name, dosage form, strength, and quantity of the controlled drug; the name and address of any person to whom the drug was administered, dispensed, sold or transferred and the date of any and all transactions involved with the controlled drug." Id. Unlike PDMP data, law enforcement officials may access a practitioner's own records without a court order. Id.

[6] The Department of Health and Human Services "may use and release information and reports from the program for program analysis and evaluation, statistical analysis, public research, public policy, and educational purposes, provided that the data are aggregated or otherwise de-identified at all levels of use." Id. § 126-A:92(III).

§ 318-B:12(II) ("[Practitioners' records] shall be open for inspection only to federal, state, county and municipal law enforcement officers [and others] . . . whose duty it is to enforce the laws of [New Hampshire] or of the United States relating to controlled drugs.").

II. FACTUAL AND PROCEDURAL BACKGROUND

On June 11, 2018, the DEA issued an administrative subpoena to "Michelle Ricco Jonas, Program Manager for the NH PDMP" pursuant to 21 U.S.C. § 876(a). The subpoena, which was served on Ricco Jonas on June 13, 2018, stated that "[p]ursuant to an investigation of violations of 21 U.S.C. 801 et seq., [she was] to provide any and all records regarding [REDACTED], being maintained by the New Hampshire Prescription Drug Monitoring Program from February 28, 2016 through present day."[7]

On July 12, 2018, Ricco Jonas objected to the subpoena in a letter from the New Hampshire Attorney General's Office sent to the DEA. The letter stated that the subpoena was issued to her in her official capacity

[7] The DEA had previously served an administrative subpoena on the PDMP requesting the same information. The New Hampshire Attorney General objected on the ground that the CSA allegedly does not authorize the DEA to subpoena states or their sovereign agencies. He further argued that, although pursuant to § 876(c) of the CSA the DEA could enforce a subpoena against "any person," neither the State nor its sovereign agencies were "persons" against whom the subpoena could be enforced. Without conceding the point, the DEA subsequently served the subpoena naming Ricco Jonas.

as the Program Manager of the PDMP, rather than in her personal capacity, and thus amounted to a subpoena issued to the State. According to Ricco Jonas, because 21 U.S.C § 876 does not authorize the DEA "to subpoena a [s]tate, its sovereign agencies, or its officials serving in their official capacities," the subpoena was unenforceable. The letter directed the DEA to follow state law and obtain a court order based on probable cause to obtain the desired information.

On August 8, 2018, the Department of Justice ("DOJ") filed a petition to compel compliance with the administrative subpoena in the United States District Court for the District of New Hampshire. In its petition, the DOJ addressed Ricco Jonas's objections from the July 12 letter and argued that those objections failed because the subpoena was issued to Ricco Jonas in her personal capacity and sought no relief from the State. In addition, the DOJ contended that even if the subpoena was directed to the State of New Hampshire, it was nonetheless enforceable because, as a matter of statutory interpretation, the CSA's use of "any person" in § 876(c) includes a state and its agencies. Finally, the DOJ submitted that the CSA preempts any state law limitations on the DEA's authority to issue administrative subpoenas.

Ricco Jonas opposed the petition for essentially the same reasons she asserted in the July 12 letter, along with a new argument based upon the Fourth Amendment. Ricco Jonas contended that even if the CSA permits the issuance of subpoenas to states, patients have a reasonable expectation of privacy in their

prescription drug records under the Fourth Amendment and the DEA must therefore secure a court order based on probable cause before it can obtain PDMP data.

After a hearing, a magistrate judge issued a Report and Recommendation ("R&R") in which she recommended that the court grant the DOJ's petition to compel. U.S. Dep't of Justice v. Ricco Jonas, No. 18-MC-56-LM, 2018 WL 6718579, at *1 (D.N.H. Nov. 1, 2018). The magistrate judge rejected Ricco Jonas's "proposition that her being served because of her position as PDMP manager convert[ed] th[e] subpoena enforcement action [under 21 U.S.C. § 876(c)] into a suit against the State of New Hampshire." Id. at *3. She reasoned that because the subpoena enforcement proceeding would not result in a judgment of any kind requiring financial payment from the State, it was not a suit against the State. Id. The magistrate judge found that the DEA issued the subpoena to Ricco Jonas because she had "custody and control over PDMP information," id., and reasoned that whether she must comply with it in her official or personal capacity was "irrelevant." Id. at *4, *5 n.5. In light of this, the magistrate judge deemed it unnecessary to reach the issue of statutory interpretation and decide whether a state is a "person" under 21 U.S.C. § 876(c) subject to the DEA's subpoena power. Id. at *4. The magistrate judge next determined that the CSA preempted New Hampshire's statutory requirement that law enforcement officials obtain an order based on probable cause before obtaining PDMP data. Id. at *4-5. Finally, because she

deemed the issue non-dispositive, the magistrate judge assumed without deciding that Ricco Jonas had standing – either in her own right or on behalf of others – to make the Fourth Amendment argument. Id. at *6. Nonetheless, she concluded that patients have no reasonable expectation of privacy in their prescription drug records. Id. She reasoned that the closely regulated nature of the prescription drug industry, the state law requirement that the information be transmitted to the PDMP, and its provisions allowing that the data be shared in certain limited circumstances "operate to diminish the privacy expectation in prescription drug records." Id. at *6-7.

After additional briefing from both sides, the district court adopted the R&R and entered judgment in the DOJ's favor. U.S. Dep't of Justice v. Ricco Jonas, No. 19-CV-030-LM, 2019 WL 251246 (D.N.H. Jan. 17, 2019). Ricco Jonas timely appealed.

III. DISCUSSION

On appeal, Ricco Jonas challenges the district court's conclusions that the subpoena is enforceable under 21 U.S.C. § 876(c) and that the Fourth Amendment poses no bar to the disclosure of the prescription drug records to the DEA without a court order based on probable cause.

We review a district court's decision to enforce an administrative subpoena for abuse of discretion, even if it "implicate[s] the privacy interests protected by the Fourth Amendment" or other questions of law. McLane

Co. v. EEOC, 137 S. Ct. 1159, 1169-70 (2017). "A district court would necessarily abuse its discretion if it based its ruling on an erroneous view of the law." Cooter & Gell v. Hartmarx Corp., 496 U.S. 384, 405 (1990); Drysdale v. Spirito, 689 F.2d 252, 256 (1st Cir. 1982) (noting that issues of statutory construction are legal issues).

A. The Target of the Administrative Subpoena

"The requirements for enforcement of an administrative subpoena are not onerous." United States v. Sturm, Ruger & Co., 84 F.3d 1, 4 (1st Cir. 1996). "In order to obtain judicial backing the agency must prove that (1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena." Id. (citing United States v. Morton Salt Co., 338 U.S. 632, 652 (1950)). Only the first requirement is at issue here. A challenge to a subpoena on that ground alone will fail "[a]s long as the agency's assertion of authority is not obviously apocryphal." Id. at 5-6 (citing FTC v. Swanson, 560 F.2d 1, 2 (1st Cir. 1977)).

The CSA provides that administrative subpoenas may be issued "[i]n any investigation relating to . . . controlled substances" to "require the production of any records . . . which the [DEA] finds relevant or material to the investigation . . . from any place in any State." 21 U.S.C. § 876(a). The CSA includes an enforcement mechanism that allows the DEA to invoke

the aid of federal courts "[i]n case of contumacy by or refusal to obey a subp[o]ena issued to any person." Id. § 876(c).

Although Ricco Jonas does not dispute the DEA's congressional authority under 21 U.S.C. § 876(a) to issue a subpoena to her, she contends that, because in order to comply with the subpoena she would need to use her state-issued credentials to access state-collected data and provide it to the DEA, the State of New Hampshire is the subpoena's "true target." This, in her view, makes the instant subpoena one issued to the State, and this enforcement proceeding a "suit" against the State. She posits that the CSA does not authorize courts to enforce subpoenas issued to states because, under her reading of 21 U.S.C. § 876(c), states are not "person[s]" to whom subpoenas may be issued. Accordingly, she concludes, the instant subpoena was not "issued for a congressionally authorized purpose" and is not enforceable.

In response, the DOJ argues that the DEA issued its subpoena to Ricco Jonas, not to the State of New Hampshire, and that "requiring a state employee to produce records is not compelling the state to act; it is requiring the employee to act by producing records over which she has control." The DOJ further argues that, even if the instant subpoena is deemed to have been issued to the State, it is enforceable because 21 U.S.C. § 876 authorizes the issuance and enforcement of subpoenas against states.

To support her argument that the instant subpoena was issued to the State and that this enforcement proceeding constitutes a suit against the State, Ricco Jonas invokes the principle, often arising in the Eleventh Amendment sovereign immunity context, that a suit against a state employee seeking relief from a state is a suit against the state. But even under case law applying that principle, courts have rejected the invitation by state officers to blur the distinction between state officers and the states. Instead, courts have validated the service of process to state officers for the production of documents or objects in their possession or control as persons independent of the states, and regardless of whether the states elect to defend on behalf of their officers. See, e.g., Fla. Dep't of State v. Treasure Salvors, Inc., 458 U.S. 670, 691-92 (1982) (plurality holding that service of process served on state officials for the transfer of some property in the state officials' possession "was directed only at state officials and not at the State itself or any agency of the State" and thus did not constitute a "direct action against the State" under the Eleventh Amendment even if "the State elected to defend on behalf of its agents"); Barnes v. Black, 544 F.3d 807, 812 (7th Cir. 2008) (noting that orders commanding non-party state officials to produce documents in the states' possession for use in a litigation between private persons "do not compromise state sovereignty to a significant degree," hence, do not violate the Eleventh Amendment); Laxalt v. McClatchy, 109 F.R.D. 632, 634-35 (D. Nev. 1986) (rejecting claim by the Nevada State Gaming Control Board that the Eleventh Amendment barred

compliance with a federal discovery subpoena served upon the Board's custodian of records for inspection and copying of records).

Furthermore, even under the principle on which Ricco Jonas relies, courts have concluded that "[t]he service of a federal subpoena on an employee of an entity [that is protected by sovereign immunity]," such as the State of New Hampshire, "is neither a suit, nor one against [the entity]." United States v. Juvenile Male 1, 431 F. Supp. 2d 1012, 1016 (D. Az. 2006); see also Allen v. Woodford, 544 F. Supp. 2d 1074, 1078-79 (E.D. Cal. 2008) (holding that the issuance and required compliance with discovery subpoenas directed to custodians of records of state agencies under the Federal Rules of Civil Procedure did not constitute a "suit in law or equity" within the meaning of the Eleventh Amendment); Juvenile Male 1, 431 F. Supp. 2d at 1016 (holding in a proceeding to enforce a subpoena duces tecum issued under Rule 17(b) and (c) of the Federal Rules of Criminal Procedure that "sovereign immunity from suit [lacks] any application to the enforcement of a federal subpoena on the custodian of records of a state or federal agency"). Some courts have reasoned that an enforcement proceeding seeking to compel a state officer to comply with a subpoena for state records that may only be obtained through the state's custodian of records does not constitute a suit against the state because such proceeding does not assert a claim in law or equity against the state or its officer. See, e.g., Allen, 544 F. Supp. 2d at 1079. "No judgment will be issued . . . against the State that could have any conceivable

effect on the State treasury; the State custodian[ ] [is] only subpoenaed to produce documents for use in [a litigation not involving the State or the State custodian]." Id. We find this reasoning persuasive. Here, the enforcement proceeding does not involve a claim in law or equity against the State of New Hampshire. Nor will a judgment be issued against the State that could have a conceivable effect on New Hampshire's treasury. The relief sought by the DEA through this enforcement proceeding is merely an order for Ricco Jonas to produce records to be used by the DEA in its investigation of violations involving controlled substances and only she, not the State, may be found to be in contempt of court for failing to comply with a court order enforcing the subpoena.

Although Ricco Jonas complains that the cases cited herein involved discovery subpoenas issued under other statutory provisions to obtain documents for pending litigation, she fails to meaningfully discuss, and we fail to see, why such distinction should lead to a different conclusion in this case.[8] After all, an administrative subpoena "amount[s] to no more than a simple direction to produce documents, subject to judicial review and enforcement." Sturm, Ruger & Co., 84 F.3d at 3 (citing, among other authority, Okl. Press Pub. Co. v. Walling, 327 U.S. 186, 195 (1946)). And a proceeding

[8] Nor does she explain why the logic of the cases cited should not control merely because, in her view, this case involves an issue "of statutory interpretation, not Eleventh Amendment immunity," especially when she herself relied on sovereign immunity principles in making her arguments.

to enforce an administrative subpoena, such as the one established in 21 U.S.C. § 876(c), is "a 'satellite' proceeding . . . designed only to facilitate the [federal agency's] investigation," McLane Co., 137 S. Ct. at 1168, by allowing the agency to use "one of the tools" that Congress placed "at its disposal in conducting its investigation[s]." Id. at 1164.

In light of the above, we are unpersuaded by Ricco Jonas's arguments that New Hampshire was the instant subpoena's true target and that this enforcement proceeding constitutes a suit against the State. Furthermore, even if we were to find that the subpoena was really issued to the State, Ricco Jonas's challenge would still fail because as explained below, states, their agencies, and their officials in their official capacities are "persons" within the meaning of 21 U.S.C. § 876(c) against whom subpoenas may be enforced.

B. Statutory Construction of 21 U.S.C. § 876

The parties dispute whether 21 U.S.C. § 876(a) authorizes the Attorney General to issue administrative subpoenas to states and to enforce them under § 876(c). Because this is an issue of statutory construction, we turn to the language of the statute. See In re Fin. Oversight & Mgmt. Bd. for P.R., 919 F.3d 121, 128 (1st Cir. 2019) ("[I]n resolving a dispute over the meaning of a statute we begin with the language of the statute itself." (citing Landreth Timber Co. v. Landreth, 471 U.S. 681, 685 (1985))).

The Attorney General's subpoena power derives from § 876(a) of the CSA. Congress used very broad language in that section: "In any investigation relating to . . . controlled substances, . . . the Attorney General may . . . require the production of any records . . . which [he] finds relevant or material to the investigation. . . . from any place in any State." 21 U.S.C. § 876(a) (emphasis added). Ricco Jonas urges us to find that, despite this broad language, the Attorney General's subpoena authority is limited by § 876(c), which provides that "[i]n the case of contumacy by or refusal to obey a subp[o]ena issued to any person, the Attorney General may invoke the aid of [federal courts]." Id. § 876(c). According to Ricco Jonas, because the CSA does not define "person," we must presume that such term does not include the sovereign, and construe § 876(a) consistent with such limitation. She further argues that "the text, structure, purpose, legislative history, and executive interpretation" of the CSA all lead to the conclusion that states, their agencies, and their officials are not "'persons' who may be targeted and commanded to comply with administrative investigatory subpoenas."

In the absence of an express statutory definition, we apply a "longstanding interpretative presumption that 'person' does not include the sovereign."[9] Return

[9] This presumption both "reflects 'common usage' " and is "an express directive from Congress," which has set forth in the Dictionary Act that, unless context indicates otherwise, "person" includes "corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." Return Mail, Inc. v. USPS, 139 S. Ct. 1853, 1862 (2019) (first

Mail, Inc. v. USPS, 139 S. Ct. 1853, 1861-62 (2019) (quoting Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens, 529 U.S. 765, 780-81 (2000)). This presumption, however, "is not a 'hard and fast rule of exclusion'" and "may be disregarded upon some affirmative showing of statutory intent to the contrary." Id. at 1862 (first quoting United States v. Cooper Corp., 312 U.S. 600, 604-05 (1941); and then quoting Stevens, 529 U.S. at 781); see also Int'l Primate Prot. League v. Adm'rs of Tulane Educ. Fund, 500 U.S. 72, 83 (1991) ("[O]ur conventional reading of 'person' may . . . be disregarded if '[t]he purpose, the subject matter, the context, the legislative history, [or] the executive interpretation of the statute . . . indicate an intent, by the use of the term, to bring state or nation within the scope of the law.'") (first and second alterations ours).

Ricco Jonas's contention that the Attorney General's authority conferred in § 876(a) is limited by § 876(c) is not the most natural reading of the statute. Furthermore, the purpose of 21 U.S.C. § 876, its context, and its legislative history all point to the conclusion that Congress intended to bring states within the scope of the Attorney General's subpoena power under § 876(a) and subject to § 876(c)'s judicial enforcement provision.

