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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

OREGON PRESCRIPTION DRUG MONITORING PROGRAM, an agency of the STATE OF OREGON,

Plaintiff,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, an agency of the UNITED STATES DEPARTMENT OF JUSTICE,

Defendant.

Case No.: 3:12-cv-02023-HA

DEFENDANT DEA'S COMBINED MEMORANDUM IN SUPPORT OF ITS CROSS-MOTION FOR SUMMARY JUDGMENT AGAINST PLAINTIFFS-INTERVENORS AND RESPONSE TO THEIR MOTION FOR SUMMARY JUDGMENT

JOHN DOE 1, JOHN DOE 2, JOHN DOE 3, JOHN DOE 4, DR. JAMES ROE, and the AMERICAN CIVIL LIBERTIES UNION OF OREGON, INC.,

Plaintiffs-Intervenors,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, an agency of the UNITED STATES DEPARTMENT OF JUSTICE,

Defendant in Intervention.

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Defendant United States Drug Enforcement Administration ("DEA"), by S. Amanda Marshall, United States Attorney for the District of Oregon, through Assistant U.S. Attorney Kevin Danielson, submits this combined memorandum in support of its cross-motion for summary judgment against Plaintiffs-Intervenors and in response to their motion for summary judgment. Dkt. 27.

Introduction

The Oregon Prescription Drug Monitoring Program ("PDMP"), a state agency in Oregon, brought this declaratory judgment action under 28 U.S.C. § 2201 to determine its rights and obligations in complying with administrative subpoenas issued by the U.S. Drug Enforcement Administration ("DEA") under 21 U.S.C. § 876. Under Oregon law, PDMP maintains a program for monitoring and reporting prescription drugs dispensed by Oregon pharmacies that are classified in schedules II through IV under the federal Controlled Substances Act. ORS § 431.966.

The Controlled Substances Act ("CSA") authorizes the DEA to issue administrative subpoenas for witnesses and records that are relevant or material to an investigation of possible violations of the Act. 21 U.S.C. § 876(a). The DEA is not required to obtain a court order based on probable cause to issue a subpoena or to have it enforced.

Plaintiffs-Intervenors are four "John Doe" patients and one "James Roe" doctor who challenge DEA's use of administrative subpoenas to obtain prescription information[1]

[1] Intervenors' allege that the Oregon PMP contains "prescription records" (*e.g.*, complaint in Intervention ¶ 19), but this is not accurate. The Oregon PMP does not contain patients' medical files or records.

from the PDMP. Plaintiffs-Intervenors claim that the issuance of administrative subpoenas pursuant to 21 U.S.C. § 876 violates the Fourth Amendment because it allows DEA to obtain prescription medical information without a warrant or other valid court order based on probable cause.

Plaintiffs-Intervenors' claims should be rejected. As an initial matter, Plainiffs-Intervenors lack standing and their claims are not ripe because they have not shown that the DEA has ever used an administrative subpoena to obtain their specific prescription medical information and Plaintiffs-Intervenors' contention that the DEA may do so in the future is purely speculative. Moreover, even if this Court had jurisdiction, Plaintiffs-Intervenors' claims would fail because Plaintiffs-Intervenors do not have a reasonable expectation of privacy interest in their prescription information that is protected by the Fourth Amendment. Accordingly, the Court does not have subject matter jurisdiction over the claims in the complaint in intervention, and should grant summary judgment in favor of the DEA.

Background

I. Federal law allows the DEA to issue administrative subpoenas for relevant or material records and witnesses when it is investigating possible violations of the CSA.

Under the CSA, Congress authorized the Attorney General to issue administrative subpoenas under the following circumstances.

> In any investigation relating to his functions under this subchapter with respect to controlled substances, listed chemicals, tableting machines, or

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Rather, it contains prescription data reported to the PMP by doctors and pharmacies. ORS §§ 431.962 - .964.

> encapsulating machines, the Attorney General may subpena [sic] 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. . . .

21 U.S.C. § 876(a). The Attorney General has delegated this authority to the DEA Administrator and supervisory personnel in the field. 28 C.F.R. Part 0, Subpart R, § 0.100; § 0.104, Appendix to Subpart R of Part 0 – Redelegation of Functions, § 4. "In the case of contumacy . . . or refusal to obey a subpena [sic]" issued by the DEA, "the Attorney General may invoke the aid of any court of the United States . . . to compel compliance with the subpoena [sic]." 21 U.S.C. § 876(c). Failure to obey an order of the court may be punished by contempt. *Id.*

Information that the DEA obtains from an administrative subpoena can only be released under limited circumstances and primarily to federal, state, and local officials engaged in the prosecution of cases involving controlled substances before courts and licensing boards. 28 C.F.R. Part 0, Subpart R, § 0.103. In addition, information received in response to a subpoena under 21 U.S.C. § 876(a) is "case sensitive and governed by significant restrictions on the dissemination of information contained in received records, subjecting employees to discipline, termination, as well as civil and criminal penalties for improper disclosure." Dec. of Lori Cassity, Dkt. 29-1, p. 121 at ¶ 2.

