No. 14-35402

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

OREGON PRESCRIPTION DRUG MONITORING PROGRAM,
Plaintiff-Appellee,

ACLU FOUNDATION OF OREGON, INC., et al.,
Plaintiffs-Intervenors-Appellees,

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,
Defendant-Appellant.

On Appeal from the United States District Court for the District of Oregon,
No. 12-02023

REPLY BRIEF FOR APPELLANT

JOYCE R. BRANDA
Acting Assistant Attorney General

BETH S. BRINKMANN
Deputy Assistant Attorney General

S. AMANDA MARSHALL
United States Attorney

MARK B. STERN
(202) 514-5089
Attorney, Appellate Staff
Civil Division, Room 7248
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page**

Statutes:

Regulations:

Other Authorities:

INTRODUCTION AND SUMMARY

I. The plaintiff and the intervenors have advanced very different claims for relief, and their arguments are entirely distinct.

Plaintiff, the State of Oregon, filed this suit against the Drug Enforcement Administration ("DEA") to obtain "a judgment declaring that it cannot be compelled to disclose an individual's [controlled substance prescription] information to the DEA pursuant to an administrative subpoena unless so ordered by a federal court." Compl. 4 (ER 24). Because administrative subpoenas are not self-enforcing, it is uncontroverted that only a court can compel compliance; "[a] subpoenaed party may obtain judicial review of the reasonableness of the demand prior to suffering penalties for refusing to comply."[1] *See v. City of Seattle*, 387 U.S. 541, 545 (1967) (explaining that reasonableness requires that the subpoena request is sufficiently tailored and relevant to the agency's investigative authority). Neither Oregon nor the intervenors have suggested that DEA's subpoenas fall short of this reasonableness standard. *See* SJ Op. 15 (ER 17) (acknowledging that "it is clear that the information sought by the DEA is relevant to its investigations").

Intervenors, on the other hand, seek to enjoin altogether DEA's use of administrative subpoenas to obtain records from Oregon's Prescription Drug

[1] *See, e.g.*, Oregon Br. 8-9 (acknowledging that "CSA subpoenas are not self-enforcing; the CSA requires a court order for enforcement of subpoenas"); Gov't Br. 5 ("Because subpoenas under § 876(a) are not self-enforcing, DEA is statutorily empowered to seek a court order to compel compliance, if necessary.")

Monitoring Program ("PDMP"). They argue that DEA can only obtain records from the Oregon PDMP if the agency first obtains a warrant based on probable cause. In short, intervenors suggest that this requirement must be satisfied whenever the government seeks access to any type of medical records, even where—as here—the federal government seeks records regarding the sale of controlled substances that are already in the possession of a state government entity. That argument cannot be squared with the Supreme Court's decision in *Whalen v. Roe*, 429 U.S. 589 (1977), and other relevant precedent.

As a threshold matter, however, intervenors have failed to demonstrate standing for their distinct claim. Intervenors urge that their claims are "antecedent," to those of the State, by which they mean that it would be unnecessary to reach the State's contentions if their own were accepted. On that reasoning, however, parties could intervene without demonstrating standing whenever their claims would preempt the need to resolve the contentions actually involved in a lawsuit.[2]

[2] The district court improperly bypassed intervenors' lack of standing and adjudicated their Fourth Amendment claim, ultimately granting the injunctive relief intervenors requested. The government has appealed that erroneous ruling, and, accordingly, our briefing focuses on the jurisdictional and substantive defects of intervenors' position. The district court did not reach plaintiff Oregon's state law claim. Following reversal of the district court's judgment, this Court may remand to the district court to dispose of Oregon's claim.

ARGUMENT

I. ADJUDICATION OF INTERVENORS' FOURTH AMENDMENT CLAIM WAS IMPROPER.

A. It Was Error To Ignore Intervenors' Lack of Standing.

The basic principles of standing are not in dispute: "standing is not dispensed in gross," *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996), and must be demonstrated for "'each claim'" that is pressed and "'for each form of relief' that is sought." *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008) (quoting *DaimlerChrysler Corp.* v. *Cuno*, 547 U.S. 332, 352 (2006)).

Here, the district court decided the case on the basis of a Fourth Amendment claim raised by the intervenors.[3] The court erred in granting the relief the intervenors sought—enjoining DEA's use of administrative subpoenas to obtain PDMP records as unconstitutional—without giving any consideration to whether threshold standing requirements were satisfied. SJ Op. 7 (ER 9).