Prior to the enactment of the Act in 1970, "most domestic drug regulations . . . generally came in the guise of revenue laws, with the Department of the

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quoting United States v. Mine Workers, 330 U.S. 258, 275 (1947); and then quoting 1 U.S.C. § 1).

Treasury serving as the Federal Government's primary enforcer".[10] Raich, 545 U.S. at 10. Before 1955, the Secretary of Treasury had no authority to subpoena witnesses or to require the production of records with respect to the enforcement of federal laws relating to narcotic drugs. H.R. Rep. No. 84-1247 (1955); H.R. Rep. No. 84-1347 (1955). At the time, it was "necessary for the enforcement officers of the Treasury Department to obtain subp[o]enas through the Federal courts upon a showing of sufficient evidence to justify the issuance of the subp[o]enas." H.R. Rep. No. 1247; H.R. Rep. No. 84-1347. Congress believed that "[t]his lack of authority handicap[ped] enforcement officers of the Treasury Department." 101 Cong. Rec. 11,683 (1955) (remarks of Rep. Cooper). Because Congress was of the view that "the power to subpoena witnesses, and to require the production of records [would be] a legitimate and effective aide to the administration of regulatory and penal statutes," H.R. Rep. No. 1347, on August 11, 1955, it passed Public Law 362. See Act of Aug. 11, 1955, ch. 800, Pub. L. No. 84-362, 69 Stat. 684, codified as 21 U.S.C. §§ 198a-198c.

Public Law 362 authorized the Secretary of the Treasury "to . . . subp[o]ena witnesses . . . and require the production of any records (including books, papers,

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[10] Congress eventually "shifted the constitutional basis for drug control from its taxing authority to its power to regulate interstate commerce, and in 1968 [narcotic enforcement] was transferred to [the Department of Justice]." Lisa N. Sacco, Cong. Research Serv., R43749, Drug Enforcement in the United States: History, Policy, and Trends 5 (2014), available at https://sgp.fas.org/crs/misc/R43749.pdf (last visited Jan. 27, 2021).

documents, and tangible things which constitute or contain evidence) which [he deemed] relevant or material to [an] investigation [in connection with the enforcement of narcotic drugs and marihuana laws]." Pub. L. No. 362, § 1 (authorizing subpoenas in connection with the enforcement of narcotic laws) (emphasis added). Under this provision, records were subject to the subpoena authority of the Secretary of Treasury as long as he deemed them relevant or material to an investigation relating to narcotic drugs or marihuana laws, regardless of who the records belonged to or who was their custodian. See 101 Cong. Rec. 11,683 (remarks of Rep. Jenkins summarizing that the House bill would authorize the Secretary of the Treasury to subpoena "any records" which the Secretary found "necessary or relevant to an investigation in connection with the enforcement of laws pertaining to narcotic drugs and marihuana"). The bill included an enforcement mechanism that allowed the Secretary of the Treasury to invoke the aid of federal courts "[i]n case of contumacy by, or refusal to obey a subp[o]ena issued to[ ] any person." Pub. L. No. 362, § 3. As explained in the Congressional Record, the intent was to "establish a contempt procedure as a means of compelling compliance with any summons issued pursuant to the authority granted [under the statute]." 101 Cong. Rec. 11,683 (remarks of Rep. Cooper) (emphasis added); see also S. Rep. No. 1247 (explaining that the bill included a provision establishing "a contempt procedure before Federal district judges as a means of compelling compliance with any summons issued" under the statute); H.R. Rep. No. 84-1347 (same).

Congress sought to provide the Secretary of the Treasury with "an invaluable weapon in the enforcement of the laws relating to narcotic drugs and marihuana." S. Rep. No. 1247; H.R. Rep. No. 84-1347; see also United States v. Pardo-Bolland, 348 F.2d 316, 321 (2d Cir. 1965) (noting "[t]he ease with which the Secretary of the Treasury [could] legally authorize the issuance of a subpoena in furtherance of a narcotics investigation").

Public Law 362 was § 876's predecessor. The statutory language of § 876 is identical in all relevant parts to that of Public Law 362. Congress's grant of authority to the Attorney General in § 876(a) is as broad as that of its predecessor, and its plain language allows for the subpoena of "any records" in "any investigation" relating to controlled substances as long as the Attorney General finds the records relevant or material to the investigation and such records are located in any State, territory, or within the jurisdiction of the United States. 21 U.S.C. § 876(a). See United States v. Mountain States Tel. & Tel. Co., 516 F. Supp. 225, 230 (D. Wyo. 1981) (stating that the subpoena powers under § 876 and Public Law 362 are coterminous); see also United States v. Moffett, 84 F.3d 1291, 1293 (10th Cir. 1996) (stating that 21 U.S.C. § 876(a) "is written to give the DEA broad powers to investigate violations of federal drug laws").

Ricco Jonas does not contest that the statutory language authorizing the Attorney General to issue administrative subpoenas under § 876(a) is broad or that its plain language does not limit law enforcement's

authority to obtain records relevant to its investigations based on who holds such records. She posits, however, that we must read § 876(a)'s language in tandem with § 876(c) which, in her view, limits the Attorney General's authority. But Ricco Jonas's proposed reading is not consistent with Congress's intent as revealed in the legislative history of Public Law 362. The legislative history reveals that § 876(c) was not meant to limit or otherwise hamper the broad authority granted to the Attorney General under § 876(a). Instead, § 876(c) was meant to give teeth to the Attorney General's authority by providing a mechanism to enforce subpoenas issued under § 876(a). And contrary to Ricco Jonas's contention, the legislative history leads to the conclusion that the scope of § 876(c) is informed by the authority granted in § 876(a), not the other way around. See 101 Cong. Rec. 11683 (remarks of Rep. Cooper noting that the enforcement mechanism was meant to "compel[] compliance with any summons issued pursuant to the authority granted").

It is clear that Congress's intention was to facilitate law enforcement investigations so that the goals of the CSA – "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances," Raich, 545 U.S. at 12 – could be accomplished. See United States v. Zadeh, 820 F.3d 746, 752 (5th Cir. 2016) (noting that because "[f]ederal control" is "essential to the effective control of the interstate incidents of . . . traffic in controlled substances," the CSA "grants the DEA broad enforcement power to prevent, detect, and investigate" drug diversion into illegal channels)

(alterations in original). To interpret § 876 in a way that restricts law enforcement's authority to request records relevant to their investigations from states – who customarily maintain records of all controlled substances distributed in their jurisdictions – would not only run afoul of the statutorily conferred broad authority, but would also be contrary to Congress's intent by significantly reverting law enforcement's investigation capabilities to its pre-1955 situation. Because the language of § 876 of the CSA is identical in all relevant respects to that of Public Law 362 and the CSA is part of a comprehensive statute that sought to "enhance federal drug enforcement powers" and "strengthen law enforcement tools against the traffic in illicit drugs," Raich, 545 U.S. at 10, 12 (emphasis added), it is clear that Congress could not have intended to revert law enforcement's investigation capabilities to its pre-1955 situation. See United States v. Hossbach, 518 F. Supp. 759, 767 (E.D. Pa. 1980) (noting that "[e]ven though [the grant of subpoena power under 21 U.S.C. § 876] may be broader than that customarily granted to agencies by Congress, the preamble to the statute as to Congressional findings and declarations, 21 U.S.C. § 801, makes clear that it was of grave concern to Congress that there should be effective methods of dealing with illegal drug manufacturing and distribution").

Ricco Jonas argues that the CSA "uses the terms 'person' and 'State' throughout its statutory text differently" which, in her view, indicates that the term "person" contained in 21 U.S.C. § 876(c) does not include the State, its agencies, or its officials in their official

capacities. As an example, she cites 21 U.S.C. § 873, a provision requiring the Attorney General to "cooperate with local, State, tribal, and Federal agencies concerning traffic in controlled substances." But that the CSA uses the more specific term "State" in some of its provisions for a more precise and coherent language does not mean that "State" cannot also be included within the meaning of "person" when such term is used in a way that encompasses several different terms, as used in § 876(c).[11] In fact, just like the CSA uses "State" as a less inclusive and more precise term than "person" in some provisions, it also uses the less inclusive and more precise term "individuals" in its text. See, e.g., 21 U.S.C. § 823(g)(1) (establishing that practitioners who dispense narcotic drugs to "individuals" for maintenance or detoxification treatments shall obtain a separate registration for that purpose). Yet, Ricco Jonas does not dispute that despite the CSA's use of "individuals" throughout its statutory text differently from "person," the term "person" contained in 21 U.S.C. § 876(c) includes "individuals."[12]

Next, Ricco Jonas posits that the CSA contemplates "cooperative arrangements" between the federal government and states, see id. § 873, "not relationships

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[11] Moreover, a single statutory term may even "take[ ] on 'distinct characters' in distinct statutory provisions" throughout a statute. Return Mail, Inc., 139 S. Ct. at 1863 (quoting Utility Air Regulatory Grp. v. EPA, 573 U.S. 302, 320 (2014)).

[12] Ricco Jonas urges us to adopt the Dictionary Act's definition of "person," which includes "corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." See 1 U.S.C. § 1 (emphasis added).

where records will be seized via administrative investigatory subpoena." But that Congress envisioned cooperation between the federal government and states does not mean that it intended the Attorney General/DEA to hopelessly rely on the states' willingness to cooperate in order to obtain needed information to perform their congressionally assigned investigative function. Legislative history makes clear that Congress intended to "strengthen law enforcement tools," Raich, 545 U.S. at 10, so that "[t]he illegal traffic in drugs [c]ould be attacked with the full power of the Federal Government," H.R. Rep. No. 91-1444, at 4575 (1970) (emphasis added), not that law enforcement be at the mercy of the states' willingness to cooperate. This very case exemplifies why it was important for Congress to provide the Attorney General/DEA with a mechanism to obtain records relevant to their investigations from states, its agencies, and its officials.

Furthermore, contrary to Ricco Jonas's contentions, providing the Attorney General/DEA with a mechanism to enforce subpoenas does not render the cooperative arrangements provision meaningless. Section 873 of the CSA, titled "Cooperative Arrangements," states that, "[t]he Attorney General shall cooperate with local, State, tribal, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances." 21 U.S.C. § 873(a). To this end, the Attorney General "is authorized to . . . assist State, tribal, and local governments in suppressing the diversion of controlled substances from legitimate medical, scientific, and

commercial channels." Id. § 873(a)(6). That the Attorney General/DEA may enforce administrative subpoenas issued to states, their agencies, or officials under § 876(c) for records relevant to their own investigations relating to controlled substances in no way hampers the Attorney General's authorization under § 873 to assist local, state, tribal, and federal agencies in their own fights against the illicit traffic of controlled substances. Nor does it hamper, as Ricco Jonas contends, the states' prerogative to conduct their own investigations and prosecute drug offenses pursuant to applicable state laws.

Finally, we note that our interpretation is consistent with the federal agency's interpretation of its statutory authority to issue administrative subpoenas for records relevant to its investigations, and, for aught that it appears, this is the first time that a state has challenged this interpretation in court in the more than six decades that such authority has been in place.[13] See, e.g., Or. Prescription Drug Monitoring Program v. U.S. DEA, 860 F.3d 1228, 1236 (9th Cir. 2017) (stating, where the DEA issued an administrative subpoena under § 876(a) to seek records from Oregon's Prescription Drug Monitoring Program – a state-maintained database like the PDMP – that "[t]he upshot of the statutory scheme is that the Attorney General can obtain testimony and documents through a subpoena and without a court order" and that "[a] court order is

[13] The parties have not pointed us to any case addressing the statutory construction question presented here, nor has our independent research revealed such a case.

needed only in the event of noncompliance ('contumacy . . . or refusal to obey') with the subpoena" (third alteration in original) (citing 21 U.S.C. §§ 876(a) and (c))); see also Return Mail, Inc., 139 S. Ct. at 1866 (stating that "[w]hen administrative and judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its administrative and judicial interpretations as well") (quoting Bragdon v. Abbott, 524 U.S. 624, 645 (1998)).

In light of the above, we find that the instant subpoena is a legitimate exercise of authority under the CSA. Hence, the district court did not abuse its discretion in concluding that it was enforceable under 21 U.S.C. § 876(c).[14]

C. The Privacy Interest in PDMP Data

Ricco Jonas argues that, even if 21 U.S.C. § 876 authorizes the issuance and enforcement of administrative subpoenas against states, their agencies, and officials in their official capacities, the Fourth Amendment nonetheless bars the enforcement of the instant subpoena. According to Ricco Jonas, individuals have a reasonable expectation of privacy in their prescription

[14] On appeal, Ricco Jonas does not challenge the district court's conclusion that the CSA preempts New Hampshire's statutory requirement that law enforcement officials obtain an order based on probable cause before obtaining PDMP data. Hence, we do not address that issue.

drug records stored in the PDMP database, thereby allowing the DEA to obtain such records only with a court order based on probable cause.

The parties dispute whether Ricco Jonas has standing to assert the substantive Fourth Amendment rights of the individual patient subject to the subpoena. The district court assumed without deciding that Ricco Jonas had standing. On appeal, Ricco Jonas and Amici argue in favor of standing, relying on the parens patriae doctrine and third-party standing, respectively. For its part, the DOJ argues that Fourth Amendment rights may not be invoked vicariously. Because this is an issue of prudential constraint, rather than Article III standing, we bypass the issue and directly address the merits of the case. See Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 125 (2014) (explaining that the "'prudential' branch of standing," which is "not derived from Article III," includes "the general prohibition on a litigant's raising another person's legal rights") (quoting Elk Grove Unified School Dist. v. Newdow, 542 U.S. 1, 12 (2004)); Warth v. Seldin, 422 U.S. 490, 509 (1975) (noting that the prudential standing rule "normally bars litigants from asserting the rights or legal interests of others in order to obtain relief from injury to themselves"); Katz v. Pershing, LLC, 672 F.3d 64, 72 (1st Cir. 2012) (explaining that prudential concerns "ordinarily require a plaintiff to show that his claim is premised on his own legal rights (as opposed to those of a third party), that his claim is not merely a generalized grievance, and that it falls within the zone of interests protected by

the law invoked") (quoting Pagán v. Calderón, 448 F.3d 16, 27 (1st Cir. 2006)); see also Gianfrancesco v. Town of Wrentham, 712 F.3d 634, 638 (1st Cir. 2013) (bypassing the prudential standing issue "in favor of a more straightforward resolution on the merits").

The Fourth Amendment applies when the person invoking its protection has a reasonable expectation of privacy in the place to be searched or the item to be seized by governmental officials. Smith v. Maryland, 442 U.S. 735, 739-40 (1979); United States v. Battle, 637 F.3d 44, 48 (1st Cir. 2011). The Supreme Court has established a "two-part test" for analyzing whether a movant has a reasonable expectation of privacy under the Fourth Amendment. United States v. Rheault, 561 F.3d 55, 59 (1st Cir. 2009). Under this test, we must determine "first, whether the movant has exhibited an actual, subjective, expectation of privacy; and second, whether such subjective expectation is one that society is prepared to recognize as objectively reasonable." Id. (citing Smith, 442 U.S. at 740). Absent such an expectation, the government may use a subpoena to acquire records in its investigation without the need of a court order based on probable cause. See Carpenter v. United States, 138 S. Ct. 2206, 2222 (2018) ("The Government will be able to use subpoenas to acquire records in the overwhelming majority of investigations. . . . [A] warrant is required in the rare case where the suspect has a legitimate privacy interest in records held by a third party.").

The DOJ argues that, contrary to Ricco Jonas's contentions, "because of the closely regulated nature of

the pharmaceutical industry and the third-party doctrine, a person cannot claim an objectively reasonable expectation of privacy" in his prescription drug records included in the PDMP database.[15] We agree.

The closely regulated industry doctrine recognizes that there is a diminished expectation of privacy for materials that are maintained by a business that is subject to pervasive regulation and inspection.[16] See Donovan v. Dewey, 452 U.S. 594, 600 (1981) (explaining that in a pervasively regulated business "the federal regulatory presence is sufficiently comprehensive and defined that the owner of commercial property cannot help but be aware that his property will be subject to periodic inspections undertaken for specific purposes"); New York v. Burger, 482 U.S. 691, 702 (1987) (explaining that "[b]ecause the owner or operator of commercial premises in a 'closely regulated' industry has a reduced expectation of privacy," administrative searches and warrantless inspections "may well be reasonable within the meaning of the Fourth Amendment"); Giragosian v. Bettencourt, 614 F.3d 25, 29 (1st Cir. 2010) (validating the government's warrantless search of a licensed firearm dealer's inventory and records because "the owner of commercial property in a closely regulated industry has a reduced

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[15] The DOJ notes that, because the individual whose prescription records are being sought was not before the district court, it is impossible to determine whether such individual claims a privacy interest in those records. The DOJ thus focuses its argument on the objective part of the test.

