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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

COMPLAINT IN INTERVENTION FOR DECLARATORY AND INJUNCTIVE RELIEF

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.

COMPLAINT IN INTERVENTION FOR DECLARATORY AND INJUNCTIVE RELIEF[1]

INTRODUCTION

1. This complaint seeks to protect the constitutional rights of patients and their medical providers to prevent confidential and sensitive prescription records from being subject to warrantless searches in violation of the Fourth Amendment and Oregon law.

2. In 2009, the State of Oregon enacted legislation creating the Oregon Prescription Drug Monitoring Program ("PDMP"), which records information about all prescription drugs dispensed by pharmacies in Oregon or to addresses in Oregon that are classified in schedules II–IV under the Federal Controlled Substances Act.

[1] Plaintiffs-Intervenors previously filed their Proposed Complaint in Intervention as an exhibit to their Motion to Intervene. ECF No. 7-2. The Court having granted the intervention motion, ECF No. 17, Plaintiffs-Intervenors now file this Complaint in Intervention, which is identical to the Proposed Complaint in Intervention with the exception of additional factual matter and minor corrections in paragraphs 12, 52, 53, 64, 93, 135, 166, and 169–171, below.

3. In order to safeguard the privacy and security of prescription records, the legislation creating the PDMP included a number of protections, including a prohibition against the PDMP releasing records to law enforcement unless presented with 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." Or. Rev. Stat. § 431.966(2)(a)(C). This requirement recognizes the unique sensitivity of the prescription records contained in the PDMP.
4. Notwithstanding Oregon law, the Drug Enforcement Administration ("DEA") has been issuing administrative subpoenas to the PDMP seeking prescription records of Oregon patients and physicians.
5. Because Oregon patients and physicians have a reasonable expectation of privacy in their prescription records, the DEA's use of subpoenas to obtain those records violates the Fourth Amendment.
6. Plaintiffs-Intervenors John Doe 1, John Doe 2, John Doe 3, John Doe 4, Dr. James Roe, and the American Civil Liberties Union of Oregon ("Plaintiffs-Intervenors") bring this Complaint in Intervention seeking declaratory and injunctive relief to prevent the DEA from being able to obtain constitutionally protected prescription records without a warrant.

PARTIES

7. Plaintiffs-Intervenors John Does 1–4 and Dr. James Roe file this action using pseudonyms in place of their real names. Unless otherwise indicated, use of the

pseudonyms "John Doe" and "James Roe" and gender pronouns does not signify that they are either female or male.

8. Plaintiff-Intervenor John Doe 4 is a medical student in the Portland area and a resident of Oregon. He was assigned female sex at birth, but now identifies strongly with a male gender identity. After being diagnosed with gender identity disorder approximately three years ago he began hormone replacement therapy, which involves self-administering injections of testosterone once every two weeks. Testosterone is a schedule III drug. Hormone replacement therapy is a necessary part of his medical treatment and ability to maintain his gender expression as male. He considers his prescription records and information about his transition to be private, and is distressed by the possibility that the DEA may access his prescription records contained in the PDMP without a warrant.
9. Plaintiff-Intervenor John Doe 3 is an Oregon small business owner who has lived in Oregon for most of his life. He takes clonazepam, a schedule IV drug, to treat anxiety and post-traumatic stress disorders. He also takes prescription Vicodin, a schedule III drug, on a regular basis to treat pain because he cannot take over-the-counter pain medications due to a genetic blood disorder. He considers his prescription records and the information about his physical and mental health that they reveal to be private, and is distressed by the possibility that the DEA may access his prescription records contained in the PDMP without a warrant.
10. Plaintiff-Intervenor John Doe 2 is an attorney and a resident of Oregon. He was assigned female sex at birth, but throughout his life has identified strongly with a male gender identity. Since being diagnosed with gender identity disorder, he has

received hormone replacement therapy in the form of weekly self-administered injections of prescription testosterone. Hormone replacement therapy is a necessary part of his medical treatment and ability to maintain his gender expression as male. He considers his prescription records and details of the status of his female-to-male transition to be private, and is distressed by the possibility that the DEA may access his prescription records contained in the PDMP without a warrant.