Prescription information subpoenaed from the PDMP by the DEA is used to investigate possible violations of the CSA. Those possible violations are connected to prescriptions fraudulently obtained by a patient, prescriptions unlawfully issued by a

physician, or prescriptions unlawfully filled by a pharmacy. Dec. of Cassity, Dkt. 29-1, p. 122 at ¶ 4. PDMP is the only resource in Oregon where this information is consolidated and is a crucial tool for DEA in its investigations. *Id*., at pp. 122-23, ¶¶ 5.

II. Oregon law requires pharmacies to report information about certain prescriptions to PDMP.

The Oregon Health Authority was authorized to establish a "prescription monitoring program for monitoring and reporting prescription drugs dispensed by pharmacies in Oregon that are classified in schedules II and IV under the federal Controlled Substances Act." ORS § 431.962(1)(a). A pharmacy is required by law to report the following information to PDMP: (1) the name, address, and date of birth of the patient; (2) the identification of the pharmacy; (3) the identification of the practitioner who prescribed the drug; (4) the identification of the drug; (5) the date of the prescription: (6) the date the drug was dispensed; and (7) the quantity of the drug dispensed. ORS § 431.964(1)(a-g).

The Oregon Health Authority may only release the information under limited circumstances. As relevant here, information may be released as follows:

> Pursuant to a valid court order based on probable cause and issued at the request of a federal, state, or local law enforcement agency engaged in an authorized drug-related investigation involving a person to whom the requested information pertains.

ORS § 431.966(2)(a)(C).

III. Plaintiffs-Intervenors allege that release of prescription information by PDMP will violate their right of privacy under the Fourth Amendment.

Plaintiffs-Intervenors John Doe 1-4 ("Does") allege that if the PDMP releases their prescription information without a warrant based on probable cause, their privacy rights will be violated because details regarding their medical disorders and medical treatment might be shared with the public. Dkt. 33, ¶¶ 24-27; Dkt. 34, ¶¶ 18-21; Dkt. 35, ¶¶ 23-26; Dkt. 36, ¶¶ 12-18; The Does also allege that they fear being scrutinized by the DEA because of the drugs they use for their treatment. *Id*. Plaintiff-Intervenor Dr. James Roe ("Dr. Roe") similarly alleges that he fears scrutiny by the DEA. Dkt. 37, ¶¶ 25-43. He alleges that he fears investigation by the DEA based on his Oregon prescriptions because federal law enforcement officers investigated him recently regarding his prescription practices for patients that live in the state of Washington, which also has a Prescription Drug Monitoring Program. *Id*.

Legal standard for summary judgment

Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In addition, a federal court must establish jurisdiction before it can proceed to the merits of a case. *Scott v. Pasadena Unified Sch. Dist.*, 306 F.3d 646, 653-54 (9th Cir. 2002). The Court's jurisdiction is limited by the "case or controversy" requirement of Article III standing and by prudential considerations, such as ripeness, that arise as federal courts work within the constitutional limitations on their judicial power. U.S. Const. art. III; *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967). If claims before the Court are not

ripe, they must be dismissed. *Addington v. U.S. Airline Pilots Ass'n*, 606 F.3d 1174, 1179 (9th Cir. 2010). Similarly, if parties do not have standing, their claims must be dismissed. *Scott*, 306 F.3d at, 654-55.

ARGUMENT

I. The Court lacks subject matter jurisdiction because Plaintiffs-Intervenors lack standing and their claims are not ripe.

A. Legal standards

Standing and ripeness are threshold jurisdictional questions that the Court must resolve before proceeding to the merits. *Sacks v. Office of Foreign Assets Control*, 466 F.3d 764, 771 (9th Cir. 2006). The burden of establishing standing and ripeness remain at all times with the Plaintiffs-Intervenors, as the party invoking federal jurisdiction. *Scott*, 306 F.3d at 655 (citations omitted).

To meet its burden to establish standing, a plaintiff must demonstrate that it has "suffered an injury in fact – an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (quotations omitted). The harm must be "distinct and palpable" and "actual or imminent." *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (quotations omitted). Allegations of possible future injury do not suffice; rather, "[a] threatened injury must be certainly impending to constitute injury in fact." *Id*. at 158.

"The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Wolfson v. Brammer*,

616 F.3d 1045, 1057 (9th Cir. 2010) (quoting *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003)) (internal quotation marks omitted). It is intended to prevent courts, through avoidance of premature adjudication, from becoming entangled in "abstract disagreements." *Addington*, 606 F.3d at 1179 (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977)).