[16] Case law uses the terms "closely regulated," "highly regulated," and "pervasively regulated" interchangeably.

expectation of privacy in those premises"). This court, as well as others, has characterized the pharmaceutical industry as a closely regulated industry. United States v. Gonsalves, 435 F.3d 64, 67 (1st Cir. 2006); see also United States v. Schiffman, 572 F.2d 1137, 1142 (5th Cir. 1978) ("The pharmaceutical industry is a 'pervasively regulated business' like the liquor and gun industries." (quoting United States v. Montrom, 345 F. Supp. 1337, 1340 (E.D. Pa. 1972))); United States v. Acklen, 690 F.2d 70, 75 (6th Cir. 1982) (holding that "the pharmaceutical industry, like the mining, firearms, and liquor industries, is a pervasively regulated industry and that consequently pharmacists and distributors subject to the Controlled Substances Act have a reduced expectation of privacy in the records kept in compliance with the Act") (footnotes omitted); United States v. Nechy, 827 F.2d 1161, 1166 (7th Cir. 1987); United States v. Motley, 443 F. Supp. 3d 1203, 1213 (D. Nev. 2020) (noting that the prescription drug industry is highly regulated); U.S. Dep't of Justice v. Utah Dep't of Commerce, No. 2:16-cv-611-DN-DBP, 2017 WL 3189868, at *8 (D. Utah July 27, 2017) (stating that "[p]rescription drugs are a highly regulated industry"); State v. Welch, 624 A.2d 1105, 1110-11 (Vt. 1992); Stone v. Stow, 593 N.E.2d 294, 300 (Ohio 1992) ("Being in such a pervasively regulated business, a pharmacist has a reduced expectation of privacy in the prescription records he or she keeps.").

Both federal and New Hampshire laws regulate controlled substances by requiring pharmacies, among other handlers of controlled substances, to maintain

prescription drug records and keep them open for inspection by law enforcement officers without the need of a warrant.

The CSA and its implementing regulations provide that every registered dispenser of a controlled substance must maintain a complete and accurate record of each such substance disposed of.[17] 21 U.S.C. § 827(a)(3); 21 C.F.R. §§ 1304.03, 1304.04(h), 1304.21(a). These records must be kept for at least two years "for inspection and copying by officers or employees of the United States authorized by the Attorney General." 21 U.S.C. § 827(b); see also 21 C.F.R. § 1304.04(a) (establishing that all required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials).

Similarly, New Hampshire law requires practitioners, including pharmacists, physicians, and hospitals, to maintain records "show[ing] the receipt and disposition of all controlled drugs." N.H. Rev. Stat. Ann. § 318-B:12(I). These records must comply with "federal laws and regulations" and must indicate at least: (1) the name, dosage form, strength, and quantity of the controlled drug; (2) the name and address of any person to whom the drug was administered, dispensed, sold or transferred; and (3) the date of any and all

[17] The records of controlled substances maintained by registered pharmacies shall include paper prescription records and electronic prescription records, which must be sortable by prescriber name, patient name, drug dispensed, and date filled. 21 C.F.R. § 1304.04(h).

transactions involved with the controlled drug. Id. Practitioners shall keep these records "open for inspection . . . to federal, state, county and municipal law enforcement officers [and others] . . . whose duty it is to enforce the laws of [New Hampshire] or of the United States relating to controlled drugs." Id. § 318-B:12(II).

Pursuant to New Hampshire law, every person or entity authorized to deliver schedule II-IV controlled substances must also report to the PDMP information about the dispensed drug, including the patient's name and address, the drug and quantity dispensed, and the date of dispensing. Id. §§ 126-A:89(VI), 126-A:91(VI)(a)-(o).

Ricco Jonas contends that, despite the closely regulated nature of the pharmaceutical industry and the availability of prescription drug records to law enforcement without a court order under both federal and state law, we should nevertheless find a reasonable expectation of privacy in prescription drug records because several courts have recognized that patients have a reasonable expectation of privacy in their medical records.[18] We reject Ricco Jonas's invitation to

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[18] In support of this argument, Ricco Jonas cites Ferguson v. City of Charleston, 532 U.S. 67 (2001). But Ferguson was not about access to prescription drug records held by a third-party. Rather, there, the hospital, in conjunction with law enforcement, developed and followed a policy for identifying and testing pregnant patients suspected of drug use. Under that policy, the hospital would take urine tests of pregnant women and provide positive results to the police. Ferguson, 532 U.S. at 70-73. The Supreme Court held that the hospital's performance of a diagnostic test to obtain incriminating evidence from their patients for

equate prescription drug records to all other medical records. As a subset of medical records, prescription drug records do not generally or necessarily contain the more personal and intimate information that other medical records do. Medical records contain "sensitive medical history and other information, including about mental illnesses, learning disabilities, birth defects, illicit drug use, pregnancy terminations, domestic-violence history," patients' complaints and symptoms, and "the patients' family members," among others. Eil v. U.S. DEA, 878 F.3d 392, 396 (1st Cir. 2017). Furthermore, unlike prescription drug records, medical records are not subject to pervasive regulatory disclosures under both federal and state law. See U.S. Dep't of Justice v. Utah Dep't of Commerce, No. 16-cv-00611-DN-DBP, 2017 WL 9131888, at *4 (D. Utah Mar. 10, 2017) (Pead, Mag.J.) (stating that "the applicable legal framework suggests prescription drug records are highly regulated, and thus less deserving of privacy [than medical records]").

Ricco Jonas also argues that individuals have a reasonable expectation of privacy in their prescription drug records stored in the PDMP database because "prescription drug records are frequently suggestive of patients' underlying medical diagnoses." But her argument crumbles in the face of the pharmaceutical

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law enforcement purposes without the patients' consent was unconstitutional. Id. at 83-84. The Court noted that its ruling did not extend to a situation "in which state hospital employees, like other citizens, may have a duty to provide law enforcement officials with evidence of criminal conduct acquired in the course of routine treatment." Id. at 78 n.13.

industry's regulatory requirements. Both New Hampshire and federal law require that practitioners and handlers of controlled substances (including pharmacies and pharmacists) maintain records containing essentially the same information stored in the PDMP database and keep such records available for law enforcement inspection without the need of a court order. The PDMP merely aggregates into one depository the information included in records that must already be maintained available and open for inspection by the DEA. Ricco Jonas does not discuss why we should find a reasonable expectation of privacy in the aggregated database records when the underlying individual records containing essentially the same information are open to on-site inspection by law enforcement. And case law suggests we should not. See Whalen v. Roe, 429 U.S. 589, 600-04 (1977) (holding that New York's collection of prescription records in a computerized database did not violate patients' and physicians' right to privacy under the Due Process Clause of the Fourteenth Amendment).

We thus find that, in light of the intense government scrutiny to which prescription drug records are subject and the availability of those records for inspection without the need of court intervention under both state and federal law, a person does not have a reasonable expectation that the information contained in prescription drug records will be kept private and free of government intrusion. See Motley, 443 F. Supp. 3d at 1213 (reasoning that, because the pharmaceutical industry is highly regulated and "is required by federal

law to keep the types of records sought by [law enforcement] in [that] case, [defendant] did not have a reasonable expectation of privacy in the [Prescription Monitoring Program] database"); Utah Dep't of Commerce, 2017 WL 3189868, at *8-9 (holding that, because "patients do not have a reasonable expectation of privacy in the highly regulated prescription drug industry," the Fourth Amendment posed no bar to enforcement of subpoena issued by the DEA to obtain records from the state-maintained database); Murphy v. State, 62 P.3d 533, 541 (Wash. Ct. App. 2003) ("Given [the] long history of government scrutiny, patients who fill prescriptions for narcotic drugs . . . should reasonably expect that their prescriptions will be available to appropriate government agents."). In fact, the expectation created by the intense regulatory requirements is that "prescription and use of controlled substances will happen under the watchful eye of [both] the federal [and state] government[s]." Utah Dep't of Commerce, 2017 WL 3189868, at *8.

Our conclusion that patients do not have a reasonable expectation of privacy in their prescription drug records is further supported by the third-party doctrine. Under that doctrine,

> a person has no legitimate expectation of privacy in information he voluntarily turns over to third parties . . . even if the information is revealed on the assumption that it will be used only for a limited purpose and the confidence placed in the third party will not be betrayed.

United States v. Morel, 922 F.3d 1, 8-9 (1st Cir. 2019) (citing Smith, 442 U.S. at 743-44) (quotation marks omitted).

This doctrine "largely traces its roots to [United States v. Miller, 425 U.S. 435 (1976)]." Carpenter, 138 S. Ct. at 2216. In Miller, the Supreme Court applied the third-party doctrine in rejecting a bank customer's claim of a reasonable expectation of privacy in his financial records held by the bank. Miller, 425 U.S. at 436-45. The Court noted that the records subpoenaed were business records and not Miller's "private papers" and that they contained information "exposed to [bank] employees in the ordinary course of business." Id. at 440, 442. The Court thus concluded that Miller had "take[n] the risk, in revealing his affairs to another, that the information [would] be conveyed by that person to the Government." Id. at 443. The Court applied the same logic to dialed phone numbers in Smith v. Maryland, where it held that, "[w]hen he used his phone, petitioner voluntarily conveyed numerical information to the telephone company and 'exposed' that information to its equipment in the ordinary course of business. In so doing, petitioner assumed the risk that the company would reveal to police the numbers he dialed." 442 U.S. at 744.

Ricco Jonas, however, resists the application of the third-party doctrine. Relying on Carpenter v. United States, 138 S. Ct. 2206 (2018), where the Supreme Court declined to extend the third-party doctrine to cell-site location information, Ricco Jonas claims that such doctrine is not applicable here because patients

do not turn over prescription records voluntarily inasmuch as the only way to avoid such sharing is by forgoing medical treatment or filling their prescriptions in another state.

But Carpenter is of no help to Ricco Jonas. Carpenter did not disturb the third-party doctrine. Carpenter, 138 S. Ct. at 2220 ("We do not disturb the application of Smith and Miller."). Rather, it reiterated that two primary rationales underlie the third-party doctrine: the nature of the information sought and the voluntariness of the exposure of that information to third parties. Id. at 2219-20. Based on these rationales, the Court refused to apply the third-party doctrine in that case because doing so would amount to "a significant extension of [the doctrine] to a distinct category of information." Id. at 2219.

In considering the nature of the information sought, the Supreme Court noted in Carpenter that cell-site location information provides an "all-encompassing record of the [cell phone] holder's whereabouts[,] . . . revealing not only his particular movements, but through them his 'familial, political, professional, religious, and sexual associations.'" Id. at 2217 (quoting United States v. Jones, 565 U.S. 400, 415 (2012) (Sotomayor, J., concurring)). In essence, it amounts to a "detailed chronicle of a person's physical presence compiled every day, every moment, over several years." Id. at 2220. In the Court's view, because the personal information that law enforcement can get from cell-site records is not limited like the information at issue in

Miller and Smith, it "implicates privacy concerns far beyond those considered in [those two cases]." Id.

Here, Ricco Jonas argues that prescription drug records contain intimate and private details because it may be possible to determine a person's illnesses from looking at such records, thus suggesting that the nature of the documents sought should cut against applying the third-party doctrine. But the nature of prescription drug records is similar to that of bank records, and much different than that at issue in Carpenter. See id. at 2219 ("There is a world of difference between the limited types of personal information addressed in Smith and Miller and the exhaustive chronicle location information casually collected by wireless carriers today."). Even though financial transactions can reveal personal information, such as "personal affairs, opinions, habits," "a person's activities, associations, and beliefs," Miller, 425 U.S. at 451, 453 (Brennan, J., dissenting), the Supreme Court characterized this type of personal information as "limited." Carpenter, 138 S. Ct. at 2219. The personal information that law enforcement could get from prescription drug records is likewise limited. At most, law enforcement could possibly decipher a patient's diagnosis or several potential diagnoses. This is thus more akin to the information at issue in Miller than to the "all-encompassing record" and "detailed chronicle" that may be ascertained from cell-site records. Id. at 2217, 2220. Furthermore, the records subpoenaed by the DEA are not the patient's "private papers." Miller, 425 U.S. at 440. A physician does not write a prescription for the

patient to keep to himself. Instead, the prescription is meant to be turned over to a drug dispenser in the ordinary course of business with instructions of what drug, what dosage and frequency, and to whom the controlled substance should be dispensed. See United States v. Gayden, 977 F.3d 1146, 1152 (11th Cir. 2020) (finding that disclosure of prescription drug records was voluntary because prescriptions "were, by their very nature, intended to be revealed to others when they were disclosed . . . to the pharmacies which filled them"). Prescription drug records are kept by the pharmacy or dispensary and subsequently shared with the PDMP, and the patient has no access to those records or control over them.

Nor does the second rationale underlying the third-party doctrine – voluntary exposure – help Ricco Jonas. In Carpenter, the Supreme Court noted that

> a cell phone logs a cell-site record by dint of its operation, without any affirmative act on the part of the user beyond powering up. Virtually any activity on the phone generates [cell-site location information]. . . . [and] [a]part from disconnecting the phone from the network, there is no way to avoid leaving behind a trail of location data.

Carpenter, 138 S. Ct. at 2220. Ricco Jonas argues that, like the cell phone user in Carpenter, patients do not voluntarily share their prescription drug information with third parties. She submits that obtaining health care and drug treatment therapies is "indispensable to participation in modern society" and apart from

forgoing health care and drug treatment therapies, there is no way to avoid leaving behind prescription drug data. Thus, in her view, in no meaningful sense does a patient voluntarily assume the risk of turning over prescription drug data. But the Supreme Court rejected a similar argument in Miller. There, Miller argued that "[f]or all practical purposes, the disclosure by individuals or business firms of their financial affairs to a bank is not entirely volitional, since it is impossible to participate in the economic life of contemporary society without maintaining a bank account." Brief for Respondent, United States v. Miller, 425 U.S. 435 (1976) (No. 74-1179), 1975 WL 173642, at *8; see also Miller, 425 U.S. at 451 (Brennan, J., dissenting) (adopting this argument). Unpersuaded, the Court found that this does not change the fact that the person affirmatively elected to turn over the document to a third party and, in so doing, "t[ook] the risk" that the information be conveyed by that third party to the government. Miller, 425 U.S. at 443. Similarly, a person who turns over his prescription for controlled substances to a third party "assume[s] the risk" (in this case the certainty, given the state and federal disclosure requirements), that the information be turned over to the government. Carpenter, 138 S. Ct. at 2220.

In sum, an analysis of the two rationales underlying the third-party doctrine lead us to conclude that the third-party doctrine applies to this case. See Gayden, 977 F.3d at 1152 (holding that "prescription records are third-party material" that may be obtained by law enforcement without a warrant). As the Court

noted in Carpenter, "society's expectation has been that law enforcement agents . . . would not – and indeed, in the main, simply could not – secretly monitor and catalogue every single movement of an individual's car for a very long period." Carpenter, 138 S. Ct. at 2217 (quotation marks omitted). In the Court's view, allowing the government to benefit from "seismic shifts in digital technology" that now makes possible the "tireless and absolute surveillance" of individuals "at practically no expense" would contravene that expectation. Id. at 2218-19.

Here, in contrast, there is no "powerful new tool," id. at 2223, that makes possible for law enforcement to now do what it could not do before. Although it may be easier and cheaper for law enforcement to obtain prescription drug records from the PDMP than from individual pharmacies, society's expectation has been for decades that law enforcement would have access to prescription drug records and would closely monitor the prescription and use of controlled substances.

Finally, Ricco Jonas argues that finding no reasonable expectation of privacy in prescription drug records may cause people to forgo treatment to maintain their privacy. But in Whalen the Supreme Court rejected a similar argument under the Fourteenth Amendment and Ricco Jonas offers no explanation for why the same reasoning should not apply under the Fourth Amendment. See Whalen, 429 U.S. at 602-04 (finding no invasion of privacy right protected by the Fourteenth Amendment despite the fact that "some individuals' concern for their own privacy may lead them to avoid

or to postpone needed medical attention" because of fear that public disclosure of this information "may reflect unfavorably on the[ir] character").