11. Plaintiff-Intervenor John Doe 1 is a retired CEO and a resident of Oregon. He takes four medications for which prescription information is recorded in the PDMP. He takes oxycodone and hydrocodone, both schedule II drugs, to treat the debilitating pain caused by frequent kidney stones. He takes Ambien and Sonata, both schedule IV drugs, to treat restless leg syndrome that prevents him from sleeping at night. He considers his prescription records and the medical information they reveal to be private, and is distressed by the possibility that the DEA may access his prescription records contained in the PDMP without a warrant.

12. Plaintiff-Intervenor James Roe, M.D., is a physician specializing in internal medicine, geriatrics, and hospice care who treats patients in Oregon. Dr. Roe was recently interviewed and investigated by the DEA and FBI in connection with prescriptions for medically necessary medications he issued to several patients. He believes that as part of that investigation, the DEA may have requested his prescription records from the PDMP. He believes his prescription records are private, and that maintaining the privacy of those records is a crucial part of

protecting the physician-patient relationship. Since learning of federal law enforcement's access to his prescription records, he has changed his prescribing practices in order to avoid further unwarranted investigation and harassment. Dr. Roe sues on his own behalf and on behalf of his patients with prescription records in the PDMP.

13. Plaintiff-Intervenor ACLU of Oregon is an Oregon non-profit corporation dedicated to the preservation and enhancement of civil liberties and civil rights. The ACLU of Oregon has approximately 11,000 members and brings this suit on behalf of patients and physicians among its members whose prescription records are contained in the PDMP and who object to the DEA's accessing those records without a warrant.

14. Plaintiff Oregon Prescription Drug Monitoring Program is an agency of the State of Oregon established by the Oregon Health Authority. Pursuant to Or. Rev. Stat. §§ 431.962–431.978, the Oregon Prescription Drug Monitoring Program administers an electronic database containing records of all prescriptions dispensed by Oregon pharmacies for drugs that are classified in schedules II–IV under the Federal Controlled Substances Act.

15. Defendant United States Drug Enforcement Administration is an agency of the United States Department of Justice. The DEA is charged with administering and enforcing the Controlled Substances Act, 21 U.S.C. § 801, *et seq*.

JURISDICTION AND VENUE

16. This case arises under the Constitution of the United States and presents a federal question within this Court's jurisdiction under 28 U.S.C. § 1331.

17. The Court has authority to issue declaratory and injunctive relief under 28 U.S.C. §§ 2201 and 2202 and Rules 57 and 65 of the Federal Rules of Civil Procedure.

18. Under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, this Court has the power to hold unlawful and set aside unconstitutional agency actions.

19. Venue is proper in this District under 28 U.S.C. § 1391(b)(2) because the events at issue took place in substantial part in this District; because a substantial part of the property that is at issue in this lawsuit—Plaintiffs-Intervenors' prescription records contained in the Oregon PDMP—is located in this District; and because compliance with any subpoenas issued by the DEA for disclosure of prescription records would take place largely in this District.

20. Venue is proper in the Portland Division under Local Rule 3-2 because a substantial part of the events giving rise to this claim occurred in the Division and a substantial part of the property that is the subject of this action is situated in the Division.

21. Plaintiffs-Intervenors satisfy the Fed. R. Civ P. 24(a) standard for intervention as a matter of right: (1) the request is timely; (2) Plaintiffs-Intervenors claim a significantly protectable interest relating to the property or transaction which is the subject of the action; (3) Plaintiffs-Intervenors are so situated that disposition of the action may as a practical matter impair or impede their ability to protect their interests; and (4) Plaintiffs-Intervenors' interests are not adequately represented by the parties to the action. Alternatively, Plaintiffs-Intervenors satisfy the standards for permissive intervention under Fed. R. Civ. P. 24(b).

FACTS

Oregon Prescription Drug Monitoring Program

22. In 2009, the State of Oregon enacted legislation creating the Oregon Prescription Drug Monitoring Program, an electronic database maintained by the Oregon Health Authority that records information about all prescription drugs dispensed by pharmacies in Oregon or to addresses in Oregon that are classified in schedules II–IV under the Federal Controlled Substances Act. *See* Or. Rev. Stat. § 431.962.