To determine whether a case is ripe, the Court must consider two factors: the "fitness of the issues for judicial decision," and "the hardship to the parties of withholding court consideration.'"[2] *Addington*, 606 F.3d at 1179 (quoting *Abbott Labs.*, 387 U.S. at 149). A claim is not fit for judicial decision when it relies upon "contingent future events that may or may not occur as anticipated, or indeed may not occur at all." *Wolfson*, 616 F.3d at 1060 **(**quoting *Texas v. United States*, 523 U.S. 296, 300 (1998)).

Regarding the "hardship" factor, litigants must show that withholding review of their claims would result in direct and immediate hardship, and would entail more than possible financial loss. *Wolfson*, 616 F.3d at 1060 (citing *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1126 (9th Cir.2009)); *see also Addington*, 606 F.3d at 1180. In its evaluation of a claim of hardship, the Ninth Circuit "consider[s] whether the regulation requires an immediate and significant change in plaintiffs' conduct of their affairs with serious

[2] The fitness and hardship factors describe the "prudential" component of ripeness. *Wolfson*, 616 F.3d at 1058. Ripeness also has a constitutional component, which overlaps with the "injury in fact" analysis for Article III standing. *Id.* (citing *Thomas v. Anchorage Equal Rights Comm'n,* 220 F.3d 1134, 1138–39 (9th Cir. 2000) (en banc); Whether framed as an issue of standing or ripeness, the inquiry is largely the same: whether the issues presented are "definite and concrete, not hypothetical or abstract." *Wolfson*, 616 F.3d at 1058 (citing *Thomas*, 220 F.3d at 1139).

penalties attached to noncompliance." *Id.* (citations omitted).

B. Plaintiffs-Intervenors' allegations and declarations do not establish that the DEA's collection of PDMP information affects all Oregon patients and doctors.

Plaintiffs-Intervenors contend that the DEA's practice of obtaining PDMP prescription information without a warrant would reveal sensitive medical information about the Does and/or subject them to law enforcement scrutiny for the medications they use. *See, e.g.*, Int. Compl. Dkt. 18, ¶¶ 54-60, 63-64, 88-87, 103, 109. But there is no evidence that this practice has or will affect Plaintiffs-Intervenors adversely, if at all. The administrative subpoenas issued by the DEA are not blanket subpoenas seeking the information from all Oregon doctors and pharmacies. Nor do the queries to the PDMP seek information for all doctors who dispensed a particular controlled substance. Rather, the subpoenas customarily seek information pertaining to a "specific doctor" or small group of doctors. *See id.* ¶ 34; *U.S. v. Oregon Prescription Drug Monitoring Program*, 3:12-mc-298, Petition to Enforce Administrative Subpoena n.4 (D. Or. Aug. 24, 2012).[3] PMP data is used as an investigative tool when the DEA is investigating a specific physician or pharmacy for illegal distribution of controlled substances. *U.S. v. OPDMP*, Petition at 5. Further, DEA's requests are not focused on all drugs prescribed by the target doctor or pharmacy. In its investigations, DEA focuses on "the prescription of

[3] Intervenors explicitly reference in their complaint the DEA's August 2012 Petition to enforce DEA's administrative subpoena, and the complaint includes information from the filings from that judicial proceeding. *See, e.g.*, Int. Compl. ¶¶ 34-37, 39; *U.S. v. OPDMP*, Petition; *id.* Declaration of Tyler D. Warner; *id.* Declaration of Lori A. Cassity. The Court may take judicial notice of the Petition. *Terenkian v. Republic of Iraq*, 694 F.3d 1122, 1137 n.8 (9th Cir. 2012) (stating that a court may take judicial notice of court filings and other matters of public record).

certain controlled substances written by the subject." *Id.* (emphasis added).

Further, PDMP data is not an avenue to public disclosure of patients' medical information. Plaintiffs-Intervenors' privacy claims center on the "belief" that patient prescription information may be shared with the public. *See, e.g.*, Int. Compl., Dkt. 18, ¶¶ 88, 131. But neither the complaint nor Plaintiffs-Intervenors' declarations support this contention. Indeed, Plaintiffs-Intervenors themselves note that the Government has taken care to redact from public filings the names of doctors for whom the DEA has sought prescription information from the Oregon PMP. *See* Int. Compl., Dkt. 18, ¶ 34; *see also U.S. v. OPDMP*, Petition, Decl. of Tyler D. Warner, Dkt. 29-1, ¶ 3. A DEA representative has declared under penalties of perjury that the DEA employs substantial measures to protect against public disclosure of the PMP information the DEA receives:

> Records received by DEA, in response to an administrative subpoena, are case sensitive and governed by significant restrictions on the dissemination of information contained in received records, subjecting employees to discipline, termination, as well as civil and criminal sanctions for improper disclosure.

Decl. of Lori A. Cassity, Dkt. 29-1, ¶ 2.