IV. CONCLUSION

In light of the above, we hold that the district court did not abuse its discretion in enforcing the instant administrative subpoena. The district court's judgment is thus affirmed.

United States Court of Appeals
For the First Circuit

No. 19-1243

UNITED STATES DEPARTMENT OF JUSTICE,

Petitioner, Appellee,

v.

MICHELLE RICCO JONAS,

Respondent, Appellant.

JUDGMENT

Entered: January 27, 2022

This cause came on to be heard on appeal from the United States District Court for the District of New Hampshire and was argued by counsel.

Upon consideration whereof, it is now here ordered, adjudged and decreed as follows: The district court's judgment is affirmed.

By the Court:

Maria R. Hamilton, Clerk

cc: Seth R. Aframe, Lawrence M. Edelman, Anthony J. Galdieri, Gilles R. Bissonnette, Henry R. Klementowicz, Nathan Wessler, Brett Max Kaufman, Jennifer Stisa Granick, Zachary Heiden, Emma Bond, Matthew R Segal, Jessie J. Rossman, William Ramirez-Hernandez, Robert Barney Mann

United States Court of Appeals
For the First Circuit

No. 19-1243

UNITED STATES DEPARTMENT OF JUSTICE,

Petitioner, Appellee,

v.

MICHELLE RICCO JONAS,

Respondent, Appellant.

Before

Howard, Chief Judge,
Thompson and Kayatta, Circuit Judges.

ORDER OF COURT

Entered: August 23, 2019

Appellant's request for a stay pending appeal is granted. The judgment below shall be stayed during the pendency of the appeal.

By the Court:

Maria R. Hamilton, Clerk

cc:
Seth R. Aframe
Lawrence M. Edelman
Anthony J. Galdieri
Gilles R. Bissonnette
Henry R. Klementowicz

Nathan Wessler
Brett Max Kaufman
Jennifer Stisa Granick
Zachary Heiden
Emma Bond
Matthew R Segal
Jessie J. Rossman
William Ramirez-Hernandez
Robert Barney Mann

Honorable Landya B. McCafferty
Daniel J. Lynch, Clerk (D.N.H.)

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

United States
Department of Justice

v.

Civil No. 19-cv-030-LM

Michelle Ricco Jonas

ORDER

After due consideration of the objection and response filed, the court finds that oral argument is unnecessary to resolve the parties' dispute. The court herewith approves the Report and Recommendation of Magistrate Judge Andrea K. Johnstone dated 11/1/2018.

SO ORDERED.

/s/ Landya B. McCafferty
Landya B. McCafferty
United States District Judge

January 17, 2019

cc: Seth R. Aframe, AUSA
Anthony Galdieri, Esq.
Lawrence Edelman, Esq.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

United States
Department of Justice

v.

Michelle Ricco Jonas

Case No. 18-mc-56-LM

REPORT AND RECOMMENDATION

(Filed Nov. 1, 2018)

Before the court is the United States Department of Justice's (DOJ) petition to compel compliance with an administrative subpoena the United States Drug Enforcement Agency (DEA) issued to Michelle Ricco Jonas, manager of the New Hampshire Prescription Drug Monitoring Program (PDMP). Doc. no. 1. The district judge ordered Jonas to show cause why she should not be compelled to obey the subpoena and produce certain PDMP records. The judge referred the matter to the undersigned magistrate judge for a recommended disposition. Doc. no. 3. See 28 U.S.C. § 636(b)(1)(B); LR 72.1. After reviewing the parties' submissions and hearing their arguments, the court recommends that the district judge grant the petition.

I. Legal Standard

"The requirements for enforcement of an administrative subpoena are not onerous." United States v. Sturm Ruger & Co, 84 F.3d 1, 4 (1st Cir. 1996). The court will enforce the subpoena if the agency proves

that: (1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena. Id. "As long as the agency satisfies these modest requirements, the subpoena is per se reasonable and Fourth Amendment concerns are deemed satisfied." Id. (citing Oklahoma Press Pub. Co. v. Walling, 327 U.S. 186, 208 (1946)). "The role of a court in a subpoena enforcement proceeding is strictly limited to inquiring whether the above requirements have been met. 'Such proceedings are designed to be summary in nature.'" United States v. Comley, 890 F.2d 539, 541 (1st Cir. 1989) (quoting EEOC v. Tempel Steel Co., 814 F.2d 482, 485 (7th Cir. 1987)). "[A]ffidavits of government officials have been accepted as sufficient to make out a prima facie showing that these requirements are satisfied." Id.

II. Background[1]

Pursuant to the Controlled Substances Act (CSA), the Attorney General is authorized to issue administrative subpoenas to investigate suspected criminal drug activity. 21 U.S.C. § 876(a). The Attorney General has delegated that authority to the DEA. 28 C.F.R. § 0.100. The subpoena power extends to "requir[ing] the production of any records (including books, papers, documents, and other tangible things which constitute

[1] The facts are drawn from the parties' filings. They are undisputed unless indicated otherwise.

or contain evidence) which the Attorney General finds relevant or material to" any investigation being conducted pursuant to the CSA. 21 U.S.C. § 876(a). The CSA permits subpoenas to be served on natural persons by personal delivery. Id. § 876(b). The CSA further provides that "[i]n the case of contumacy by or refusal to obey a subp[o]ena issued to any person," the federal court has jurisdiction to compel compliance. Id. § 876(c).

The New Hampshire Board of Pharmacy operates the PDMP. N.H. Rev. Stat. Ann. § 318-B:33, I. All "prescribers and dispensers" of certain controlled substances are required to submit information to the PDMP database, including the patient's name and address and the type, quantity and refill regimen of the prescribed substance. Id. § 318-B:33, IV (a)-(o). Information the PDMP gathers is confidential and can be released for research and educational purposes if the data is "de-identified." Id. § 318-B:34. As particularly relevant here, the PDMP can release information to "authorized law enforcement officials . . . for the purpose of investigation and prosecution of a criminal offense when presented with a court order based on probable cause." Id. § 318-B:35, I(a)(3).

On June 13, 2018, the DEA served a subpoena on Ricco Jonas which requested all PDMP records pertaining to a particular individual dating back to February 2016.[2] Subpoena, doc. no. 1-3. Ricco Jonas,

[2] The DEA first served the subpoena naming PDMP. The New Hampshire Attorney General objected on the ground that

represented by the New Hampshire Attorney General, objected to providing the requested information. Galdieri Ltr., doc. no. 1-2. The instant petition followed.

III. Analysis

Ricco Jonas claims that the petition "is nothing more than an attempt to circumvent federal law," Def. Obj., doc. no. 7, at 3, and asserts several grounds for denial. The court addresses them in turn.

A. Threshold burden

Ricco Jonas first argues that the DOJ has failed to meet its burden of showing that its investigation has a legitimate authorized purpose. Id. DEA Investigator Stern's declaration doc. no. 8-1, persuades the court that DOJ has met these "modest requirements."[3] Sturm Ruger & Co, 84 F.3d at 4. She states that the New Hampshire Board of Pharmacy provided her with information "regarding the potential diversion of large amounts of opiates through pharmacies" in New Hampshire. Id. ¶ 2. Investigator Stern stated further

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the PDMP was not a "person" within the meaning of the CSA. Without conceding the point, the DEA nevertheless subsequently served the subpoena naming Ricco Jonas.

[3] The DOJ asserts that it appended Stern's declaration to its reply memorandum, rather than its original petition, because Ricco Jonas raised this threshold argument for the first time in her objection to the Petition, rather than in the letter announcing her refusal to comply with the subpoena. Reply. Mem., doc no. 8, at 2 n.1. The court takes no issue with the timing of the submission.

that "an individual [was] reported to be filling fraudulent prescriptions for . . . control[led] substances which he receives from out-of-state practitioners in New Hampshire." Id.

"The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." Gonzalez v. Raich, 545 U.S. 1, 12-13 (2005) (footnotes omitted). Given this mandate and the Attorney General's authority under 21 U.S.C. § 876(a) to "require production of any records . . . which the Attorney General finds relevant or material to the investigation," the court has little trouble finding that the DOJ has proven that the subpoena is relevant to a congressionally authorized purpose, the information sought is adequately described and DEA followed proper procedures. Sturm Ruger & Co., 84 F.3d at 4. Ricco Jonas does not contest the adequacy of the DOJ's evidence on this issue.

B. Suit against the State of New Hampshire

Ricco Jonas next asserts that the subpoena cannot be enforced because it was issued to her in her official capacity as PDMP Program Manager, rather than in her personal capacity. This distinction, she argues, has significant ramifications. Ricco Jonas contends that such an "official capacity" subpoena is the equivalent of an action against the State of New Hampshire. And,

she argues, because the State is not a "person" under 21 U.S.C. § 876(c), the subpoena is unenforceable. Def. Mem., doc no. 7, at 13. Ricco Jonas's argument founders on the initial premise – that DOJ has sued the State by serving her with a subpoena. As will be explained in more detail below, the court finds that this action is not a suit against the State.

Ricco Jonas has cited no authority for her proposition that her being served because of her position as PDMP manager converts this subpoena enforcement action into a suit against the State of New Hampshire. Indeed, the weight of persuasive authority is against her.

Generally speaking, "[f]ederal subpoenas routinely issue to state and federal employees to produce official records or appear and testify in court and are fully enforceable despite any claim of immunity." United States v. Juvenile Male 1, 431 F. Supp. 2d 1012, 1016 (D. Ariz. 2006). Although the First Circuit Court of Appeals has not addressed the precise issue Ricco Jonas raises, another district court in this Circuit has recently observed that a motion to compel non-party discovery from a state agency is not a suit against the state because it "will not result in a judgment of any kind requiring financial payment from the state." United States v. Univ. of. Mass., 167 F. Supp. 2d 221, 225 (D. Mass. 2016). In reaching this conclusion, the court relied on Allen v. Woodford, 544 F. Supp. 2d 1074 (E.D. Cal. 2008), adopting rep. and rec., 543 F. Supp. 2d 1138. In Allen, a prison inmate sought document production from several state agencies under the Federal

Rules of Civil Procedure. Id. at 1075. The agencies claimed Eleventh Amendment immunity. Id. The court defined the "threshold issue [as] whether issuance and required compliance with a third-party subpoena by State custodians of records in an action in which the State is not a party constitutes" a suit against the state. Id. at 1078. The court concluded that the subpoena was not a suit. Id.

Several aspects of the Allen court's reasoning are instructive here. First, the court observed that discovery from a state agency can only be obtained through the custodians of records or "other employees having custody and control of the information or documents sought." Id. at 1079. In this case, the DEA served the subpoena on Ricco Jonas because, as her counsel conceded at oral argument, she has custody and control over PDMP information. Next, the Allen court remarked that:

> Neither the State, nor any of its employees to whom subpoenas have been directed to obtain the information sought, that have been found essential to the prosecution of the Plaintiff's case, are parties, nor has any relief in law or equity been sought against them or the State. No judgment will be issued in this action against the State that could have any conceivable effect on the State treasury; the State custodians are only subpoenaed to produce documents for use in the prosecution of this federal civil rights action. The Non-Parties' assertion that they must comply with the subpoenas in their official capacities as

> custodians of record is irrelevant; no judgment or other relief of any kind is sought against them in this litigation.

Id. (emphasis added).

The Allen court also cited two cases that further persuade the court that this action is not a suit against the State. First, in Florida Dept. of State v. Treasure Salvors, Inc., 458 U.S. 670 (1982), the plurality approved service of process on state officials in possession of certain artifacts. Rejecting the state's immunity argument, the Court declared that "[i]t is clear that the process at issue was directed only at state officials and not at the State itself or any agency of the State." Id. at 691. The Court concluded: "Treasure Salvors is not asserting a claim for damages against either the State of Florida or its officials. . . . The relief sought is not barred by the Eleventh Amendment." Id. at 699.

Allen also cited with approval Laxalt v. C.K. McClatchy, 109 F.R.D. 632 (D. Nev. 1986), a libel suit in which the district court rejected a Nevada gaming agency's claim that the Eleventh Amendment barred compliance with a federal subpoena. Id. at 633. The Laxalt court first noted that only assertions of liability and claims for relief against the state are considered to be "lawsuits against a state." Id. at 634. It then found the case's similarity to Treasure Salvors, Inc., dispositive, because "inspection and copying of state records is all that is being sought. . . ." Id. at 634-35. Other cases have employed the same analysis and reached the same result. See, e.g., Jackson v. AFSCME

Local 196, No. 3:07CV0471(JCH), 2008 WL 1848900, at *2 (D. Conn. Apr. 25, 2008) (finding that subpoena on state agency official was not an action against the state); Arista Records LLC v. Does 1-14, No. 7:08cv00205, 2008 WL 5350246, at *5 (W.D. Va. Dec. 22, 2008) (same; citing Jackson).

Ultimately, Ricco Jonas's argument that the State of New Hampshire is not a "person," within the meaning of the CSA begs the question of whether DOJ has initiated a suit against the State merely by naming her and her title in the subpoena. Given the one-sided authority that Ricco Jonas has not contradicted, the court finds that her assertion that she "must comply with the subpoenas in [her] official capacity[y] as custodians of record is irrelevant." Allen, 544 F. Supp. 2d at 1079. "[I]nspection and copying of state records is all that is being sought. . . ." Laxalt, 109 F.R.D. at 634-35. This action is not a suit against the State of New Hampshire. The court therefore need not reach the question of whether the State is a "person" within the meaning of the CSA.[4]

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[4] DOJ also relies on Ott v. City of Milwaukee, 682 F.3d 552, 556 (7th Cir. 2012) in which the court rejected an immunity defense in a discovery dispute. Ott, however, is inapposite, as it relied on federal discovery rules definitions to find that a city agency was a "person." By contrast, this case involves a federal statute. Also misplaced is Ricco Jonas's reliance on Al Fayed v. CIA, 229 F.3d 272 (D.C. Cir. 2000), in which the Court held that the CIA is not a "person" within the meaning 28 U.S.C. § 1782, which gives district courts power to order a person to produce documents for use in foreign or international tribunals. Id. at 275-76. Al Fayed, however, involved a federal discovery subpoena served on a

C. Supremacy Clause

Ricco Jonas next argues that DOJ must demonstrate probable cause to seize the PDMP records as required by N.H. Rev. Stat. Ann. § 318-B:35(I)(b)(3). This argument fails because the Supremacy Clause of the Constitution preempts the provisions of New Hampshire law upon which Ricco Jonas relies. Under the Supremacy Clause, state laws that "interfere with, or are contrary to the laws of [C]ongress" are invalid. U.S. Const. art. VI, cl. 2. Unless Congress directs otherwise, the Supremacy Clause preempts state laws which are in conflict with federal law. Hillman v. Maretta, 569 U.S. 483, 490 (2013). Such conflicts exist when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Wisconsin Pub. Intervenor v. Mortier, 501 U.S. 597 (1991) (quoting Hines v. Davidowitz, 312 U.S. 52 (1941)). "If the purpose of the [federal] act . . . must be frustrated and its provisions be refused their natural effect," then a conflict exists. Savage v. Jones, 225 U.S. 501, 533 (1912).

Several courts have invoked the Supremacy Clause in enforcing administrative subpoenas issued under the CSA. As especially relevant here, three of those cases involved prescription drug databases similar to the NH PDMP. For example, in Oregon

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federal agency in private litigation, not, as here, an administrative subpoena served by a federal agency on a state-agency record custodian. Regardless, because the court finds that this action is not a "suit" against the State, it does not reach the issue of whether the State is a "person" under the CSA.

Prescription Drug Monitoring Program v. U.S. Drug Enforcement Admin., 860 F.3d 1228 (9th Cir. 2017) the court held that the CSA preempted an Oregon statute requiring "a valid court order" before that state's PDMP could comply with a DEA subpoena. Id. at 1236. The Court observed that the "Oregon statute stands as an obstacle to the full implementation of the CSA because it interferes with the methods by which the federal statute was designed to reach [its] goal." Id. (citing Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 103 (1992)) (internal quotation marks omitted). Similarly, in United States Dep't of Justice v. Utah Dep't of Commerce, No. 2:16-cv-611, 2017 WL 3189868 (D. Utah July 27, 2017), the court, relying on the Supremacy Clause, found that the CSA preempted the state's requirement of a warrant to access a state prescription database. Id. at *6. Also, in United States Dep't of Justice v. Colo. Bd. Of Pharm, Civ. No. 10-cv-0116-WYD-MEH, 2010 WL 3547898 (D. Colo. Aug. 13, 2010), rep. and rec. aff'd and adopted, 2010 WL 3547896 (Sept. 3, 2010), the court addressed a DEA subpoena issued to the Colorado PDMP seeking information about three prescription prescribers. The PDMP did not comply, arguing that a Colorado statute only allowed the release information related to patients. After observing that the state statute would require the DEA to individually review the records of hundreds of pharmacies to find information on three prescribers, the court found that the state statute was an "obstacle to the DEA's efforts to conduct its investigation," id. at *4, and that the CSA therefore preempted the state restriction. Id.; see also United States v. Mich. Dep't of Cmty. Health,

No. 1:10-mc-109, 2011 WL 2412602 (W.D. Mich. June 9, 2011) (enforcing DEA subpoena seeking information from state medical marijuana database despite state confidentiality provision).