Intervenors urge that that their Fourth Amendment argument is "part and parcel" of plaintiff Oregon's argument, and therefore no independent showing of standing is required. Intervenors' Appellate Brief ("Int. Br.") 17. In fact, the parties' claims are distinct in all respects, including the nature of relief requested.

[3] Intervenors are the ACLU, an anonymous physician, and several anonymous patients who have filled prescriptions for controlled substances.

Intervenors have fought to have the issuance of an administrative subpoena for PDMP records declared unconstitutional under the Fourth Amendment and permanently enjoined. They have maintained that "a warrant [based on probable cause] is required." Int. Br. 25; *see also* Oregon's Appellate Br. ("Oregon Br.") 3.

Oregon, by contrast, "has not relied on the Fourth Amendment," and has not urged that a warrant based on probable cause is required. Oregon Br. 18-19 (explaining that "Oregon does not take the position that the DEA may not have the records" in response to a subpoena request, only that judicial review of the request is necessary). In fact, the State has consistently conceded that probable cause is *not* a requirement. *See id.* at 19 (agreeing that federal law preempts a state law provision that purports to impose a probable cause requirement); Pl's MSJ 8 (Docket No. 25). Oregon's suit has sought only a declaration that "it cannot be compelled" to comply with a request for PDMP records until there is judicial review and a court order. Compl. 4 (ER 24).

The assertion that judicial review is required to compel compliance is not merely entirely distinct from intervenors' argument—it is not even in dispute. It is uncontroverted that DEA cannot take action against Oregon for failing to comply with an administrative subpoena, and must turn to a court to do so. 21 U.S.C. § 876(a); *see* Oregon Br. 19 (acknowledging that this is "precisely the enforcement mechanism contemplated for any administrative subpoena"). The parties agree that, as

a matter of federal law, judicial review is thus available and that only reasonable subpoenas will be enforced. *See generally City of Seattle*, 387 U.S. at 545. DEA disputes only Oregon's insistence that *state law* requires or independently justifies seeking such review.[4]

Nonetheless, intervenors persist in describing their claim as a "subset of" or "antecedent to" the plaintiff's claim on the theory that a ruling in their favor would eliminate the need to address the plaintiff's statutory claim. Int. Br. 14, 16-17 (insisting that adjudication of their constitutional challenge to § 876(a) is a proper "first step" because, if successful, it will deprive § 876(a) of any effect, and thus eliminate any need to settle any other questions). But the potential for intervenors' constitutional claim to supplant the plaintiff's state law claim only underscores how different the two arguments are, and why it was error for the district court to bypass the standing issue. Indeed, on intervenors' reasoning, it would be proper for a court to consider virtually any constitutional challenge to a federal statute, without regard to an intervenor's standing, to avoid any other set of challenges. *Id.* at 16. This misperceives

[4] Federal law establishes the prerequisites for § 876(a) subpoenas, and, as we have explained, a subpoena recipient may challenge a request for failing to satisfy those requirements. *Cf.* Oregon Br. 15 (concurring as to the scope of review). A court order, however, is not a prerequisite for lawful disclosure. For this reason, DEA disputes Oregon's claim that it is "required" by state statute "to wait for judicial review and a court order before it [can] turn over the [requested] records." *Id.* at 19. Such a state statutory requirement is necessarily preempted.

the meaning of "subset," inverts the normal order of operations, and is nothing less than an end-run around fundamental Article III requirements.

Finally, intervenors suggest that their lack of standing is inconsequential because, even if Oregon were the only party to this litigation, "the constitutionality of the DEA's use of administrative subpoenas under the Fourth Amendment would still be squarely presented[.]" Int. Br. 20-21. That assertion is plainly incorrect: as we have noted, Oregon makes no claim whatsoever with regard to the Fourth Amendment and does not purport to have standing to raise Fourth Amendment claims. *See* Oregon Br. 1. Moreover, Oregon has affirmatively acknowledged that any state law effort to impose a probable cause requirement on DEA subpoenas is preempted by federal law, *id.* at 19. The objective of Oregon's complaint is thus a narrow one, and intervenors' Fourth Amendment argument is not "part and parcel of" nor "antecedent to" the State's claim.

B. Intervenors' Claim Must Be Dismissed For Lack Of Standing Or Ripeness.

Intervenors claim, in the alternative, that they have "adduced sufficient facts" to demonstrate standing. Int. Br. 20. They do not, however, identify what those facts are, or respond to the relevant case law discussed in the government's opening brief, including *Clapper v. Amnesty International USA*, 133 S. Ct. 1138 (2013), and *Wolfson v. Brammer*, 616 F.3d 1045 (9th Cir. 2010).