C. John Does 1-4 lack standing and their claims are not ripe.

The Does lack standing and have not asserted ripe claims. Their claims "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Wolfson*, 616 F.3d at 1064; *Scott*, 306 F.3d at 655, 662. "The mere existence of a statute, which may or may not ever be applied to plaintiffs, is not sufficient to create a case or controversy within the meaning of Article III." *Id.* at 656.

The Does contend that the DEA's practice of collecting prescription information

from the Oregon PMP through administrative subpoenas could reveal sensitive medical information about the Does or subject them to law enforcement scrutiny. *See, e.g.*, Int. Compl. ¶¶ 54-60, 63-64, 88-87, 103, 109. The Does' claims, however, are rife with speculative and conjectural "if's" "could's" "would's," "might's" and "fears." For instance, John Doe 2 alleges the following:

- *If* the DEA (or the public) obtained information about John Doe 2....
- John Doe 2 *might* take steps to protect his privacy....
- *If* his testosterone dosage decreased in the future....
- [I]t *could* indicate that he had had his uterus and ovaries removed.
- He *fears* that because of the quantity of testosterone he uses... law enforcement *might* think he is using testosterone for an illicit purpose.

Int. Compl. Dkt. 18, ¶¶ 109-112 (emphasis added). Accordingly, for the Does to have a cognizable harm, this Court would have to assume that: (1) the DEA will undertake an investigation of each Doe's particular doctors or pharmacies; (2) the investigation will concern the specific prescription drug(s) being used by the Doe; (3) the Doe's prescription information will be among the information that the DEA obtains from the Oregon PMP; (4) there will be inadvertent public disclosure by the DEA of that information; and/or (5) the PMP data will lead to further investigation of the doctor and/or the Doe. The complaint and declarations submitted by the Does do not provide any basis to assume any of the foregoing speculative contingencies will ever materialize, let alone all of them. *See generally* Int. Compl.; *supra* Section II.A.

The contingent and speculative nature of each stage makes this case similar to others in which the Supreme Court and the Ninth Circuit have found standing and ripeness wanting. In *Clapper v. Amnesty Int'l USA*, 568 U.S. __, 2013 WL 673253 (Feb. 26, 2013), for example, the plaintiffs – "attorneys and human rights, labor, legal, and media organizations," – challenged Section 702 of the Foreign Intelligence Surveillance Act (FISA), 50 U.S.C. § 1881a, on the grounds that they frequently communicate with individuals who are likely targets of surveillance. *Id*. at 1145. Plaintiffs attempted to establish an injury in fact by alleging that there was a reasonable likelihood that their communications would be the subject of surveillance in the future. The Supreme Court held that the plaintiffs lacked Article III standing because their alleged future injuries were not "certainly impending." *Id*. at 1148. The Court explained that plaintiffs' alleged harm

> rests on their highly speculative fear that: (1) the Government will decide to target the communications of non-U.S. persons with whom they communicate; (2) in doing so, the Government will choose to invoke its authority under § 1881a rather than utilizing another method of surveillance; (3) the Article III judges who serve on the Foreign Intelligence Surveillance Court will conclude that the Government's proposed surveillance procedures satisfy § 1881a's many safeguards and are consistent with the Fourth Amendment; (4) the Government will succeed in intercepting the communications of respondents' contacts; and (5) respondents will be parties to the particular communications that the Government intercepts.

Id. The Court concluded that the plaintiffs' "theory of standing, which relies on a highly attenuated chain of possibilities, does not satisfy the requirement that threatened injury must be certainly impending." *Id*.

Similarly, in *Portland Police Association v. City of Portland*, the plaintiffs sued for an injunction against enforcement of an order by the chief of police. *Portland Police*, 658 F.2d at 1273. The order required police officers to create an official report of their actions after a "major incident" (*e.g.*, discharge of a firearm), and stated that officers did not have the right to consult an attorney when creating the report. *Id.* at 1273. Plaintiffs claimed that the order violated various constitutional provisions. *Id.* at 1273. The Ninth Circuit held that the claim depended on too many unrealized and speculative contingencies, and, therefore, was not ripe. Specifically, for plaintiffs to suffer an arguable violation of their rights, the court would have had to assume the following series of contingencies:

> the officer must be in a "major incident"; he or she must be at least partly culpable for its occurrence; he or she must request counsel; that request must be denied or counsel must not otherwise be supplied; and, finally, disciplinary or criminal proceedings must be instigated for either failure to complete reports or because of the utterance of incriminating statements during the report process.