23. The PDMP began collecting information in June 2011 and was fully operational in September of that year.

24. After dispensing a schedule II–IV prescription drug in Oregon, pharmacies are required to electronically report to the PDMP the following information: (a) Name, address, and date of birth of the patient; (b) Identification of the pharmacy dispensing the prescription drug; (c) Identification of the practitioner who prescribed the drug; (d) Identification of the prescription drug by a national drug code number; (e) Date of origin of the prescription; (f) Date the drug was dispensed; and (g) Quantity of drug dispensed. Or. Rev. Stat. § 431.964(1).

25. According to the Oregon Health Authority, approximately seven million prescriptions are uploaded to the PDMP system annually.

26. Information in the PDMP that identifies an individual patient is retained for three years. Or. Rev. Stat. § 431.966(4).

27. Drugs classified in schedules II–IV under the Controlled Substances Act include a wide range of medications for treatment of serious medical conditions, such as weight loss associated with AIDS, anxiety disorders, post-traumatic stress

disorder, panic disorders, alcohol addiction withdrawal symptoms, heroin addiction treatment, gender identity disorder or gender dysphoria, testosterone deficiency, chronic and acute pain, seizure disorders, narcolepsy, insomnia and conditions that cause insomnia, attention deficit hyperactivity disorder, and migraines.

28. Many schedule II–IV medications are closely and widely associated with the conditions they treat. For example, a prescription for testosterone can reveal a diagnosis of gender identity disorder and that the patient is transitioning from female to male gender identity; a prescription for Xanax or Ativan indicates that the patient is being treated for mental illness; and a prescription for methadone can indicate that a person is in treatment for heroin addiction.

29. In recognition of the sensitive nature of the information contained in the PDMP, the Oregon Legislature specifically enacted privacy protections that sharply limit access to personally identifiable prescription information in the database.

30. The State of Oregon is prohibited from disclosing prescription records in the PDMP to law enforcement agencies unless presented with 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." Or. Rev. Stat. § 431.966(2)(a)(C).

DEA Subpoenas for PDMP Records

31. 21 U.S.C. § 876 permits certain federal law enforcement officials to issue and serve subpoenas seeking records relevant or material to a controlled substances investigation.

32. These subpoenas are judicially enforceable if the recipient of the subpoena declines to honor them. 21 U.S.C. § 876(c).

33. The DEA regularly issues subpoenas under 21 U.S.C. § 876 to the PDMP requesting protected prescription information.

34. For example, on January 5, 2012, the DEA issued an administrative subpoena to the PDMP pursuant to § 876 requesting production of "a Physician Profile for all Schedule II-V controlled substance prescriptions written by [a specific doctor, whose name is redacted from public filings] from 6/1/2011 through 1/06/2012."

35. The subpoena sought the protected health information of individual patients who filled prescriptions written by the doctor under investigation. The DEA insisted that redacted protected health information could not reasonably be used in the investigation.

36. The PDMP refused to comply with the DEA's subpoena on the ground that it did not satisfy the state-law requirement of a court order based on probable cause.

37. The DEA sought judicial enforcement of the subpoena as well as a declaration that Oregon Revised Statute § 431.966(2)(a)(C) is preempted by 21 U.S.C. § 876. On August 27, 2012, a magistrate judge in the District of Oregon granted the DEA's petition to enforce the subpoena and found the state law to be preempted.

Order to Enforce DEA Administrative Subpoena, *United States v. State of Oregon Prescription Drug Monitoring Program*, 12-MC-298 (D. Or. Aug. 27, 2012).

38. The PDMP complied with the magistrate judge's order and disclosed the protected prescription information requested by the subpoena to the DEA.

39. As of August 2012, the DEA estimated that it would issue approximately two administrative subpoenas per month to the PMDP for the foreseeable future.

State of Oregon Lawsuit Against the DEA

40. After the August 2012 magistrate judge's order, the State of Oregon maintained its position that state law precluded it from complying with the DEA's administrative subpoenas for protected health information in the PDMP.

41. The DEA issued new administrative subpoenas to the PDMP on September 11, 2012 and September 17, 2012.

42. By letter dated September 20, 2012, the State of Oregon notified the DEA of its objection to the subpoenas and refusal to disclose protected health information without a valid court order.

43. The DEA maintains the position that the requirement of a court order based on probable cause imposed by Oregon Revised Statutes § 431.966(2)(a)(C) is preempted by federal law.