Instead, intervenors urge that the matter be remanded to the district court, although they simultaneously observe that this would be a "senseless exercise." Int. Br. 20. Indeed, it would be pointless because the record is fully developed.[5] The intervenors allege no concrete or imminent injury. The four patient intervenors are individuals "distressed by the prospect of the DEA's gaining access to [their PDMP records] without a warrant," Int. Br. 12—a wholly abstract and speculative concern. The physician intervenor is registered with DEA to lawfully prescribe pain medications, and he has already had his prescription records inspected by DEA, acting under its authority under 21 U.S.C. § 880(d). *See* Decl. of James Roe (I-ER 274, 279, 281-82). He is seemingly concerned that DEA might request some of the same prescription records from Oregon PDMP and that this might become publicly known. *Id.* (I-ER 282); *see* Int. Br. 12. The alleged risk of public disclosure resulting from a future records request is especially non-imminent and speculative; the Privacy Act and internal DEA regulations protect against improper public disclosures. The intervenors simply cannot overcome the entirely speculative and unripe nature of their claims. *See Amnesty Int'l USA*, 133 S. Ct. at 1147-48; *Wolfson*, 616 F.3d at 1058, 1064.

[5] Intervenors cite one case in support of a remand—*Friery v. L.A. Unified Sch. District*, 448 F.3d 1146 (9th Cir. 2006). Int. Br. 20. In *Friery*, the court remanded because standing was first challenged during supplemental briefing in the Ninth Circuit, and the record had not been developed in district court to resolve relevant factual questions. 448 F.3d at 1150. In this case, the question of intervenors' standing was addressed in district court papers.

II. DEA'S ADMINISTRATIVE SUBPOENAS FOR PDMP RECORDS DO NOT RUN AFOUL OF THE FOURTH AMENDMENT.

Assuming this Court reaches the merits, intervenors' challenge to the constitutionality of DEA's administrative subpoenas must be rejected.

By its terms, the Fourth Amendment is implicated only where the government conducts a search or seizure—meaning that government action intrudes upon a subjectively and objectively reasonable expectation of privacy. Even then, the Fourth Amendment permits intrusions so long as they are reasonable. As our opening brief explained, DEA's administrative subpoenas that request Oregon PDMP records regarding highly-regulated scheduled pharmaceuticals do not unreasonably intrude upon any legitimate privacy expectation.

A. The Fourth Amendment Permits The Use Of Administrative Subpoenas Where A Person Has A Reasonable Expectation Of Privacy.

1. The Supreme Court has long recognized that, by statute, Congress may authorize federal agencies to subpoena private documents from individuals or entities with recognized privacy interests, thereby implicating the Fourth Amendment.[6] As noted, administrative subpoenas are not self-enforcing, so that serving a subpoena "commences an adversary process during which the person served with the subpoena may challenge it in court before complying with its demands." *In re Subpoena Duces Tecum*, 228 F.3d 341, 348 (4th Cir. 2000) (citing *City of Seattle*, 387 U.S. at 544-45). This

[6] The present case presents the rare instance in which the subpoenaed party, the Oregon PDMD, does not claim any privacy interest in the subpoenaed documents.

stands in contrast with the "immediacy and intrusiveness of a search or seizure conducted pursuant to a warrant," which "demand[s] the safeguard of demonstrating probable cause …." *Ibid.* (describing the "unannounced and unanticipated physical intrusion" associated with search warrants); *see Becker v. Kroll*, 494 F.3d 904, 916-17 (10th Cir. 2007) (contrasting subpoenas, which may be challenged, and warrants, which are immediate). Moreover, because the very point of an administrative subpoena is investigative, the Supreme Court has compared it to the subpoena authority of a grand jury, which likewise is deployed to investigate potential violations of law and does not require probable cause. *See, e.g.*, *United States v. Morton Salt Co.*, 338 U.S. 632, 642-43 (1950)*; see also In re Subpoena Duces Tecum*, 228 F.3d at 348 (explaining that if probable cause were required for investigative subpoenas, "the result would be the virtual end to any investigatory efforts by governmental agencies, as well as grand juries").