Id. at 1274. The Ninth Circuit held, "The series of contingencies is not only long, but the appellants have failed to demonstrate that each stage necessarily follows its predecessor." *Id.* The court found that the plaintiffs had not shown any history that their rights had been violated; nor could they assert with assurance that they would be deprived of their rights in the future. The court therefore held, "As such, their claim is abstract at best." *Id.*

The same is true here. The Does' claims rest on a series of speculative contingencies. Andthey have "failed to demonstrate that each stage necessarily follows

its predecessor." *Portland Police*, 658 F.2d at 1274. The Does have not shown that either their doctors or their pharmacies have been targets in an active DEA investigation, or even that the DEA is scrutinizing the practices of their doctors or pharmacies. The Does also have not shown that, even if the DEA were focused on their doctors, that the drugs subject to investigation are the drugs that the Does have been prescribed. Nor have the Does shown that the DEA has used the Oregon PMP information as an investigatory tool, rather than relying on information obtained pursuant to a Notice of Inspection, Administrative Inspection Warrant or a Judicial Warrant. *Compare* Int. Compl. *with* 21 U.S.C. § 880; 21 C.F.R. § 1316.03-11.[4] Thus, the Does have not demonstrated – as it is their burden to do – that the DEA will definitely obtain medical information pertaining to Does from the Oregon PMP. Finally, the Does have not alleged that the DEA's collection of medical information has ever resulted in public disclosure of that information, or law enforcement scrutiny of the Does.

The Does' claims are "abstract at best." *Portland Police*, 658 F.2d at 1274. The Does can neither "offer any history of alleged deprivations" (here, the alleged right to privacy), nor assert with assurance that there will be deprivations in the future. *Id.* Accordingly, this Court lacks jurisdiction over the Does' claims.

D. Dr. James Roe lacks standing and his claim is not ripe.

Dr. James Roe lacks standing and his claims are not ripe for similar reasons – namely, he has not shown that the DEA has or certainly will in the immediate future

[4] The statutes and regulations governing the oversight of DEA registrants and the distribution of controlled substances describe alternative investigative tools available to the DEA to identify and address the illicit diversion of prescription drugs.

obtain information on his prescriptions through the Oregon PMP.

Dr. James Roe contends that he fears scrutiny of his prescription practices and prosecution by the DEA if the DEA is permitted to examine Oregon PMP prescription information obtained through administrative subpoenas, without a judicial warrant.[5] *See* Int. Compl., Dkt. 18, ¶¶ 153, 157, 171-172. He further claims that "if" it became publicly known that he was being investigated by the DEA, it could result in a loss of business and harm to his career. *Id.* ¶ 154. Dr. Roe finally contends that he has changed his prescribing practices as a result. *Id.* ¶ 172. None of these assertions, however, is sufficient to establish an injury in fact, or any harm that is beyond hypothesis and conjecture.

The Ninth Circuit has held that a plaintiff must have a *plausible* and *reasonable* fear of prosecution to state a valid claim. *Wolfson*, 616 F.3d at 1058. Bare allegations that a plaintiff's conduct (here, prescribing schedule II – IV drugs) has been chilled by an agency practice is insufficient to establish a reasonable fear of prosecution. *Id.* (stating that alleged chilling effect on the First Amendment right to free speech was insufficient). Where, as here, a plaintiff has not alleged that he has been subject to or threatened with an enforcement action under an agency practice, and does not submit any history of enforcement under the agency practice, the allegations do not support the claimed fear of

[5] In addition to the absence of standing and ripeness for Dr. Roe's claim that he "fears" DEA scrutiny, the claim is confounding. For the privilege of holding a DEA registration, Dr. Roe has consented to allow the DEA to inspect his records and facilities at any time. *See* 21 U.S.C. § 880 (authorizing DEA inspectors to enter registrants' premises at any "reasonable time" to inspect the premises and to inspect, copy and verify the correctness of documents). Therefore, DEA access to Oregon PMP data does not expose Dr. Roe to any scrutiny to which he has not already consented as a DEA registrant.

prosecution. *Id.* at 1062.

Dr. Roe has not alleged that the DEA has investigated him or prosecuted him for his prescription practices in Oregon. Nor has he alleged that the DEA has obtained Oregon PMP data pursuant to any investigation of Dr. Roe. Instead, Plaintiffs-Intervenors' complaint and declarations set forth at length details of a federal investigation of Dr. Roe for Dr. Roe's prescription practices in the state of *Washington*. *See* Int. Compl., Dkt. 18, ¶¶ 158-171.