Courts have also relied on the Supremacy Clause to uphold administrative subpoenas in other contexts. See, e.g., Presly v. United States, 895 F.3d 1284 (8th Cir. 2018) (rejecting argument that Florida Constitution's privacy provisions can affect Internal Revenue Service's ability to subpoena bank records); United States ex rel. Office of Inspector Gen. v. Philadelphia Hous. Auth., Misc. No. 10-0205, 2011 WL 382765, at *5 (E.D. Pa. Feb. 4, 2011) (rejecting city housing authority's reliance on state privacy laws because they "obstruct fulfillment" of an administrative subpoena issued by the Officer of Inspector General of the Department of Housing and Urban Development); Massanari v. Nw. Cmty. Mental Health Ctr., No. 01-MC-50E, 2001 WL 1518137, at *1 (W.D.N.Y. Nov. 7, 2001) (finding that defendant must comply with Social Security Commissioner's administrative subpoena despite privacy provisions of New York law); St. Luke's Reg'l Med. Ctr., Inc. v. United States, 717 F. Supp. 665, 666 (N.D. Iowa 1989) (rejecting doctor's reliance on state disclosure prohibitions to avoid complying with Department of Health and Human Services administrative subpoena in Medicaid investigation).

Given the consistent weight of authority, the court is persuaded that giving effect to New Hampshire's requirement of a court order based on probable cause would create "an obstacle to the full implementation of

the CSA because it interferes with the methods by which the federal statute was designed to reach [its] goal." Oregon Prescription Drug Monitoring Program, 860 F.3d at 1236. The state statute is therefore preempted and must give way to the CSA's subpoena process.

D. Fourth Amendment

Even if New Hampshire's warrant requirement is pre-empted, Ricco Jonas argues that DOJ must nevertheless satisfy the Fourth Amendment's protection against unreasonable searches and seizures.[5]

Ricco Jonas asserts both the State's and other individuals' Fourth Amendment privacy interests in the

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[5] Ricco Jonas also contends that the DOJ, apparently fearful of her argument that the State of New Hampshire is not a "person" under the CSA, is now claiming that it served her in her individual capacity. In that capacity, she argues, she can only comply with the subpoena by violating state law because, in her personal capacity, she has no legal right to the information." Def. Obj., doc. no. 7, at 9. As the court has already concluded, however, the official capacity/personal capacity analysis is irrelevant here.

Moreover, the court does not interpret the DOJ's argument in the manner Ricco Jonas suggests. The CSA allows service on a "natural person," 21 U.S.C. § 876(b), and allows court enforcement of a subpoena issued to "any person." Id. § 876(c). "If a party is going to subpoena documents from the government, they need to subpoena the person who has possession, custody, or control over the documents. . . ." United States v. 2121 Celeste Road SW, Albuquerque, N.M., 307 F.R.D. 572, 590-91 (D.N.M. 2015) (emphasis added). Ricco Jonas does not dispute that she is that person. Def. Obj., doc. no. 7, at 6 (citing N.H. Admin. R. Ph. 1505.03(c)).

personal information PDMP possesses. DOJ argues that Rico Jonas does not have standing to raise this argument on others' behalf. The standing issue is not dispositive. Assuming without deciding that Ricco Jonas does have standing – either in her own right or on behalf of others – the Court of Appeals has held that "Fourth Amendment concerns are deemed satisfied" if the agency proves that the subpoena seeks information relevant to an authorized purpose, is adequately described and was issued in accordance with proper procedures. Sturm Ruger, 84 F.3d at 4; see also United States v. Tivian Labs., Inc., 589 F.2d 49, 54 (1st Cir. 1978) ("A subpoena may be issued without first obtaining a court's permission . . . and may be judicially enforced without a showing that probable, or even reasonable, cause exists to believe that a violation of law has occurred.") (citation omitted). As previously noted, supra, p. 6, DOJ has already cleared this hurdle.

But that is not the end of the inquiry. As the Supreme Court recently observed, "[t]he Government will be able to use subpoenas to acquire records in the overwhelming majority of investigations" but "a warrant is required in the rare case where the suspect has a legitimate privacy interest in records held by a third party." Carpenter v. United States, 138 S. Ct. 2206, 2222 (2018). In Carpenter, the Court found that the criminal defendant had a reasonable expectation of privacy in "cell-site location information" that ostensibly tracked his whereabouts based on information retrieved from cell phone towers. Accordingly, it found that the government could not use a court order authorized by the

Stored Communications Act which required only "reasonable grounds," rather than probable cause, to retrieve the information. Id. at 2222-23; see 18 U.S.C. § 2703(d). Here, however, the patients whose interests Ricco Jonas advances do not have such a reasonable expectation of privacy.

Ricco Jonas relies on two cases for the proposition that patients have a Fourth Amendment-based expectation of privacy in their prescription drug records and that DOJ must therefore demonstrate probable cause. See Douglas v. Dobbs, 419 F.3d 1097, 1102 (10th Cir. 2005); Doe v. Se. Pa. Transp. Auth., 72 F.3d 1133, 1138 (3d Cir. 1995). But neither case supports the weight that Ricco Jonas places upon them. While both noted the patient's privacy interest in prescription information, both also noted that the right is "not absolute." Douglas, 419 F.3d at 1102 n.3; Doe, 72 F.3d at 1138. See also Whalen v. Roe, 429 U.S. 589, 602 (1977) (holding that patients' expectation of privacy in their prescription drug use must be weighed against the state's interest in monitoring the use of controlled substances). Moreover, Dobbs explicitly declined to resolve the issue of whether a warrant is required to conduct an investigatory search of prescription records, finding only that, for purposes of a qualified immunity analysis, the issue was unsettled. 419 F.3d at 1103; see also, Pyle v. Woods, 874 F.3d 1257, 1264 (10th Cir. 2017) (observing that as of April 2013 "no court had conducted the necessary analysis and no judicial opinion held that a warrantless search of a prescription drug database by state law enforcement officials is unconstitutional.").

Ultimately, Rico Jonas cites no case holding that the Fourth Amendment requires DOJ to obtain a warrant to secure information from a state prescription database and the only case to directly address the issue has held that the DEA may access state prescription databases without a warrant. In Utah Dep't of Commerce, supra, the court enforced a DEA subpoena issued to the Utah equivalent of the PDMP. The court's reasoning is persuasive. It first noted that "the pharmaceutical industry, like the mining, firearms, and liquor industries, is a pervasively regulated industry and that consequently pharmacists and distributors subject to the [CSA] have a reduced expectation of privacy in the records kept in compliance with the [CSA]." Id. at *8 (quoting United States v. Acklen, 690 F.2d 70, 75 (6th Cir. 1982)); see also New York v. Burger, 482 U.S. 691, 702 (1987) ("Because the owner or operator of commercial premises in a 'closely regulated' industry has a reduced expectation of privacy, the warrant and probable-cause requirements, which fulfill the traditional Fourth Amendment standard of reasonableness for a government search . . . have lessened application in this context."). The CSA, the court concluded, created the expectation that "the prescription and use of controlled substances will happen under the watchful eye of the federal government." Id.

Next, the court observed that the Utah prescription database's mandatory reporting requirements further eroded patients' claimed right to privacy. In trusting a prescribing physician with health information, "a patient takes the risk – in this

circumstance, a certainty – that his or her information will be conveyed to the government as required by the Database Act." Id. (citing United States v. Miller, 425 U.S. 435, 443 (1976) (holding that the Fourth Amendment does not bar the government from obtaining information "revealed to a third party and conveyed by him to Government authorities, even if the information is revealed on the assumption that it will be used only for a limited purpose and the confidence placed in the third party will not be betrayed.")). As a result, the Court found, the mandatory reporting requirement "means the State already has decided that any individual right to privacy in one's prescription drug records is outweighed by a countervailing interest in the government monitoring the prescriptions for unlawful or improper use," id., and that "physicians and patients have no reasonable expectation of privacy from the DEA in the Utah database." Id.

The Utah Dep't of Commerce court's reasoning is an appropriate fit for this case. While New Hampshire law treats PDMP information as confidential, see N.H. Rev. Stat. Ann. § 318-B:34, I, it also makes clear that program information about a patient can be disclosed "to others who are authorized by state or federal law" to receive such information. Id. In addition, the law allows the PDMP to provide information to a variety of entities, including state medical boards and other states' prescription safety programs. See id., § 318-B:35, I-III.

Ricco Jonas argues that the holding in Utah Dep't of Commerce is contrary to the Tenth Circuit Court of

Appeals's declaration in Dobbs, that patients have a right to privacy in their prescription drug records. But as previously noted, Dobbs cautioned that that right is not absolute. In addition, Dobbs presciently observed that "state law can operate to diminish the privacy expectation in prescription drug records." 419 F.3d at 1102 n.3. New Hampshire law has done exactly that. To the extent that Ricco Jonas has standing to assert their claims, patients do not have a reasonable expectation of privacy in the records maintained by the PDMP.

IV. Conclusion

The court agrees with the government's view that "Ricco Jonas's objection . . . make[s] the simple complicated. Gov. Rep., doc no. 8, at 1. The CSA authorizes the court to enforce subpoenas issued to "any person." 21 U.S.C. § 876(c). The government has met its burden to satisfy the "modest requirements" for enforcement. "The State has, admirably, placed considerable controls and precautions on [PDMP] access. The determination that a[n] [order supported by probable cause] is required of . . . State and local law enforcement officers . . . is within the State's authority. But the State's attempt to regulate federal law enforcement fails." Utah Dep't of Commerce, 2017 WL 3189868 at *9 (internal quotation marks and footnote omitted). Accordingly, the court recommends that the district judge grant the government's petition to compel doc. no. 1.

Any objections to this report and recommendation must be filed within fourteen days of receipt of this notice. See Fed.R.Civ.P. 72(b)(2). Failure to file specific written objections to this Report and Recommendation within the specified time waives the right to appeal the district court's order. See Santos-Santos v. Torres-Centeno, 842 F.3d 163, 168 (1st Cir. 2016).

/s/ Andrea K. Johnstone
Andrea K. Johnstone
United States Magistrate Judge

November 1, 2018

cc: Seth R. Aframe, Esq.
Anthony Galdieri, Esq.
Lawrence Edelman, Esq.

United States Court of Appeals
For the First Circuit

No. 19-1243

UNITED STATES DEPARTMENT OF JUSTICE,

Petitioner - Appellee

v.

MICHELLE RICCO JONAS

Respondent - Appellant

Before

Barron, Chief Judge,
Lynch, Howard, Thompson, Kayatta, and Gelpi,
Circuit Judges.

ORDER OF COURT

Entered: April 15, 2022

Pursuant to First Circuit Internal Operating Procedure X(C), the petition for rehearing en banc has also been treated as a petition for rehearing before the original panel. The petition for rehearing having been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en

banc, it is ordered that the petition for rehearing and petition for rehearing en banc be denied.

By the Court:

Maria R. Hamilton, Clerk

From Title 1 – GENERAL PROVISIONS
CHAPTER 1 – RULES OF CONSTRUCTION
Text contains those laws in effect on June 1, 2022

§1. Words denoting number, gender, and so forth

In determining the meaning of any Act of Congress, unless the context indicates otherwise-

words importing the singular include and apply to several persons, parties, or things;

words importing the plural include the singular;

words importing the masculine gender include the feminine as well; words used in the present tense include the future as well as the present;

the words "insane" and "insane person" shall include every idiot, insane person, and person non compos mentis;

the words "person" and "whoever" include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals;

"officer" includes any person authorized by law to perform the duties of the office;

"signature" or "subscription" includes a mark when the person making the same intended it as such;

"oath" includes affirmation, and "sworn" includes affirmed;

"writing" includes printing and typewriting and reproductions of visual symbols by

photographing, multigraphing, mimeographing, manifolding, or otherwise.

(July 30, 1947, ch. 388, 61 Stat. 633 ; June 25, 1948, ch. 645, §6, 62 Stat. 859 ; Oct. 31, 1951, ch. 655, §1, 65 Stat. 710 ; Pub. L. 112–231, §2(a), Dec. 28, 2012, 126 Stat. 1619.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part A – Introductory Provisions

§801. Congressional findings and declarations: controlled substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce,

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the

effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

(Pub. L. 91–513, title II, §101, Oct. 27, 1970, 84 Stat. 1242.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part C – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§802. Definitions

As used in this subchapter:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner, whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Drug Enforcement Administration" means the Drug Enforcement Administration in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are

defined or used in subtitle E of the Internal Revenue Code of 1986.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means—

(A) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its

stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(12) The term "drug" has the meaning given that term by section 321(g)(1) of this title.

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "isomer" means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term "isomer" means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term "isomer" means any optical or geometric isomer.

(15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(16)(A) Subject to subparagraph (B), the term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.

(A) The term "marihuana" does not include—

(i) hemp, as defined in section 1639o of title 7; or

(ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term "narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which

cocaine, ecgonine, and derivatives of ecdonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term "opiate" or "opioid" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.

(20) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled

substance in the course of professional practice or research.

(22) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term "immediate precursor" means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health and Human Services.

(25) The term "serious bodily injury" means bodily injury which involves—

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

(26) The term "State" means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(27) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term "detoxification treatment" means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32) (A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance—

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a

controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) Such term does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 355 of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

(33) The term "listed chemical" means any list I chemical or any list II chemical.

(34) The term "list I chemical" means a chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter and is

important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

(A) Anthranilic acid, its esters, and its salts.
(B) Benzyl cyanide.
(C) Ephedrine, its salts, optical isomers, and salts of optical isomers.
(D) Ergonovine and its salts.
(E) Ergotamine and its salts.
(F) N-Acetylanthranilic acid, its esters, and its salts.
(G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.
(H) Phenylacetic acid, its esters, and its salts.
(I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.
(J) Piperidine and its salts.
(K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.
(L) 3,4-Methylenedioxyphenyl-2-propanone.
(M) Methylamine.
(N) Ethylamine.
(O) Propionic anhydride.
(P) Isosafrole.
(Q) Safrole.
(R) Piperonal.
(S) N-Methylephedrine.
(T) N-methylpseudoephedrine.
(U) Hydriodic acid.

(V) Benzaldehyde.
(W) Nitroethane.
(X) Gamma butyrolactone.
(Y) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term "list II chemical" means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:

(A) Acetic anhydride.
(B) Acetone.
(C) Benzyl chloride.
(D) Ethyl ether.
(E) Repealed. Pub. L. 101–647, title XXIII, §2301(b), Nov. 29, 1990, 104 Stat. 4858.
(F) Potassium permanganate.
(G) 2-Butanone (or Methyl Ethyl Ketone).
(H) Toluene.
(I) Iodine.
(J) Hydrochloric gas.