For all these reasons, administrative subpoenas "are limited by the general reasonableness standard of the Fourth Amendment …, not by the probable cause requirement." *In re Subpoena Duces Tecum*, 228 F.3d at 348, 349 (explaining that "judicial supervision of subpoenas" under the reasonableness standard balances "constraining governmental power" with "preserv[ing] the governmental power of investigation"). *See, e.g.*, *United States v. Powell*, 379 U.S. 48, 57 (1964); *United States v. Whispering Oaks Residential Care Facility*, 673 F.3d 813, 816-17 (8th Cir. 2012) (applying general

reasonableness, or "reasonable cause," standard in upholding subpoena investigating health care fraud).

Contrary to intervenors' assertion, it is well settled that a reasonable administrative subpoena may be enforced even where a person holds a legitimate privacy interest in the requested records. *See*, *e.g., Ryan v. United States*, 379 U.S. 61, 62 (1964) (enforcing an administrative subpoena of an individual's personal financial records under the general reasonableness standard articulated in *United States v. Powell*, 379 U.S. 48).

The standard used to assess reasonableness is sufficiently flexible so as to allow courts to consider any individual privacy interests that may be implicated. *Cf. Virginia v. Moore*, 553 U.S. 164, 171 (2008) (explaining that "traditional standards of reasonableness" ask the courts to weigh "the degree to which [the government's action] intrudes upon an individual's privacy" against "the degree to which it is needed for the promotion of legitimate governmental interests") (internal quotation marks and citations omitted). Critically, the question remains one of reasonableness, and there is no general prohibition against the use of subpoenas. *See, e.g.*, *Big Ridge, Inc. v. Fed. Mine Safety & Health Review Comm'n*, 715 F.3d 631, 648-52 (7th Cir. 2013) (upholding administrative subpoenas that required mine operators to produce miners' medical records because miners' privacy interest was outweighed by the government's

interest); *In re Subpoena Duces Tecum*, 228 F.3d at 345, 351 (upholding administrative subpoenas that sought physician's private financial records, as well as patient records).

Intervenors do not address the reasonableness of DEA's subpoenas. Instead, they argue that assessing reasonableness is irrelevant because administrative subpoenas simply cannot be used where there is any legitimate expectation of privacy at stake; according to intervenors, administrative subpoenas are permitted "[o]nly if there is *no* reasonable expectation of privacy." Int. Br. 23-24 (emphasis added).

That is plainly contrary to the Supreme Court's jurisprudence. Where there is *no* reasonable expectation of privacy at stake, the Fourth Amendment is not implicated and imposes no requirements. For administrative subpoenas, however, the Supreme Court has not hesitated to articulate what "the Fourth Amendment requires." *City of Seattle*, 387 U.S. at 544-45. *See*, *e.g., Ryan*, 379 U.S. at 62 (enforcing an IRS subpoena of a taxpayer's personal financial records as reasonable).

2. Intervenors cite two cases (Br. 24)—neither of which supports their erroneous assertion that administrative subpoenas are prohibited where there is any legitimate expectation of privacy in the records requested.

First, in *United States v. Plunk*, 153 F.3d 1011, 1020 (9th Cir. 1998), DEA served a subpoena on a telephone company requesting an individual's records, and the company complied. The individual, Plunk, later tried to challenge DEA's use of the subpoena to obtain information. This Court observed that the subpoena request was

"'not directed at [Plunk]'" but at a third party business, and that Plunk had no reasonable expectation of privacy in his phone records. *Plunk*, 153 F.3d at 1020 (citation omitted) (alteration in the original). Accordingly, he could not challenge the subpoena. The Court explained that only a person with a "legitimate expectation of privacy attaching to the [subpoenaed] records" could challenge the reasonableness of the government's subpoena. *Ibid.* The decision reflects the well-established third-party doctrine,[7] and confirms that an administrative subpoena is subject to the Fourth Amendment's reasonableness review when challenged by an individual or entity with an expectation of privacy.

Second, intervenors cite *United States v. Golden Valley Electric Ass'n*, 689 F.3d 1108 (9th Cir. 2012), which similarly supports the government's position. In *Golden Valley*, DEA subpoenaed power consumption records concerning three residential customers from an energy cooperative. The energy cooperative, possessing a privacy interest in its own business records, challenged the subpoena. The Court reached the merits, but rejected the cooperative's challenge, finding the subpoena was reasonable and not overly broad. The Court also indicated, consistent with the third-party doctrine, that the cooperative's customers could not challenge the reasonableness of

[7] As discussed *infra*, the government generally does not violate the Fourth Amendment if it obtains information about a person from a third party, even if the information was revealed to the third party on the assumption that it would be kept confidential. *United States v. Miller*, 425 U.S. 435, 443 (1976).

the subpoena because they held no reasonable expectation of privacy in the cooperative's business records. *Golden Valley*, 689 F.3d at 1116.