The Ninth Circuit has held that where a plaintiff does not face a "*genuine* threat of *imminent* prosecution," the plaintiff's claim is not ripe. *Wolfson*, 616 F.3d at 1063. Although it is established in the Ninth Circuit that an individual does not have to await prosecution under a law or regulation before challenging it, the Ninth Circuit still requires a genuine threat of imminent prosecution and not merely an "imaginary or speculative fear of prosecution." *Sacks v. Office of Foreign Assets Control*, 466 F.3d 764, 773 (9th Cir. 1006) (citations omitted). This is a requirement for both ripeness and standing. *Id.*

Here, Dr. Roe's allegations do not establish a genuine threat of imminent prosecution. Dr. Roe's fears are similar to the plaintiff's in *Takhar v. Kessler*, 76 F.3d 995 (9th Cir. 1996). In *Takhar*, a veterinarian alleged that "*if* he were to prescribe legally obtained antibiotics in post-surgical care of food-producing animals, he *could* be prosecuted for extra-label drug use." *Id.* at 1000. The Ninth Circuit held in *Takhar* that the alleged injury stemming from the burden of knowing he might be subject to prosecution could not constitute a legally cognizable "injury in fact" sufficient to confer

standing. *Id.* Similarly, "[such] fear concerns a *possibility*, and is insufficient to satisfy the constitutional component of ripeness." *Wolfson*, 616 F.3d at 1058, 1063 (citing, *inter alia*, *Younger v. Harris*, 401 U.S. 37, 42 (1971) ("imaginary or speculative" fears of prosecution are not ripe)).

Further, Plaintiffs-Intervenors have not shown that the DEA's practice of obtaining Oregon PMP data inflicts upon Dr. Roe the kind of hardship that underlies a ripe claim. "Hardship ... does not mean just anything that makes life harder; it means hardship of a legal kind, or something that imposes a significant practical harm upon the plaintiff." *Nat'l Resources Def. Council v. Abraham*, 388 F.3d 701, 706 (9th Cir. 2004).. The DEA's use of administrative subpoenas to obtain Oregon PMP data does not "grant, withhold, or modify any formal legal license, power, or authority"; nor does it "subject anyone to any civil or criminal liability"; nor does it create "legal rights or obligations." *Id.* (citations omitted). Nor does DEA's use of administrative subpoenas "force" Dr. Roe to modify his behavior to avoid future adverse consequences." *Id.* (citation omitted). According to Plaintiffs-Intervenors' allegations, there are no disciplinary actions or criminal charges pending against Dr. Roe. Int. Compl. ¶ 163. Simply because DEA's practice raises some uncertainties about what Dr. Roe *might* do in the future, that does not constitute cognizable hardship. *NRDC*, 388 F.3d at 706 (citing *Nat'l Park Hospitality Ass'n v. Dep't of Interior,* 538 U.S. 803, 811 (2005)).

For these reasons, the Court should dismiss Plaintiffs-Intervenors' claims for lack of subject matter jurisdiction.

II. Plaintiffs-Intervenors do not have a constitutionally protected privacy interest under the Fourth Amendment in their prescription medical information.

Plaintiffs-Intervenors argue they have a constitutionally protectable interest under the Fourth Amendment that prohibits the prescription medical information collected by PDMP from being obtained by law enforcement without probable cause. Contrary to Plaintiffs-Intervenors' argument, they have no constitutionally protected privacy interest in that information.

The Supreme Court has held that a person does not have a constitutionally protected interest in prescription information. In *Whalen v. Roe*, 429 U.S. 589 (1977), physicians and patients challenged the constitutionality of a New York law that required the State to be provided with a copy of every prescription for all schedule II drugs. *Id.* at 593. The completed prescription form identified the prescribing physician, the pharmacy, the drug and dosage, and the name, address, and age of the patient. *Id.* The information was to be recorded in a centralized computer file by the New York State Department of Health. *Id.* The patients argued that release of the information to the State violated their right of privacy as protected under the Fourteenth Amendment. *Id.* at 599. The physicians argued that release of the information to the State impaired their right to practice medicine free of unwarranted state interference. *Id.* at 604. *Whalen* remains controlling precedent.

In *Whalen*, the Court noted that the physicians and patients also raised a constitutional challenge based on the privacy right under the Fourth Amendment. 429 U.S. at 604, n.32. However, the Court rejected that challenge and stated "[w]e have

never carried the Fourth Amendment's interest in privacy as far as the Roe appellees would have us. We decline to do so now." *Id*.

In upholding the constitutionality of the law, the Court stated as follows:

> Nevertheless, disclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient. Requiring such disclosures to representatives of the State having responsibility for the health of the community does not automatically amount to an impermissible invasion of privacy.

Whalen, 429 U.S. at 602. The Court held that the law mandating release of the prescription information did not violate any constitutional right of privacy or liberty protected by the Fourteenth Amendment. *Id*. at 603-05.

Although Plaintiffs-Intervenors cite cases for the proposition that a patient's medical records may by protected under the Constitution, it does not follow that prescription medical *information* has the same protection. For example, Plaintiffs-Intervenors cite to *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 550 (9th Cir. 2004) to show the Ninth Circuit has recognized that "patients and doctors have a reasonable expectation of privacy in medical records." Dkt. 28,, p. 14. However, in *Tucson Woment's Clinic*, the plaintiffs were physicians who challenged the constitutionality of a state statutory and regulatory scheme for the licensing and regulation of abortion clinics. The Arizona law required doctors who performed abortions to allow warrantless inspections of their offices and access to patient records. 379 F.3d at 537.