(36) The term "regular customer" means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term "regular importer" means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term "regulated person" means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term "regulated transaction" means—

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include—

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 830 of this title;

(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], subject to clause (v), unless—

(I) the Attorney General has determined under section 814 of

this title that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General;

(v) any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under section 830(b)(3) of this title; or

(vi) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this subchapter and subchapter II based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

(B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(40) The term "chemical mixture" means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(41) (A) The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes—

(i) androstanediol—
  (I) 3β,17β-dihydroxy-5α-androstane; and
  (II) 3α,17β-dihydroxy-5α-androstane;

(ii) androstanedione (5α-androstan-3,17-dione);

(iii) androstenediol—
  (I) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene);
  (II) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene);
  (III) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene); and

(IV) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene);

(iv) androstenedione—

(I) 1-androstenedione ([5α]-androst-1-en-3,17-dione);

(II) 4-androstenedione (androst-4-en-3,17-dione); and

(III) 5-androstenedione (androst-5-en-3,17-dione);

(v) bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(vi) boldenone (17β-hydroxyandrost-1,4,-diene-3-one);

(vii) calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(viii) clostebol (4-chloro-17β-hydroxy-androst-4-en-3-one);

(ix) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1,4-dien-3-one);

(x) Δ1-dihydrotestosterone (a.k.a. "1-testosterone") (17β-hydroxy-5α-androst-1-en-3-one);

(xi) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one);

(xii) drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one);

(xiii) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene);

(xiv) fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxy-androst-4-en-3-one);

(xv) formebolone (2-formyl-17α-methyl-11α,17β-dihydroxy-androst-1,4-dien-3-one);

(xvi) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]-furazan);

(xvii) 13β-ethyl-17β-hydroxygon-4-en-3-one;

(xviii) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one);

(xix) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one);

(xx) mestanolone (17α-methyl-17β-hydroxy-5α-androstan-3-one);

(xxi) mesterolone (1α-methyl-17β-hydroxy-[5α]-androstan-3-one);

(xxii) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one);

(xxiii) methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene);

(xxiv) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one);

(xxv) 17α-methyl-3β, 17β-dihydroxy-5α-androstane;

(xxvi) 17α-methyl-3α,17β-dihydroxy-5α-androstane;

(xxvii) 17α-methyl-3β,17β-dihydroxy-androst-4-ene.

(xxviii) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one);

(xxix) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one);

(xxx) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9-11-trien-3-one);

(xxxi) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one);

(xxxii) mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one);

(xxxiii) 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. "17-α-methyl-1-testosterone");

(xxxiv) nandrolone (17β-hydroxyestr-4-en-3-one);

(xxxv) norandrostenediol—

(I) 19-nor-4-androstenediol (3β, 17β-dihydroxyestr-4-ene);

(II) 19-nor-4-androstenediol (3α, 17β-dihydroxyestr-4-ene);

(III) 19-nor-5-androstenediol (3β, 17β-dihydroxyestr-5-ene); and

(IV) 19-nor-5-androstenediol (3α, 17β-dihydroxyestr-5-ene);

(xxxvi) norandrostenedione—

(I) 19-nor-4-androstenedione (estr-4-en-3,17-dione); and

(II) 19-nor-5-androstenedione (estr-5-en-3,17-dione;

(xxxvii) norbolethone (13β,17α-diethyl-17β-hydroxygon-4-en-3-one);
(xxxviii) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one);
(xxxix) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one);
(xl) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one);
(xli) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-[5α]-androstan-3-one);
(xlii) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one);
(xliii) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-[5α]-androstan-3-one);
(xliv) stanozolol (17α-methyl-17β-hydroxy-[5α]-androst-2-eno[3,2-c]-pyrazole);
(xlv) stenbolone (17β-hydroxy-2-methyl-[5α]-androst-1-en-3-one);
(xlvi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
(xlvii) testosterone (17β-hydroxy-androst-4-en-3-one);
(xlviii) tetrahydrogestrinone (13β,17α-diethyl-17β-hydroxygon-4,9,11-trien-3-one);
(xlix) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one);
(l) 5α-Androstan-3,6,17-trione;
(li) 6-bromo-androstan-3,17-dione;
(lii) 6-bromo-androsta-1,4-diene-3,17-dione;

(liii) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;
(liv) 4-chloro-17α-methyl-androst-4-ene-3β,17β-diol;
(lv) 4-chloro-17α-methyl-17β-hydroxy-androst-4-en-3-one;
(lvi) 4-chloro-17α-methyl-17β-hydroxy-androst-4-ene-3,11-dione;
(lvii) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;
(lviii) 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one;
(lix) 2α,17α-dimethyl-17β-hydroxy-5β-androstan-3-one;
(lx) 2α,3α-epithio-17α-methyl-5α-androstan-17β-ol;
(lxi) [3,2-c]-furazan-5α-androstan-17β-ol;
(lxii) 3β-hydroxy-estra-4,9,11-trien-17-one;
(lxiii) 17α-methyl-androst-2-ene-3,17β-diol;
(lxiv) 17α-methyl-androsta-1,4-diene-3,17β-diol;
(lxv) Estra-4,9,11-triene-3,17-dione;
(lxvi) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one;
(lxvii) 6α-Methyl-androst-4-ene-3,17-dione;
(lxviii) 17α-Methyl-androstan-3-hydroxyimine-17β-ol;
(lxix) 17α-Methyl-5α-androstan-17β-ol;
(lxx) 17β-Hydroxy-androstano[2,3-d]isoxazole;

(lxxi) 17β-Hydroxy-androstano[3,2-c]isoxazole;
(lxxii) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5α-androstan-17β-ol;
(lxxiii) [3,2-c]pyrazole-androst-4-en-17β-ol;
(lxxiv) [3,2-c]pyrazole-5α-androstan-17β-ol; and
(lxxv) any salt, ester, or ether of a drug or substance described in this paragraph.

The substances excluded under this subparagraph may at any time be scheduled by the Attorney General in accordance with the authority and requirements of subsections (a) through (c) of section 811 of this title.

(B)(i) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).

(C)(i) Subject to clause (ii), a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in subparagraph (A) and is derived from, or has

a chemical structure substantially similar to, 1 or more anabolic steroids listed in subparagraph (A) shall be considered to be an anabolic steroid for purposes of this chapter if—

(I) the drug or substance has been created or manufactured with the intent of producing a drug or other substance that either—

(aa) promotes muscle growth; or

(bb) otherwise causes a pharmacological effect similar to that of testosterone; or

(II) the drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

(ii) A substance shall not be considered to be a drug or hormonal substance for purposes of this subparagraph if it—

(I) is—

(aa) an herb or other botanical;

(bb) a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical; or

(cc) a combination of 2 or more substances described in item (aa) or (bb);

(II) is a dietary ingredient for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(III) is not anabolic or androgenic.

(iii) In accordance with section 885(a) of this title, any person claiming the benefit of an exemption or exception under clause (ii) shall bear the burden of going forward with the evidence with respect to such exemption or exception.

(42) The term "international transaction" means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(43) The terms "broker" and "trader" mean a person that assists in arranging an international transaction in a listed chemical by—

(A) negotiating contracts;
(B) serving as an agent or intermediary; or
(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(44) The term "felony drug offense" means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, anabolic steroids, or depressant or stimulant substances.

(45) (A) The term "scheduled listed chemical product" means, subject to subparagraph (B), a product that—

(i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and

(ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] as a nonprescription drug.

Each reference in clause (i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(B) Such term does not include a product described in subparagraph (A) if the product contains a chemical specified in such subparagraph that the Attorney General has under section 811(a) of this title added to any of the schedules under section 812(c) of this title. In the absence of such scheduling by the Attorney General, a chemical specified in such subparagraph may not be considered to be a controlled substance.

(46) The term "regulated seller" means a retail distributor (including a pharmacy or a mobile retail vendor), except that such term does not include an employee or agent of such distributor.

(47) The term "mobile retail vendor" means a person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

(48) The term "at retail", with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

(49) (A) The term "retail distributor" means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

(B) For purposes of this paragraph, entities are defined by reference to the Standard Industrial Classification (SIC) code, as follows:

(i) A grocery store is an entity within SIC code 5411.

(ii) A general merchandise store is an entity within SIC codes 5300 through 5399 and 5499.

(iii) A drug store is an entity within SIC code 5912.

(50) The term "Internet" means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

(51) The term "deliver, distribute, or dispense by means of the Internet" refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(52) The term "online pharmacy"—

(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet; and

(B) does not include—

(i) manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 823 of this title who do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners who are registered under section 823(f) of this title and whose activities are authorized by that registration;

(iii) any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 823(f) of this title;

(iv) a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian

Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.];

(v) any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;

(vi) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(vii) a person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

(viii) a pharmacy registered under section 823(f) of this title whose dispensing of controlled substances via the Internet consists solely of—

(I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (55); or

(II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (56); or

(ix) any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health and safety to exempt from the definition of an "online pharmacy".

(53) The term "homepage" means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

(54) The term "practice of telemedicine" means, for purposes of this subchapter, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of title 42, which practice—

(A) is being conducted—

(i) while the patient is being treated by, and physically located in, a

hospital or clinic registered under section 823(f) of this title; and

(ii) by a practitioner—

(I) acting in the usual course of professional practice;

(II) acting in accordance with applicable State law; and

(III) registered under section 823(f) of this title in the State in which the patient is located, unless the practitioner—

(aa) is exempted from such registration in all States under section 822(d) of this title; or

(bb) is—

(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(BB) registered under section 823(f) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under

section 823(f) of this title;

(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner—

(i) acting in the usual course of professional practice;

(ii) acting in accordance with applicable State law; and

(iii) registered under section 823(f) of this title in the State in which the patient is located, unless the practitioner—

(I) is exempted from such registration in all States under section 822(d) of this title; or

(II) is—

(aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(bb) registered under section 823(f) of this title in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823(f) of this title;

(C) (is being conducted by a practitioner—

(i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or

tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.];

(ii) acting within the scope of the employment, contract, or compact described in clause (i); and

(iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 831(g)(2) of this title;

(D) (i) is being conducted during a public health emergency declared by the Secretary under section 247d of title 42; and

(ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5;

(1) is being conducted by a practitioner who has obtained from the Attorney General a special registration under section 831(h) of this title;

(2) is being conducted—

(i) in a medical emergency situation—

(I) that prevents the patient from being in the physical presence of a practitioner registered under section 823(f) of this title

who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

(II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 823(f) of this title;

(III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) by a practitioner that—is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(II) is registered under section 823(f) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823(f) of this title; and

(III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or

(3) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

(55) The term "refilling prescriptions for controlled substances in schedule III, IV, or V"—

(A) means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 829 of this title, as appropriate; and

(B) does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(56) The term "filling new prescriptions for controlled substances in schedule III, IV, or V" means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if—

(A) the pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 829 of this title (in this paragraph referred to as the "original prescription");

(B) the pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and

(C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

(57) [1] The term "suspicious order" may include, but is not limited to—

(A) an order of a controlled substance of unusual size;
(B) an order of a controlled substance deviating substantially from a normal pattern; and
(C) orders of controlled substances of unusual frequency.

(57) [1] The term "serious drug felony" means an offense described in section 924(e)(2) of title 18 for which—

(A) the offender served a term of imprisonment of more than 12 months; and

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(Pub. L. 91–513, title II, §102, Oct. 27, 1970, 84 Stat. 1242; Pub. L. 93–281, §2, May 14, 1974, 88 Stat. 124; Pub. L. 95–633, title I, §102(b), Nov. 10, 1978, 92 Stat. 3772; Pub. L. 96–132, §16(a), Nov. 30, 1979, 93 Stat. 1049; Pub. L. 98–473, title II, §507(a), (b), Oct. 12, 1984, 98 Stat. 2071; Pub. L. 98–509, title III, §301(a), Oct. 19, 1984, 98 Stat. 2364; Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 99–570, title I, §§1003(b), 1203, 1870, Oct. 27, 1986, 100 Stat. 3207–6, 3207-13, 3207-56; Pub. L. 99–646, §83, Nov. 10, 1986, 100 Stat. 3619; Pub. L. 100–690, title VI, §6054, Nov. 18, 1988, 102 Stat. 4316; Pub. L. 101–647, title XIX, §1902(b), title XXIII, §2301, title XXXV, §3599I, Nov. 29, 1990, 104 Stat. 4852, 4858, 4932; Pub. L. 103–200, §§2(a), 7–9(a), Dec. 17, 1993, 107 Stat. 2333, 2340; Pub. L. 103–322, title IX, §90105(d), title XXXIII, §330024(a), (b), (d)(1), Sept. 13, 1994, 108 Stat. 1988, 2150; Pub. L. 104–237, title II, §§204(a), 209, title IV, §401(a), (b), Oct. 3, 1996, 110 Stat. 3102, 3104, 3106, 3107; Pub. L. 104–294, title VI, §§604(b)(4), 607(j), Oct. 11, 1996, 110 Stat. 3506, 3512; Pub. L. 105–115, title I, §126(c)(3), Nov. 21, 1997, 111 Stat. 2328; Pub. L. 106–172, §§3(c), 5(a), Feb. 18, 2000, 114 Stat. 9, 10; Pub. L. 106–310, div. B, title XXXVI, §3622(a), Oct. 17, 2000, 114 Stat.

(B) the offender's release from any term of imprisonment was within 15 years of the commencement of the instant offense.

(58) The term "serious violent felony" means—

(A) an offense described in section 3559(c)(2) of title 18 for which the offender served a term of imprisonment of more than 12 months; and

(B) any offense that would be a felony violation of section 113 of title 18, if the offense were committed in the special maritime and territorial jurisdiction of the United States, for which the offender served a term of imprisonment of more than 12 months.

1231; Pub. L. 107–273, div. B, title IV, §4002(c)(1), Nov. 2, 2002, 116 Stat. 1808; Pub. L. 108–358, §2(a), Oct. 22, 2004, 118 Stat. 1661; Pub. L. 109–162, title XI, §1180, Jan. 5, 2006, 119 Stat. 3126; Pub. L. 109–177, title VII, §§711(a)(1), (2)(A), 712(a)(1), Mar. 9, 2006, 120 Stat. 256, 257, 263; Pub. L. 110–425, §3(a), Oct. 15, 2008, 122 Stat. 4821; Pub. L. 113–260, §2(a), Dec. 18, 2014, 128 Stat. 2929; Pub. L. 114–198, title III, §303(a)(2), July 22, 2016, 130 Stat. 722; Pub. L. 115–271, title III, §§3202(c), 3292(a), Oct. 24, 2018, 132 Stat. 3945, 3956; Pub. L. 115–334, title XII, §12619(a), Dec. 20, 2018, 132 Stat. 5018; Pub. L. 115–391, title IV, §401(a)(1), Dec. 21, 2018, 132 Stat. 5220.)

From Title 21 – FOOD AND DRUGS

CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL

Subchapter I – CONTROL AND ENFORCEMENT

Part C – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§822. Persons required to register

(a) Period of registration

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(3) (A) Except as provided in subparagraph (C), the registration of any registrant under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals terminates if and when such registrant

(i) dies;

(ii) ceases legal existence;

(iii) discontinues business or professional practice; or

(iv) surrenders such registration.

(B) In the case of such a registrant who ceases legal existence or discontinues business or professional practice, such registrant shall promptly notify the Attorney General in writing of such fact.

(C) No registration under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals, and no authority conferred thereby, may be assigned or otherwise transferred except upon such conditions as the Attorney General may specify and then only pursuant to written consent. A registrant to whom a registration is assigned or transferred pursuant to the preceding sentence may not manufacture, distribute, or dispense controlled substances or list I chemicals pursuant to such registration until the Attorney General receives such written consent.

(D) In the case of a registrant under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals desiring to discontinue business or professional practice altogether or with respect to controlled substances and list I chemicals (without assigning or transferring such business or professional practice to another entity), such registrant shall return to the Attorney General for cancellation—

(i) the registrant's certificate of registration;

(ii) any unexecuted order forms in the registrant's possession; and

(iii) any other documentation that the Attorney General may require.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 802(25) 1 of this title.

(d) Waiver

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration

(1) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(2) Notwithstanding paragraph (1), a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(g) Delivery of controlled substances by ultimate users for disposal

(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this subchapter may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this subchapter to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's

property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

(5) (A) In the case of a person receiving hospice care, an employee of a qualified hospice program, acting within the scope of employment, may handle, without being registered under this section, any controlled substance that was lawfully dispensed to the person receiving hospice care, for the purpose of disposal of the controlled substance so long as such disposal occurs onsite in accordance with all applicable Federal, State, Tribal, and local law and—

(i) the disposal occurs after the death of a person receiving hospice care;

(ii) the controlled substance is expired; or

(iii) (I) the employee is—

(aa) the physician of the person receiving hospice care; and

(bb) registered under section 823(f) of this title; and

(II) the hospice patient no longer requires the controlled substance because the plan of care of the hospice patient has been modified.

(B) For the purposes of this paragraph:

(i) The terms "hospice care" and "hospice program" have the meanings given to those terms in section 1395x(dd) of title 42.

(ii) The term "employee of a qualified hospice program" means a physician, physician assistant, nurse, or other person who—

(I) is employed by, or pursuant to arrangements made by, a qualified hospice program;

(II) (aa) is licensed to perform medical or nursing services by the jurisdiction in which the person receiving hospice care was located; and

(bb) is acting within the scope of such employment in accordance with applicable State law; and has completed training through the qualified hospice program regarding the disposal of controlled substances in a secure and responsible manner so as to discourage abuse, misuse, or diversion.