B. The Subpoena Of Oregon PDMP Records Is Eminently Reasonable.

1. Intervenors err in claiming a "high expectation of privacy" in third-party records for closely-regulated controlled substances.

Intervenors place great emphasis on the personal nature of "medical information" generally, and argue that a warrant is required because of their "high expectation of privacy." Int. Br. 59. Nowhere, however, do intervenors come to grips with the specific nature of the records subpoenaed by DEA: the information at issue relates exclusively to the dispensing of *controlled substances* by regulated pharmacies. This information is not only subject to ongoing oversight by state and federal authorities, but is regularly shared with a variety of third parties, including but not limited to the Oregon PDMP.

Whatever right to privacy an individual may have in his medical information, it is not absolute. *See* SJ Op. 13 (ER 15). Thus, the question for this Court is *not* whether it is conceivable that some government action might conceivably intrude upon an individual's reasonable expectation of medical privacy.[8] Rather, the question is

[8] In *Ferguson v. City of Charleston*, 532 U.S. 67 (2001), relied on by intervenors, the Court conducted a balancing test and concluded that plaintiffs' reasonable expectation of privacy was violated when a state hospital conducted unannounced and nonconsensual drug tests on patients for law enforcement purposes. Contrary to intervenors' suggestion, *Ferguson* did *not* hold that patient medical records are necessarily protected by the Fourth Amendment. The Court addressed whether the

whether such an intrusion occurs when the DEA issues an investigatory subpoena for the Oregon PDMP's records. As explained below, it does not.

a. Courts have consistently recognized that context matters: the extent to which an industry or environment is regulated will affect the reasonableness of privacy expectations. *Cf. United States v. Acklen*, 690 F.2d 70, 75 (6th Cir. 1982) (concluding that pharmacists "have a reduced expectation of privacy in the records kept in compliance with the [CSA]"); *cf., e.g.*, *Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646 (1995) (reduced expectation of privacy in school reflects, in part, the need for close supervision).

Because of the government's compelling interest in avoiding abuses and diversion, the prescribing and dispensing of controlled substances are heavily regulated under both state and federal law. Use of controlled substance is lawful only on the terms provided by the government, which includes provisions permitting access to patients' prescription information. *See* Gov't Br. 3-5, 34-36; *see also Whalen*, 429 U.S. at 603 n.30 (explaining that it is "well settled" that the government has broad powers in regulating the availability and administration of drugs).[9]

---

hospital's covert testing policy was contrary to reasonable expectations.

[9] Intervenors, in fact, concede that both state and federal authorities may obtain their controlled substance prescription information from individual pharmacies or other regulated entities without a warrant. Int. Br. 56. For reasons that are altogether unclear, they maintain that this "does not reduce the expectation of privacy" in the same records when they are in the possession of the PDMP. *Ibid.*

Moreover, the nature of the health care marketplace is such that prescription information is typically revealed to government and private entities. *See* Gov't Br. 34. Accordingly, the Supreme Court in *Whalen v. Roe* expressly rejected the notion of a Fourth Amendment right to "anonymity in the course of medical treatment." 429 U.S. at 604 n.32; *see id.* at 602 (observing that "many facets of healthcare" involve accepted incursions on privacy, and that "an essential part of modern medical practice" involves "disclosures of private medical information").

The *Whalen* Court acknowledged the potential sensitivity of prescription information, but held that New York's collection and inspection of all controlled substance prescription information—akin to the practice of the Oregon PDMP—did not tread unreasonably on any privacy expectation. *Id.* at 604 n.32 (explaining that it would be unprecedented to "carr[y] the Fourth Amendment's interest in privacy" that far).

Intervenors nevertheless suggest that more limited requests for records from the State's database run afoul of constitutional privacy protections. To support this proposition, they note that the Court in *Whalen* distinguished the facts of the case before it from cases such as *Katz v. United States*, 389 U.S. 347 (1967), which involve "affirmative, unannounced, narrowly focused intrusions into individual privacy during the court of criminal investigations." *Whalen*, 429 U.S. at 604 n32. Comparison to *Katz,* in which police wiretapped phone conversations without prior judicial sanction

or safeguards, does not advance intervenors' argument here. As we have discussed, the essence of administrative subpoenas is that they are not "unannounced" incursions, and they provide ready opportunity for the owners or custodians of the subpoenaed material to contest the disclosures. The subpoenaed information is expected to advance an investigative inquiry in the same way that a grand jury subpoena functions. Additional safeguards exist because the subpoenas must be issued consistent with statutory authority and pursuant to agency regulations. Under § 876(a), DEA may only serve subpoenas following the agency's determination that the information to be requested is relevant or material to an investigation.