In *Tucson Women's Clinic*, the court balanced five factors to determine whether the government's interest in obtaining the medical records outweighed the individual's privacy interest: "(1) the type of information requested, (2) the potential for harm in any subsequent non-consensual disclosure; (3) the adequacy of safeguards to prevent unauthorized disclosure, (4) the degree of need for access, and (5) whether there is an express statutory mandate, articulated public policy, or other public interest militating toward access." 379 F.3d at 551. Because the clinic provided a service that was grounded in the constitutionally protected right to an abortion, the Court found that the law allowing a warrantless search was unconstitutional and that the medical records were protected. 379 F.3d at 551, 553.

The facts of *Tucson Woman's Clinic* are clearly distinguishable from this case because the medical records in that case related to constitutional rights related to abortions, not prescription medical information. *See, e.g.*, *United States v. Acklen*, 690 F.2d 70, 75 (6th Cir. 1982) ("the pharmaceutical industry . . . is a pervasively regulated industry and th[us] 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"); *United States v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532 (8th Cir. 1981) (holding that pharmacist had no reasonable expectation of privacy in items subject to administrative inspection under the Food, Drug, & Cosmetic Act). *Tucson Women's Clinic* simply does not apply here and does not establish that the Plaintiffs-Intervenors have a protected privacy interest in the PDMP's prescription

information.

Plaintiffs-Intervenors also cite *Doe v. Southeastern Penn. Trans. Auth.*(*SEPTA*), 72 F.3d 1133, 1138 (3rd Cir. 1995) for the proposition that "the right to privacy in medical information includes prescription records." Dkt. 25, p. 25. However, the court found that such a right is not absolute and, citing *Whalen*, stated that the right "must be weighed against the state's interest in monitoring the use of dangerously addictive drugs." *Id*. at 1138. The court then held that the employer's need for access to prescription records under its health plan outweighed the employee's interest in keeping his prescription information confidential. *Id.* at 1143

In *Seaton v. Mayberg*, 610 F.3d 530, 539 (9th Cir. 2010), the Ninth Circuit applied the five-part balancing test of *Tucson Women's Clinic* to determine whether a prisoner had a constitutionally protected right of privacy to his medical records. In *Seaton*, a state prisoner, who was convicted of sexual offenses, brought a civil action claiming that his constitutional right to privacy in his medical records was violated when those records were examined by psychologists to determine whether he should be civilly committed following his release from prison. *Id*. at 532-33.

The court balanced the factors and found the prisoner had no right of privacy in his medical records when they were being used to determine if he was likely to continue as a sexual predator. 610 F.3d at 541. The Court made clear that there is no absolute right to privacy of medical records and stated that "[o]ne who goes to a physician in order to obtain medical benefit to himself or his family has substantial privacy interests that

may or may not be constitutionally protected." *Id*. at 541. *See In re Grand Jury Proceedings v. United States*, 801 F. 2d 1164, 1170 (9th Cir. 1986) ("a person possesses no reasonable expectation that his medical history will remain completely confidential.").

Here, a balancing of the five factors establishes that DEA's interest in obtaining the prescription medical information outweighs the privacy interest of the Plaintiffs-Intervenors for the following reasons: (1) the information is only related to certain prescription drugs and not the patient's comprehensive medical records; (2) the potential for harm in any subsequent non-consensual disclosure is minimal because the DEA is only allowed to release the information under limited circumstances, and primarily to federal, state, and local officials engaged in the prosecution of cases involving controlled substances before courts and licensing boards; (3) the information is adequately safeguarded because it is being held by the DEA and its employees who can be terminated and penalized for releasing the information; (4) the information is needed to investigate violations of the Controlled Substances Act; and (5) DEA has express statutory authority to investigate possible violations of the Controlled Substances Act under 21 U.S.C. § 876.

Importantly, the Supreme Court has ruled that there is no constitutional right of privacy to prescription information. *Whalen*, 429 U.S. at 603-05. The Ninth Circuit recently summarized the holding in *Whalen* when it stated: "The holding in *Whalen* was that the New York law did not violate any constitutional rights of the patient whose prescriptions were revealed to the government." *Seaton*, 610 F.3d at 537.

Here, Plaintiffs-Intervenors do not have a constitutionally protected Fourth Amendment right in their prescription information. Accordingly, DEA is not required to obtain a judicial warrant based on probable cause before issuing an administrative subpoena for information collected by PDMP.

III. An administrative subpoena issued under 21 U.S.C. § 876 does not require a judicial order based on probable cause.

Plaintiffs-Intervenors argue that because they have a reasonable expectation of privacy in their prescription medical information (which is wrong for the reasons explained above), the DEA should be required to obtain a judicial warrant based on probable cause for each administrative subpoena. However, in the context of an administrative subpoena, Fourth Amendment rights are restricted and the DEA is not required to first obtain a judicial order based on probable cause.