(iii) The term "qualified hospice program" means a hospice program that—

(I) has written policies and procedures for assisting in the disposal of the controlled substances of a person receiving hospice care after the person's death;

(II) at the time when the controlled substances are first ordered—

(aa) provides a copy of the written policies and procedures to the patient or patient representative and family;

(bb) discusses the policies and procedures with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe disposal of controlled substances; and

(cc) documents in the patient's clinical record that the written policies and procedures were provided and discussed; and

(III) at the time following the disposal of the controlled substances—

(aa) documents in the patient's clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and

(bb) the time, date, and manner in which that disposal occurred.

(Pub. L. 91–513, title II, §302, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 98–473, title II, §510, Oct. 12, 1984, 98 Stat. 2072; Pub. L. 103–200, §3(b), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 111–273, §3(a), Oct. 12, 2010, 124 Stat. 2859; Pub. L. 113–143, §2, Aug. 1, 2014, 128 Stat. 1750; Pub. L. 115–271, title III, §3222(a), Oct. 24, 2018, 132 Stat. 3948; Pub. L. 117–53, §2, Nov. 10, 2021, 135 Stat. 411.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part C – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§822a. Prescription drug take back expansion

(a) Definition of covered entity

In this section, the term "covered entity" means—

(1) a State, local, or tribal law enforcement agency;

(2) a manufacturer, distributor, or reverse distributor of prescription medications;

(3) a retail pharmacy;

(4) a registered narcotic treatment program;

(5) a hospital or clinic with an onsite pharmacy;

(6) an eligible long-term care facility; or

(7) any other entity authorized by the Drug Enforcement Administration to dispose of prescription medications.

(b) Program authorized

The Attorney General, in coordination with the Administrator of the Drug Enforcement Administration, the Secretary of Health and Human Services, and the Director of the Office of National Drug Control Policy, shall coordinate with covered entities in expanding

or making available disposal sites for unwanted prescription medications.

(Pub. L. 114–198, title II, §203, July 22, 2016, 130 Stat. 717.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part C – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§832. Suspicious orders

(a) Reporting

Each registrant shall—

(1) design and operate a system to identify suspicious orders for the registrant;

(2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and

(3) upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

(b) Suspicious order database

(1) In general

Not later than 1 year after October 24, 2018, the Attorney General shall establish a centralized database for collecting reports of suspicious orders.

(2) Satisfaction of reporting requirements

If a registrant reports a suspicious order to the centralized database established under paragraph (1), the registrant shall be considered to have complied with the requirement under subsection (a)(3) to notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

(c) Sharing information with the States

(1) In general

The Attorney General shall prepare and make available information regarding suspicious orders in a State, including information in the database established under subsection (b)(1), to the point of contact for purposes of administrative, civil, and criminal oversight relating to the diversion of controlled substances for the State, as designated by the Governor or chief executive officer of the State.

(2) Timing

The Attorney General shall provide information in accordance with paragraph (1) within a

reasonable period of time after obtaining the information.

(3) Coordination

In establishing the process for the provision of information under this subsection, the Attorney General shall coordinate with States to ensure that the Attorney General has access to information, as permitted under State law, possessed by the States relating to prescriptions for controlled substances that will assist in enforcing Federal law.

(Pub. L. 91–513, title II, §312, as added Pub. L. 115–271, title III, §3292(b), Oct. 24, 2018, 132 Stat. 3956.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part E – Administrative and Enforcement Provisions

§873. Cooperative arrangements

(a) Cooperation of Attorney General with local, State, tribal, and Federal agencies

The Attorney General shall cooperate with local, State, tribal, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he is authorized to—

(1) arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances;

(2) cooperate in the institution and prosecution of cases in the courts of the United States and before the licensing boards and courts of the several States;

(3) conduct training programs on controlled substance law enforcement for local, State, tribal, and Federal personnel;

(4) maintain in the Department of Justice a unit which will accept, catalog, file, and otherwise utilize all information and statistics, including records of controlled substance abusers and other controlled substance law offenders, which may be received from Federal, State, tribal, and local agencies, and make such information available for Federal, State, tribal, and local law enforcement purposes;

(5) conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted;

(6) assist State, tribal, and local governments in suppressing the diversion of controlled substances from legitimate medical, scientific, and commercial channels by—

(A) making periodic assessments of the capabilities of State, tribal, and local governments to adequately control the diversion of controlled substances;

(B) providing advice and counsel to State, tribal, and local governments on the methods by which such governments may strengthen their controls against diversion; and

(C) establishing cooperative investigative efforts to control diversion; and

(7) notwithstanding any other provision of law, enter into contractual agreements with State, tribal, and local law enforcement agencies to provide for cooperative enforcement and regulatory activities under this chapter. 1

(b) Requests by Attorney General for assistance from Federal agencies or instrumentalities

When requested by the Attorney General, it shall be the duty of any agency or instrumentality of the Federal Government to furnish assistance, including technical advice, to him for carrying out his functions under this subchapter; except that no such agency or instrumentality shall be required to furnish the name of, or other identifying information about, a patient or research subject whose identity it has undertaken to keep confidential.

(c) Descriptive and analytic reports; limitation on court challenges

(1) The Attorney General shall, once every 6 months, prepare and make available to regulatory, licensing, attorneys general, and law enforcement agencies of States a standardized report containing descriptive and analytic information on the actual distribution patterns, as gathered through

the Automated Reports and Consolidated Orders System, or any subsequent automated system, pursuant to section 827 of this title and which includes detailed amounts, outliers, and trends of distributor and pharmacy registrants, in such States for the controlled substances contained in schedule II, which, in the discretion of the Attorney General, are determined to have the highest abuse.

(2) If the Attorney General publishes the report described in paragraph (1) once every 6 months as required under paragraph (1), nothing in this subsection shall be construed to bring an action in any court to challenge the sufficiency of the information or to compel the Attorney General to produce any documents or reports referred to in this subsection.

(d) Grants by Attorney General

(1) The Attorney General may make grants, in accordance with paragraph (2), to State, tribal, and local governments to assist in meeting the costs of—

(A) collecting and analyzing data on the diversion of controlled substances,

(B) conducting investigations and prosecutions of such diversions,

(C) improving regulatory controls and other authorities to control such diversions,

(D) programs to prevent such diversions,

(E) preventing and detecting forged prescriptions, and

(F) training law enforcement and regulatory personnel to improve the control of such diversions.

(2) No grant may be made under paragraph (1) unless an application therefor is submitted to the Attorney General in such form and manner as the Attorney General may prescribe. No grant may exceed 80 per centum of the costs for which the grant is made, and no grant may be made unless the recipient of the grant provides assurances satisfactory to the Attorney General that it will obligate funds to meet the remaining 20 per centum of such costs. The Attorney General shall review the activities carried out with grants under paragraph (1) and shall report annually to Congress on such activities.

(3) To carry out this subsection there is authorized to be appropriated $6,000,000 for fiscal year 1985 and $6,000,000 for fiscal year 1986.

(Pub. L. 91–513, title II, §503, Oct. 27, 1970, 84 Stat. 1271; Pub. L. 96–359, §8(a) Sept. 26, 1980, 94 Stat. 1194; Pub. L. 98–473, title II, §517, Oct. 12, 1984, 98 Stat. 2074; Pub. L. 99–570, title I, §1868, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 99–646, §85, Nov. 10, 1986, 100 Stat. 3620; Pub. L. 111–211, title II, §232(c), July 29, 2010, 124 Stat. 2278; Pub. L. 115–271, title III, §3273(b), Oct. 24, 2018, 132 Stat. 3953.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part E – Administrative and Enforcement Provisions

§876. Subpenas

(a) Authorization of use by Attorney General

In any investigation relating to his functions under this subchapter with respect to controlled substances, listed chemicals, tableting machines, or encapsulating machines, the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and 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. The attendance of witnesses and the production of records may be required from any place in any State or in any territory or other place subject to the jurisdiction of the United States at any designated place of hearing; except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place where he was served with a subpena. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

(b) Service

A subpena issued under this section may be served by any person designated in the subpena to

serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered on a true copy thereof by the person serving it shall be proof of service.

(c) Enforcement

In the case of contumacy by or refusal to obey a subpena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpena. The court may issue an order requiring the subpenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

(Pub. L. 91–513, title II, §506, Oct. 27, 1970, 84 Stat. 1272; Pub. L. 100–690, title VI, §6058, Nov. 18, 1988, 102 Stat. 4319.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part E – Administrative and Enforcement Provisions

§878. Powers of enforcement personnel

(a) Any officer or employee of the Drug Enforcement Administration or any State, tribal, or local law enforcement officer designated by the Attorney General may—

(1) carry firearms;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, subpenas, and summonses issued under the authority of the United States;

(3) make arrests without warrant (A) for any offense against the United States committed in his presence, or (B) for any felony, cognizable under the laws of the United States, if he has probable cause to believe that the person to be arrested has committed or is committing a felony;

(4) make seizures of property pursuant to the provisions of this subchapter; and

(5) perform such other law enforcement duties as the Attorney General may designate.

(b) State and local law enforcement officers performing functions under this section shall not be deemed Federal employees and shall not be

subject to provisions of law relating to Federal employees, except that such officers shall be subject to section 3374(c) of title 5.

(Pub. L. 91–513, title II, §508, Oct. 27, 1970, 84 Stat. 1273; Pub. L. 96–132, §16(b), Nov. 30, 1979, 93 Stat.1049; Pub. L. 99–570, title I, §1869, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 99–646, §86, Nov. 10, 1986, 100 Stat. 3620; Pub. L. 111–211, title II, §232(d), July 29, 2010, 124 Stat. 2278.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part E – Administrative and Enforcement Provisions

§882. Injunctions

(a) Jurisdiction

The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this subchapter.

(b) Jury trial

In case of an alleged violation of an injunction or restraining order issued under this section, trial shall,

upon demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure.

(c) State cause of action pertaining to online pharmacies

(1) In general

In any case in which the State has reason to believe that an interest of the residents of that State has been or is being threatened or adversely affected by the action of a person, entity, or Internet site that violates the provisions of section 823(f), 829(e), or 831 of this title, the State may bring a civil action on behalf of such residents in a district court of the United States with appropriate jurisdiction—

(A) to enjoin the conduct which violates this section;

(B) to enforce compliance with this section;

(C) to obtain damages, restitution, or other compensation, including civil penalties under section 842(b) of this title; and

(D) to obtain such other legal or equitable relief as the court may find appropriate.

(2) Service; intervention

(A) Prior to filing a complaint under paragraph (1), the State shall serve a copy of the complaint upon the Attorney General and upon the United States Attorney for the judicial district in which the complaint is to be filed. In any case where such prior service is

not feasible, the State shall serve the complaint on the Attorney General and the appropriate United States Attorney on the same day that the State's complaint is filed in Federal district court of the United States. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or any other proceedings under this subchapter or any other laws of the United States.

(B) Upon receiving notice respecting a civil action pursuant to this section, the United States shall have the right to intervene in such action and, upon so intervening, to be heard on all matters arising therein, and to file petitions for appeal.

(C) Service of a State's complaint on the United States as required in this paragraph shall be made in accord with the requirements of rule 4(i)(1) of the Federal Rule 1 of Civil Procedure.

(3) Powers conferred by State law

For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general of a State by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses of or the production of documentary or other evidence.

(4) Venue

Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28. Process in such action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

(5) No private right of action

No private right of action is created under this subsection.

(6) Limitation

No civil action may be brought under paragraph (1) against—

(A) the United States;

(B) an Indian Tribe or tribal organization, to the extent such tribe or tribal organization is lawfully carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]; or

(C) any employee of the United States or such Indian tribe or tribal organization, provided such agent or employee is acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee therewith.

(Pub. L. 91–513, title II, §512, Oct. 27, 1970, 84 Stat. 1278; Pub. L. 110–425, §3(h), Oct. 15, 2008, 122 Stat. 4830.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part E – Administrative and Enforcement Provisions

§885. Burden of proof; liabilities

(a) Exemptions and exceptions; presumption in simple possession offenses

(1) It shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this subchapter, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

(2) In the case of a person charged under section 844(a) of this title with the possession of a controlled substance, any label identifying such substance for purposes of section 353(b)(2) of this title shall be admissible in evidence and shall be prima facie evidence that such substance was obtained pursuant to a valid prescription from a practitioner while acting in the course of his professional practice.

(b) Registration and order forms

In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this subchapter, he shall be presumed not to be the holder of such registration or form, and the burden of going forward with the evidence with respect to such registration or form shall be upon him.

(c) Use of vehicles, vessels, and aircraft

The burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with controlled substances in schedule I was used in accordance with the provisions of this subchapter shall be on the persons engaged in such use.

(d) Immunity of Federal, State, local and other officials

Except as provided in sections 2234 and 2235 of title 18, no civil or criminal liability shall be imposed by virtue of this subchapter upon any duly authorized Federal officer lawfully engaged in the enforcement of this subchapter, or upon any duly authorized officer of any State, territory, political subdivision thereof, the District of Columbia, or any possession of the United States, who shall be lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

(Pub. L. 91–513, title II, §515, Oct. 27, 1970, 84 Stat. 1279.)

From Title 21 – FOOD AND DRUGS
CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL
Subchapter I – CONTROL AND ENFORCEMENT
Part E – Administrative and Enforcement Provisions

§903. Application of State law

No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

(Pub. L. 91–513, title II, §708, Oct. 27, 1970, 84 Stat. 1284.)

TITLE X
PUBLIC HEALTH

CHAPTER 126-A
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Controlled Drug Prescription Health and Safety Program

Section 126-A:89

126-A:89 Definitions.–

In this subdivision:

I. (a) "Chronic pain" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that might or might not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years. It also includes intermittent episodic pain that might require periodic treatment.

(1) For the purpose of this subdivision, chronic pain does not cover or in any way determine treatment for pain from terminal disease.

(2) For the purpose of this subdivision, chronic pain includes but may not be limited to pain defined as "chronic," "intractable," "high impact," "chronic episodic," and "chronic relapsing."

(b) A diagnosis of chronic pain made by a practitioner licensed in any of the states in the United States or the District of Columbia and supported by written documentation of the diagnosis by the treating practitioner

shall constitute proof that the patient suffers from chronic pain.

II. "Commissioner" means the commissioner of the department of health and human services.

III. "Controlled substance" means controlled drugs as defined in RSA 318-B:1, VI.

IV. "Department" means the department of health and human services, established in RSA 126-A:4.

V. "Dispense" means to deliver a controlled substance by lawful means and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

VI. "Dispenser" means a person or entity who is lawfully authorized to deliver a schedule II-IV controlled substance, but does not include:

(a) A licensed hospital pharmacy under RSA 318 that dispenses less than a 48-hour supply of a schedule II-IV controlled substance from a hospital emergency department or that dispenses for administration in the hospital;

(b) A practitioner, or other authorized person who administers such a substance;

(c) A wholesale distributor of a schedule II-IV controlled substance or its analog;

(d) A prescriber who dispenses less than a 48-hour supply of a schedule II-W controlled substance from a hospital emergency department to a patient;

(e) A veterinarian who dispenses less than a 48-hour supply of a schedule II-IV controlled substance to a patient; or

(f) A practitioner who does not hold or operate under an active Drug Enforcement Agency registration number to prescribe or dispense controlled substances.

VII. "Patient" means the person or animal who is the ultimate user of a controlled substance for whom a lawful prescription is issued and for whom a controlled substance or other such drug is lawfully dispensed.

VIII. "Practitioner" means a physician, dentist, podiatrist, veterinarian, pharmacist, APRN, physician assistant, naturopath, or other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled substance in the course of licensed professional practice. "Practitioner" shall also include practitioners with a federal license to prescribe or administer a controlled substance.

IX. "Prescribe" means to issue a direction or authorization, by prescription, permitting a patient to lawfully obtain controlled substances.

X. "Prescriber" means a practitioner or other authorized person who prescribes a schedule II, III, or IV controlled substance.

XI. "Program" means the controlled drug prescription health and safety program that electronically facilitates the confidential sharing of information relating to the prescribing and dispensing of controlled

substances listed in schedules II-IV, established by the department pursuant to RSA 126-A:90.

Source. 2021, 91:45, eff. July 1, 2021; 148:6, eff. July 1, 2021.