b. As our opening brief explained (Gov't Br. 31-34), intervenors' claim of a "high expectation of privacy" is further undermined by the fact that the records at issue belong to a third party, the Oregon PDMP. The Supreme Court "'has held repeatedly that the Fourth Amendment does not prohibit the obtaining of 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.'" *United States v. Jacobsen*, 466 U.S. 109, 117 (1984) (citation omitted). *See, e.g.*, *Big Ridge, Inc.*, 715 F.3d at 649 (opining that, in light of the third-party doctrine, "[a]ny possible Fourth Amendment right" that employees might have in their medical

records was "limited by the fact" that the records were in the custody of their employer).

Intervenors argue that the third-party doctrine is inapplicable because patients do not directly volunteer their prescription information to the PDMP; instead, the information is provided to the PDMP via pharmacies, as a result of patients' decisions to fill controlled substance prescriptions. Intervenors assert that the decision to fill a prescription is not voluntary in any meaningful sense.

The case law makes clear, however, that voluntariness in the sense invoked by intervenors has no controlling significance in this context. Foundational Supreme Court rulings concerning the third-party doctrine involved such "choices" as individuals' decisions to use a telephone, *Smith v. Maryland,* 442 U.S. 735 (1979), or to deposit money in a bank, *United States v. Miller*, 425 U.S. 435 (1976)—hardly examples of conduct for which individuals have meaningful alternatives in intervenors' sense.

Because state law requires that controlled substance prescription information is transmitted from pharmacies to the PDMP, patients are fully on notice of the transmission,[10] which distinguishes this case from scenarios in which individuals are unaware that their personal information is being conveyed to a third party. *See* Int. Br.

[10] Oregon Revised Statute § 431.962 requires that, before or when a controlled substance drugs is dispensed, the patient is notified about the existence of the PDMP and informed that the prescription will be entered in the system. Or. Rev. Stat. Ann. § 431.962(2)(g).

52 (discussing *In re Application of the U.S. for an Order Directing a Provider … to Disclose Records to the Gov't*, 620 F.3d 304, 318-19 (3d Cir. 2010)).

Intervenors argue that the PDMP's prescription records are best analogized to "emails stored in an email provider's servers, in which people retain an expectation of privacy." Int. Br. 55. This comparison highlights intervenors' misconception of the role of the PDMP. Whereas an email provider may act as a mere custodian of password-protected data, the PDMP takes ownership of the records, using them to assemble a tool that facilitates state-wide management of controlled substance prescriptions. The PDMP's very purpose is to *disclose* patients' prescription information to others—principally to health care providers and pharmacists, but also to other entities, including the State Medical Examiner, health professional regulatory boards, and other States' prescription drug monitoring programs. *See, e.g.,* Or. Rev. Stat. Ann. § 431.966(2)(a)(E) (providing, for example, for disclosure of PDMP records in response to requests from "a health professional regulatory board" for information "necessary for an investigation related to licensure …. [of a] registrant"); *see also* Gov't Br. 7-8 (describing circumstances for such disclosures).

c. Intervenors suggest that state laws bolster their assertion of a reasonable expectation of privacy in Oregon PDMP records. They note that Oregon and nine other states with prescription drug monitoring programs (out of the 50 programs

currently operating across the United States[11]) have enacted legislation requiring law enforcement to produce a warrant or otherwise demonstrate probable cause before accessing prescription records. Int. Br. 43.

Intervenors make this claim without apparent irony, and do not address the obvious counterpoint: Oregon has conceded that, insofar as its legislation would require a warrant or other demonstration of probable cause, it is preempted by the CSA. In short, intervenors appear to take the position that Fourth Amendment standards should look to state law even when it is preempted.

Moreover, intervenors do not address the other provisions in these state laws that support disclosures and belie the establishment of an expectation of privacy. *See, e.g.*, Or. Rev. Stat. Ann. § 431.966(2). Likewise, they do not address the provisions of Oregon law that would diminish any expectation of privacy. *See, e.g.*, Or. Rev. Stat. Ann. § 192.558 (health care provider or state health plan may disclose health information as "permitted or required by state or federal law"); Or. Rev. Stat. Ann.

[11] Intervenors claim that 10 states is a "significant number," but there are currently 50 prescription drug monitoring programs established by statutes across the United States (49 states plus the District of Columbia). *See* Bureau of Justice Assistance & Brandeis Univ., The Heller School, PDMP Training and Technical Assistance Ctr., *Frequently Asked Questions*, http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.