Traditionally, administrative subpoenas allow agencies in the executive branch to issue a compulsory request for documents or testimony without prior approval from a court. The Supreme Court has recognized that an agency's power to subpoena is based on the power to get information from those who are most interested in not providing it. *United States v. Morton Salt Co.*, 338 U.S. 632, 642. The government has a "power of inquisition," analogous to that of a grand jury, that does not depend on a case or controversy for power to obtain evidence. *Id*. An agency charged with seeing that the laws are enforced can investigate on mere suspicion that a law is being violated or to assure itself that the law is not being violated. *Id*.

In the context of an administrative subpoena, the Fourth Amendment inquiry is limited. *United States v. Golden Valley Electric Assoc.*, 689 F.3d 1108, 1115 (9th Cir. 2012). In *Golden Valley*, the DEA subpoenaed the power consumption records for three residential customers as part of a drug investigation but the power company did not comply. As one of its arguments, the power company alleged that the DEA violated the Fourth Amendment and should have obtained a search warrant or a grand jury subpoena. 689 F.3d at 1113. In analyzing the Fourth Amendment challenge, the Ninth Circuit set forth the test as follows:

> [I]t is sufficient [for Fourth Amendment purposes] if the inquiry is within the authority of the agency, the demand is not too indefinite and the information is reasonably relevant. The gist of the protection is in the requirement that the disclosure sought shall not be unreasonable.

Id. at 1115, quoting *Morton Salt Co*., 338 U.S. at 652-53. The requirement of reasonableness comes down to whether the specifications of the documents subpoenaed are adequate, but not excessive, in light of the relevant inquiry. *Golden Valley Electric Assoc.*, 689 F.3d at 1115. A subpoena should be enforced unless the party being investigated proves the inquiry is unreasonable because it is unduly burdensome or overly broad. *Id*.

Specifically, "[t]he Supreme Court has refused to require that an agency have probable cause to justify the issuance of a subpoena." *Golden Valley Electric Assoc.*, 689 F.3d at 1115, citing *United States v. Powell*, 379 U.S. 48, 57 (1964); *Oklahoma Press Pub. Co. v. Walling*, 327 U.S. 188, 215-16. Probable cause is not required for an administrative subpoena because the object of many investigations is "to determine

whether probable cause exists to prosecute a violation." *In re Subpoena Duces Tecum*, 228 F.3d 341, 348 (4th Cir. 2000). The court in *Golden Valley Electric* held that DEA's subpoena was relevant to the drug investigation, proper, reasonable, not overly broad and complied with the Fourth Amendment.

Any Fourth Amendment scrutiny of an administrative subpoena issued by the DEA to PDMP focuses on the reasonableness of the subpoena. In addition, it is black-letter law that an agency is not required to have probable cause to justify the issuance of a subpoena. Therefore, DEA is not required to obtain a judicial warrant based on probable cause before issuing an administrative subpoena for information collected by PDMP.

IV. Plaintiffs-Intervenors have no reasonable expectation of privacy in prescription information maintained in the business records of a pharmacy.

Plaintiffs-Intervenors can have no expectation of privacy in information held by a third party, such as a pharmacy, because the information is not in their control or possession. In *Golden Valley Electric*, the power company attempted to assert its customers' rights under the Fourth Amendment. 689 F.3d at 1116. However, the court stated that a customer does not ordinarily have an expectation of privacy in a business record in which he has no possession or ownership interest. *Id.* Courts have found that a person can have no reasonable expectation of privacy in motel registration records, bank records, or electricity records. *Id.* Therefore, the court rejected the Fourth Amendment challenge because the records were business records owned and possessed by the power company.

Here too, the prescription medical information is maintained in the business records of the pharmacies (and subsequently the database maintained by the State) over which Plaintiffs-Intervenors have no possession or ownership interest. Therefore, Plaintiffs-Intervenors have no reasonable expectation of privacy in the prescription information collected by PDMP from the pharmacies.

For similar reasons, Plaintiffs-Intervenors lack standing to challenge administrative subpoenas issued to PDMP. "When DEA administrative subpoenas are issued to third parties pursuant to § 876(a), courts have held [other parties] lack standing to dispute their issuance." *United States v. Thompson*, 2010 WL 4641663, at *15 (W.D. Pa. Nov. 8, 2010) (citing cases). Because the subpoenas Plaintiffs-Intervenors seek to challenge were issued to PDMP and not Plaintiffs-Intervenors themselves, Plaintiffs-Intervenors lack standing to challenge them.

CONCLUSION

For the reasons stated herein, the DEA asks the Court to dismiss the claims of the Plaintiffs-Intervenors in their entirety.

Dated this 20th day of August 2013.

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