TITLE X
PUBLIC HEALTH

CHAPTER 126-A
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Controlled Drug Prescription Health and Safety Program

Section 126-A:90

126-A:90 Controlled Drug Prescription Health and Safety Program Established. –

I. The department shall design, establish, and contract with a third party for the implementation and operation of an electronic system to facilitate the confidential sharing of information relating to the prescribing and dispensing of schedule II-IV controlled substances, by prescribers and dispensers within the state.

I-a. The department may enter into agreements or contracts to facilitate the confidential sharing of information relating to the prescribing and dispensing of schedule II-IV controlled substances, by practitioners within the state and to establish secure connections

between the program and a practitioner's electronic health record keeping system. An electronic health record keeping system may allow for the query and retrieval of the provider specified, individual's program information for display and retention in the patient's medical information; provided that nothing in this section shall allow the electronic health record keeping system owner or license holder to perform data queries unrelated to individuals under the practitioner's care. The electronic health record keeping system owner or license holder shall be responsible for ensuring that only authorized individuals have access to program information. The program shall record and retain in its database what information was transferred and the identity of the organization who received the information. The program shall include this information when a patient requests a report pursuant to RSA 126-A:93, I(b)(1).

II. The department may establish fees for the establishment, administration, operations and maintenance of the program. The program may also be supported through grants and gifts. The fee charged to individuals requesting their own prescription information shall not exceed the actual cost of providing that information.

III. Prescription information held by the program relating to any individual shall be deleted 3 years after the initial prescription was dispensed. All de-identified data may be kept for statistical and analytical purposes in perpetuity.

IV. The commissioner shall establish an advisory council, as provided in RSA 126-A:96.

Source. 2021, 91:45, eff. July 1, 2021; 148:7, eff. July 1, 2021.

TITLE X
PUBLIC HEALTH

CHAPTER 126-A
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Controlled Drug Prescription Health and Safety Program

Section 126-A:91

126-A:91 Controlled Drug Prescription Health and Safety Program Operation. –

I. The department shall develop a system of registration for all prescribers and dispensers of schedule II-IV controlled substances within the state. The system of registration shall be established by rules adopted by the department, pursuant to RSA 541-A.

II. All prescribers and dispensers authorized to prescribe or dispense schedule II-IV controlled substances within the state shall be required to register with the program as follows:

(a) Practitioners who prescribe but do not dispense schedule II-IV controlled substances shall register with the program as a prescriber;

(b) Practitioners who dispense but do not prescribe schedule II-IV controlled substances shall register with the program as a dispenser unless exempted pursuant to RSA 126-A:89, VI; and

(c) Practitioners who prescribe and dispense schedule II-IV controlled substances shall register with the program as both a prescriber and a dispenser unless exempted pursuant to RSA 126-A:89, VI.

III. Only registered prescribers, dispensers, or their designees, and federal health prescribers and dispensers working in federal facilities located in New Hampshire, Massachusetts, Maine, and Vermont shall be eligible to access the program.

IV. The chief medical examiner and delegates may register and access the program.

V. Each dispenser shall submit to the program the information regarding each dispensing of a schedule II-IV controlled substance. Any dispenser located outside the boundaries of the state of New Hampshire and who is licensed and registered by the pharmacy board, established in RSA 318:2, shall submit information regarding each prescription dispensed to a patient who resides within New Hampshire.

VI. Each dispenser required to report under paragraph V of this section shall submit to the program by electronic means information for each dispensing that shall include, but not be limited to:

(a) Dispenser's Drug Enforcement Administration (DEA) registration number.

(b) Prescriber's DEA registration number.

(c) Date of dispensing.

(d) Prescription number.

(e) Number of refills granted.

(f) National Drug Code (NDC) of drug dispensed.

(g) Quantity dispensed.

(h) Number of days supply of drug.

(i) Patient's name.

(j) Patient's address.

(k) Patient's date of birth.

(l) Patient's telephone number, if available.

(m) Date prescription was written by prescriber.

(n) Whether the prescription is new or a refill.

(o) Source of payment for prescription.

VII. (a) Except as provided in subparagraphs (b) and (c), each dispenser shall submit the required information in accordance with transmission methods daily by the close of business on the next business day from the date the prescription was dispensed.

(b) Veterinarians shall submit the information required under subparagraph (a) no more than 7 days from the date the prescription was dispensed.

(c) Dispensers who have a federal Drug Enforcement Administration license, but who do not dispense controlled substances may request a waiver from the requirements of subparagraph (a) from the department.

VIII. The program administrator may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required by paragraph VI is submitted in this alternative format and within the established time limit.

IX. The program administrator may grant a reasonable extension to a dispenser that is unable, for good cause, to submit all the information required by paragraph V within the established time limits.

X. Any dispenser who in good faith reports to the program as required by paragraphs V and VI shall be immune from any civil or criminal liability as the result of such good faith reporting.

Source. 2021, 91:45, eff. July 1, 2021.

TITLE X
PUBLIC HEALTH

CHAPTER 126-A
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Controlled Drug Prescription Health and Safety Program

Section 126-A:92

126-A:92 Confidentiality. –

I. Information contained in the program, information obtained from it, and information contained in the records of requests for information from the program, is confidential, is not a public record or otherwise subject to disclosure under RSA 91-A, and is not subject to discovery, subpoena, or other means of legal compulsion for release and shall not be shared with an agency or institution, except as provided in this subdivision. This paragraph shall not prevent a practitioner from using or disclosing program information about a patient to others who are authorized by state or federal law or regulations to receive program information.

II. The department shall establish and maintain procedures to ensure the privacy and confidentiality of patients and patient information.

II-a. A practitioner who intends to request and use information from the program about a patient shall post a sign that can be easily viewed by the public that discloses to the public that the practitioner may access and use information contained in the program. In lieu

of posting a sign, the practitioner may provide such notice in written material provided to the patient.

III. The department may use and release information and reports from the program for program analysis and evaluation, statistical analysis, public research, public policy, and educational purposes, provided that the data are aggregated or otherwise de-identified at all levels of use. The department shall not acquire, use or release information from the program for these purposes unless all patient-specific protected health information has been de-identified in accordance with section 164.514(b)(2) of the HIPAA Privacy Rule.

Source. 2021, 91:45, eff. July 1, 2021; 148:8, eff. July 1, 2021.

TITLE X
PUBLIC HEALTH

CHAPTER 126-A
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Controlled Drug Prescription Health and Safety Program

Section 126-A:93

126-A:93 Providing Controlled Drug Prescription Health and Safety Information. –

I. The program administrator may provide information in the prescription health and safety program upon request only to the following persons:

(a) By electronic or written request to prescribers, dispensers, and the chief medical examiner and delegates within the state who are registered with the program:

(1) For the purpose of providing medical or pharmaceutical care to a specific patient with whom the requester has a practitioner-patient relationship. This shall not include department staff seeking to access the program for state, federal or private agency purposes, or on behalf of the department or other requesting agency;

(2) For reviewing information regarding prescriptions issued or dispensed or for conducting medication reconciliation by the requester;

(3) For the purpose of investigating the death of an individual; or

(4) For the purpose of administering RSA 318:29-a, VI, RSA 326-B:36-a, RSA 329:13-b, and other participating health professional boards.

(b) By written request, to:

(1) A patient who requests his or her own prescription monitoring information.

(2) The board of dentistry, the board of medicine, the board of nursing, the board of registration in optometry, the board of podiatry, the board of veterinary medicine, and the pharmacy board; provided, however, that the request is pursuant to the boards' official duties and responsibilities and the disclosures to each board

relate only to its licensees and only with respect to those licensees whose prescribing or dispensing activities indicate possible fraudulent conduct.

(3) Authorized law enforcement officials on a case-by-case basis for the purpose of investigation and prosecution of a criminal offense when presented with a court order based on probable cause. No law enforcement agency or official shall have direct access to query program information.

(4) [Repealed.]

(c) By electronic or written request on a case-by-case basis to:

(1) A controlled prescription drug health and safety program from another state; provided, that there is an agreement in place with the other state to ensure that the information is used or disseminated pursuant to the requirements of this state.

(2) An entity that operates a secure interstate prescription drug data exchange system for the purpose of interoperability and the mutual secure exchange of information among prescription drug monitoring programs, provided that there is an agreement in place with the entity to ensure that the information is used or disseminated pursuant to the requirements of this state.

II. The program administrator shall notify the appropriate regulatory board listed in subparagraph I(b)(2) and the prescriber or dispenser at such regular intervals as may be established by the department if there

is reasonable cause to believe a violation of law or breach of professional standards may have occurred. The program administrator shall provide prescription information required or necessary for an investigation.

III. The program administrator shall review the information to identify information that appears to indicate whether a person may be obtaining prescriptions in a manner that may represent misuse or abuse of schedule II-IV controlled substances. When such information is identified, the program administrator shall notify the practitioner who prescribed the prescription.

IV. The program administrator shall make a report, at least annually, commencing on November 1, 2021, to the senate president, the speaker of the house of representatives, the oversight committee on health and human services, established in RSA 126-A:13, the advisory council established in RSA 126-A:96 and the licensing boards of all professions required to use the program relative to the effectiveness of the program.

Source. 2021, 91:45, eff. July 1, 2021; 148:9, 10, eff. July 1, 2021.

TITLE X
PUBLIC HEALTH

CHAPTER 126-A
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Controlled Drug Prescription Health and Safety Program

Section 126-A:94

126-A:94 Unlawful Act and Penalties. –

I. Any dispenser or prescriber who fails to submit the information required in RSA 126-A:91 or knowingly submits incorrect information shall be subject to a warning letter and provided with an opportunity to correct the failure. Any dispenser or prescriber who subsequently fails to correct or fails to resubmit the information may be subject to discipline by the appropriate regulatory board.

II. Any dispenser or prescriber whose failure to report the dispensing of a schedule II-IV controlled substance that conceals a pattern of diversion of controlled substances into illegal use shall be guilty of a violation and subject to the penalties established under RSA 318-B:26 and the department's and appropriate regulatory board's rules as applicable. In addition, such dispenser or prescriber may be subject to appropriate criminal charges if the failure to report is determined to have been done knowingly to conceal criminal activity.

III. Any person who engages in prescribing or dispensing of controlled substances in schedule II-IV without having registered with the program may be subject to discipline by the appropriate regulatory board.

IV. Any person, including department staff, authorized to receive program information who knowingly discloses such information in violation of this subdivision shall be subject to discipline by the appropriate regulatory board and to all other relevant penalties under state and federal law.

V. Any person authorized to receive program information who uses such information for a purpose in violation of this subdivision shall be subject to disciplinary action by the appropriate regulatory board and to all other relevant penalties under state and federal law.

VI. Unauthorized use or disclosure of program information shall be grounds for disciplinary action by the relevant regulatory board.

VII. Any person who knowingly accesses, alters, destroys, or discloses program information except as authorized in this subdivision or attempts to obtain such information by fraud, deceit, misrepresentation, or subterfuge shall be guilty of a class B felony.

Source. 2021, 91:45, eff. July 1, 2021.

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EXHIBIT A-3

U.S. DEPARTMENT OF JUSTICE/DRUG ENFORCEMENT ADMINISTRATION SUBPOENA

In the matter of the investigation of
Case No: CG-18-2001
Subpoena No. CG-18-701292

TO: Michelle Ricco Jonas,
Program Manager for the
NH PDMP
AT: 121 South Fruit Street
Concord, NH 03301

PHONE: 6032716980
FAX: 6032712856

GREETING: By the service of this subpoena upon you by DI Gabrielle Stern who is authorized to serve it, you are hereby commanded and required to appear before DI Gabrielle Stern, an officer of the Drug Enforcement Administration to give testimony and to bring with you and produce for examination the following books, records, and papers at the time and place hereinafter set forth:

Pursuant to an investigation of violations of 21 U.S.C. 801 et seq., you are to provide any and all records regarding [redacted], being maintained by the New Hampshire Prescription Drug Monitoring Program from February 28, 2016 through present day. This is an administrative subpoena issued by the Drug Enforcement Administration (DEA), a federal

law enforcement agency, for records that may include protected health information. DEA is authorized by 21 U.S.C. § 876 to issue an administrative subpoena and is permitted by 45 C.F.R. § 164.512(f) to request protected health information. The information sought is relevant and material to a legitimate law enforcement inquiry; the subpoena is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and de-identified information cannot reasonably be used. NONDISCLOSURE: Disclosure of any information concerning this subpoena would impede a federal law enforcement investigation. Pursuant to 45 C.F.R. § 164.528(a)(2), you must suspend notice to any individual whose protected health Information is disclosed in response to this subpoena for a period of two (2) years.

Please do not disclose the existence of this request or investigation for an indefinite time period. Any such disclosure could impede the criminal investigation being conducted and interfere with the enforcement of the Controlled Substances Act.

Please direct questions concerning this subpoena and/or responses to Diversion Investigator Gabrielle Stern, 603-628-7411ext169.

Place and time for appearance: At Manchester District Office 324 South River Road, Bedford, NH 03110 on the ~~29th day of June~~ 13th of July (*GS*), 2018 at 09:00 AM. In lieu of personal appearance, please email records to Gabrielle.N.Stern@usdoj.gov or fax to 603-628-7488.

Failure to comply with this subpoena will render you liable to proceedings in the district court of the United States to enforce obedience to the requirements of this subpoena, and to punish default or disobedience.

Issued under authority of Sec. 506 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law No. 91-513 (21 U.S.C. 876)

ORIGINAL

Signature: Claire M. Brennan

Claire M. Brennan
Diversion Program Manager

Issued this 11th day of Jun 2018

FORM DEA-79

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

UNITED STATES
DEPARTMENT OF JUSTICE,

Petitioner

v. Case No. 18-mc-00056

MICHELLE RICCO JONAS,

Respondent

DECLARATION OF MICHELLE RICCO JONAS

I, Michelle Ricco Jonas, make the following declaration:

1. I presently serve as the Program Manager for the New Hampshire Prescription Drug Monitoring Program (the "PDMP"), which is aimed at advancing the health and well-being of this State's residents.

2. In that capacity, I am "the person designated by the [B]oard [of Pharmacy] to oversee the implementation and operation of the [PDMP] by [a third party] program vendor." N.H. Admin. R. Ph. 1502.01(m), (n) [New Hampshire Controlled Drug Prescription Health and Safety Program – Definitions].

3. The PDMP database contains patient identification and prescription information entered by

dispensers of schedule II-IV controlled substances for a substantial segment of this State's residents.[1]

4. Pursuant to RSA 318-B:34 [PDMP – Confidentiality], patient prescription data within the PDMP database is highly confidential and may not be accessed or disclosed, except as provided in RSA 318-B:35 [Providing Controlled Drug Prescription Health and Safety Information].

5. I have reviewed the "U.S. Department of Justice/Drug Enforcement Administration Subpoena," which is dated June 11, 2018 and addressed

TO: Michelle Ricco Jonas, Program Manager for the NH PDMP
AT: 121 South Fruit Street[,] Concord, NH 03301

PHONE: 6032716980
FAX: 6032712856

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[1] Schedule II-IV controlled substances include such medications as

- Xanax, Valium, Ativan, and Librium (each non-narcotic Schedule IV)
- Ritalin and Adderall (both non-narcotic Schedule II)
- Tylenol with Codeine (narcotic Schedule III)
- Demerol, Percocet and Oxycontin (each narcotic Schedule II)
- Ambien, Lunesta and Sonata (each non-narcotic Schedule IV)
- Testosterone (non-narcotic Schedule III)
- Marinol (non-narcotic Schedule III)
- Nembutol (non-narcotic Schedule II)

6. The Subpoena correctly states

- my name
- my official capacity with the Board of Pharmacy's PDMP
- the office address of the Board and the PDMP
- the telephone and fax numbers for the PDMP

7. The Subpoena commands that I am "to provide any and all records regarding [redacted], being maintained by the [PDMP] from February 28, 2016 through the present day."

8. Except in my capacity as Program Manager for the PDMP, I am not in the possession, custody or control of *any* "records . . . being maintained by the [PDMP]."

9. The Subpoena directs that I undertake an act that I cannot perform *except* (a) in my *official* capacity as PDMP Program Manager, and even then as limited by RSA 318-B:35 (to which the Subpoena does not conform) or (b) in my *individual* capacity via the commission of a Class B felony. *See* RSA 318-B:36, VII.

I declare under penalty of perjury that the foregoing is true and correct.

Date: August 23, 2018 /s/ Michelle Ricco Jonas
Michelle Ricco Jonas