§ 689.155(8) (registered pharmacies are subject to warrantless inspections of their records, including prescription records).[12]

In any event, as intervenors acknowledge (Int. Br. 43 n.25), Fourth Amendment rules are not determined by state law. A State may make the policy choice to offer heightened privacy protection, but that does not control the federal constitutional analysis. *See, e.g.*, *Moore*, 553 U.S. at 168 (holding that search incident to arrest that was illegal under state law was reasonable under the Fourth Amendment); *California v. Greenwood,* 486 U.S. 35, 43-44 (1988) (rejecting the argument that California law prohibiting warrantless searches and seizures of garbage can create an expectation of privacy that does not otherwise exist under the Fourth Amendment).[13] The question is not whether government action is permissible in the particular State where it occurs, but whether—as a nation—we regard particular expectations as objectively reasonable.

---

[12] Intervenors also point out that many states have enacted a general patient-physician privilege. Int. Br. 45. It is settled that no such privilege is recognized federally. *See, e.g.*, *Northwestern Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 926 (7th Cir. 2004); *see also Whalen*, 429 U.S. at 602 n. 28. In any case, such a privilege does not alter the regulatory treatment of controlled substances or the disclosures that pharmacies must make. DEA's subpoena of PDMP records would not implicate such a privilege.

[13] The brief of amici curiae medical associations notes that, under the Health Insurance Portability and Accountability Act ("HIPAA"), state laws that provide heightened privacy protections are not preempted. 45 C.F.R. § 160.203(b). The state law then remains effective in state practice, but the absence of preemption does not—as amici suggest—elevate the state law to federal practice or permit it to supplant HIPAA in federal fora.

As a matter of federal statutes and regulations, it is established that the government may access medical records for purposes of exercising oversight of the health care delivery system. In addition to DEA's subpoena authority under 21 U.S.C. § 876(a), Congress has granted the Attorney General the power to use administrative subpoenas to investigate violations of health care fraud. 18 U.S.C. § 3486(a). And the health care privacy protection provisions of HIPAA expressly authorize various "covered entities" (a category that generally includes doctors and pharmacies, as well as private and government insurers) to disclose protected health information to agencies, such as DEA, engaged in law enforcement or health oversight activities.[14]

2. Applying even the most robust of Fourth Amendment balancing tests, it is clear that DEA's use of administrative subpoenas is reasonable.

a. Intervenors argue that they have a privacy interest in Oregon PDMP's records, and assert, in conclusory fashion, that a warrant is thus required. They fail to address the second part of a proper Fourth Amendment analysis: whether DEA's use of administrative subpoenas is a reasonable incursion on their claimed privacy

[14] HIPAA authorized the Department of Health and Human Services to adopt privacy rules for individually identifiable health information held by covered entities. 42 U.S.C. §§ 1320d, 1320d-1; *see* 45 C.F.R. § 160.103. The rules adopted by HHS set out the circumstances in which a covered entity may disclose such information without the prior written authorization of a patient or his representative. 45 C.F.R. Pt. 160, Pt. 164, Subpts. A & E. These permitted circumstances include disclosures in response to administrative subpoenas from law enforcement, 45 C.F.R. § 164.512(f), as well as requests from agencies (including law enforcement agencies) conducting "health oversight activities"—as when DEA investigates the handling of scheduled pharmaceuticals or otherwise enforces the CSA. 45 C.F.R. § 164.512(d); *see* 65 Fed. Reg. 82462, 82492, 82593 (Dec. 28, 2000).

interest. As we have discussed, intervenors' insistence that reasonableness is irrelevant is contrary to both the text of the Fourth Amendment and Supreme Court precedents. *See, e.g.*, *Whalen*, 429 U.S. at 602 (recognizing that government action may invade individuals' privacy without violating the Fourth Amendment).

b. Assuming intervenors are found to hold a cognizable privacy interest in the PDMP records, the question for this court is then one of "general reasonableness" under the Fourth Amendment. *See supra* Section II.A.1. Where there is ambiguity about the protections afforded by the Fourth Amendment, courts have turned to "traditional standards of reasonableness"—weighing the government's need against the extent of the intrusion on an individual's privacy. *Moore*, 553 U.S. at 171.

In re Subpoena Duces Tecum, 228 F.3d 341 (4th Cir. 2000), is instructive. In that case, the Department of Justice, acting under its authority to investigate federal health care offenses, issued subpoenas to a physician. The subpoenas required, *inter alia*, the production of "patient records and documentation concerning patients whose services were billed to Medicare, Medicaid, [etc.]" and "original accounting and bank records." *Id.* at 344. The doctor asserted that he was the target of the Department's fraud investigation, and objected on Fourth Amendment grounds, claiming the subpoenas constituted an unlawful intrusion on his "papers and effects" for lack of probable cause. *Id.* at 345, 347. He also urged an assessment of reasonableness in light of his "patient's privacy interests." *Id.* at 351. He claimed that the subpoenas would

require producing more than 15,000 patient files, and urged that their "interests in their medical files outweigh the government's interest in those files." *Id.* at 345, 351.

The Fourth Circuit rejected all of these claims and enforced the subpoenas. Addressing the potential privacy interests of patients, the court found the disclosure of patient files unremarkable. *In re Subpoena Duces Tecum*, 228 F.3d at 351 (explaining that "'many facets of health care'" involve disclosures, such as sharing of information with insurance companies) (quoting *Whalen*, 429 U.S. at 602). The court found that the government, on the other hand, had a "compelling interest" in detecting and deterring unlawful activity, and that it furthermore placed internal limits on the uses of subpoenaed information. *Ibid.* The court held that, on balance, the government's interest outweighed any individual privacy interests, and that the subpoenas passed muster under the Fourth Amendment's general reasonableness standard. *Ibid.*

In *Tucson Woman's Clinic v. Eden*, 379 F.3d 531 (9th Cir. 2004), this Court cited five factors meriting consideration:

> (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 recognizable public interest militating toward access.

Id. at 551. The facts of *Tucson Woman's Clinic* differed significantly from the present case, and application of the factors cited in that case supports DEA here. *See id.* 551-53 (rejecting warrantless physical inspections of abortion clinics, which are "not

heavily regulated," and would give the state agency "extremely broad," "unbounded access" to patients' "full medical histories," despite "little, if any, need" by the agency for patients' identifying information); *see also Seaton v. Mayberg*, 610 F.3d 530 (9th Cir. 2010).

In 2013, the Seventh Circuit examined these five factors in *Big Ridge, Inc. v. Fed. Mine Safety & Health Review Commission*, 715 F.3d 631. The court was asked to evaluate the constitutionality of administrative subpoenas that required mine operators to produce their employees' medical records. The court concluded that the subpoenas did not violate the Fourth Amendment "despite the personal nature of the medical records demanded . . . because the government's need for the records outweighs the miners' privacy interest in the records, the records are no longer in the miners' custody, and the Privacy Act and [agency]'s training and protocols adequately protect against unwarranted disclosure by [the agency's] agents." 715 F.3d at 652.

All of the same considerations apply here. There is an express statutory mandate that authorizes DEA to obtain the records by invoking the administrative subpoena procedures, and the government's need for the records is evident. The Oregon PDMP was established because of the recognized need for access to aggregated records, which facilitates the identification of diversion patterns. By barring DEA from subpoenaing PDMP records, the district court's decision severely limits DEA's ability to conduct timely, effective investigations. Furthermore, as in *Big*

Ridge, the Privacy Act, along with DEA's own policies and procedures, protects against the unauthorized disclosure of information obtained by the agency. *See, e.g.*, 5 U.S.C. § 552a(b), (c). In sum, as our opening brief explained, DEA's subpoenas of PDMP records are reasonable and cannot be said to violate the Fourth Amendment rights of any party.

CONCLUSION

For the foregoing reasons and those presented in the government's opening brief, the judgment of the district court should be reversed.

Respectfully submitted,

JOYCE R. BRANDA
Acting Assistant Attorney General

BETH S. BRINKMANN
Deputy Assistant Attorney General

S. AMANDA MARSHALL
United States Attorney

MARK B. STERN
(202) 514-5089
Attorney, Appellate Staff
Civil Division, Room 7248
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

January 20, 2015

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(5), (6), (7)(B) and (C) and Ninth Circuit Rule 32, I certify that the attached Reply Brief for Appellees contains 6006 words, and complies with type-volume limitations because it is prepared in Microsoft Word 2000, Garamond, font 14.

/s/ Mark B. Stern
MARK B. STERN
Counsel for Appellant

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of January, 2015, I caused the foregoing brief to be electronically filed with the United States Court of Appeals for the Ninth Circuit, and served to counsel, via the ECF system.

/s/ Mark B. Stern
MARK B. STERN
Counsel for Appellant