44. On November 9, 2012, the State of Oregon filed an action seeking a judgment declaring that Oregon's restrictions on law enforcement access are not preempted and that the PDMP "cannot be compelled to disclose an individual's protected health information to the DEA pursuant to an administrative subpoena unless so

ordered by a federal court." Complaint 4. Plaintiffs-Intervenors seek to intervene in that suit.

45. Plaintiffs-Intervenors do not take a position on the preemption issue; rather, Plaintiffs-Intervenors seek to join this action to protect their Fourth Amendment rights to privacy in their protected health information.

The Constitutional Rights of the Intervenors are at Stake

46. For each prescription for a schedule II–IV drug filled by John Does 1–4 at an Oregon pharmacy, the PDMP records the Plaintiff-Intervenor's name, address, and date of birth; identification of the dispensing pharmacy; identification of the practitioner who prescribed the drug; identification of the prescription drug; date of origin of the prescription; date the drug was dispensed; and quantity of the drug dispensed. The same information is recorded for every prescription for a schedule II–IV drug prescribed by Dr. Roe and filled at an Oregon pharmacy.

47. Plaintiffs-Intervenors' prescription records in the PDMP are protected by the privacy and security safeguards imposed by Oregon law, including the requirement that law enforcement secure a court order based on probable cause before requesting PDMP records.

48. By explicitly imposing a warrant requirement on law enforcement access to PDMP records, the Oregon legislature has recognized a legitimate privacy interest in the information contained in the PDMP. The requirement of a court order based on probable cause guarantees the privacy of prescription records in the PDMP against unwarranted intrusion.

49. Plaintiffs-Intervenors consider their prescription records and the sensitive medical information that they reveal to be private and confidential. The information contained in the PDMP is highly personal and private, and a reasonable person would believe that such information should be kept confidential and should not be publicly disclosed.

50. If the DEA were permitted to obtain prescription records from the PDMP using an administrative subpoena instead of a warrant obtained from a neutral magistrate based on probable cause, it would violate the Plaintiffs-Intervenors' reasonable expectations of privacy in their prescription records.

The Effect on the Intervenors of the DEA's Administrative Subpoenas Seeking Prescription Records from the PDMP

John Doe 4

51. John Doe 4 is a medical student in the Portland area and a resident of Oregon.

52. He takes prescription testosterone on a regular basis. Testosterone is classified in schedule III under the Federal Controlled Substances Act.

53. This medication is prescribed by John Doe 4's Oregon-based physician and he obtains refills of the prescription at pharmacies in Oregon. As a result, records of his testosterone prescriptions are recorded by the PDMP. John Doe 4 has obtained a copy of his own PDMP record from the Oregon Health Authority. That record confirms that information about his testosterone prescription is recorded in the PDMP.

54. John Doe 4 was assigned female sex at birth, but he has come to identify strongly with a male gender identity.

55. Approximately three years ago he was diagnosed with gender identity disorder ("GID"), which is now frequently called Gender Dysphoria ("GD"). Gender identity disorder is a recognized medical condition listed in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (revised 4th ed. 2000) ("DSM-IV-TR"). As described by the DSM-IV-TR, GID involves strong and persistent cross-gender identification and persistent discomfort about one's assigned sex.

56. After John Doe 4 was diagnosed with GD, his physician recommended hormone replacement therapy, in the form of testosterone injections, to help him transition from female to male sex.

57. Hormone replacement therapy is a necessary part of his medical treatment and ability to maintain his gender expression as male. John Doe 4 has consistently lived as a man since he started his transition.

58. He expects to continue using prescribed testosterone for the foreseeable future.

59. John Doe 4's prescription for testosterone comes in the form of bottles of the medication that he self-administers via injection once every two weeks. He refills his prescription approximately every four months.

60. John Doe 4 does not generally hide his status as a person engaged in the transition from female to male gender identity. However, he believes that detailed information about his prescription for testosterone should remain between him and his doctor, and he does not want it shared with the public.

61. John Doe 4 is aware that the DEA claims the authority to obtain prescription records from the PDMP without a warrant. He believes the privacy protections

created by Oregon law, including the requirement that law enforcement obtain a court order based on probable cause before requesting prescription records from the PDMP, are extremely important.

62. John Doe 4 does not want the DEA to access or obtain his prescription information because he takes testosterone for a legal and medically necessary purpose and he considers information about his prescriptions to be private.

63. As a result of the recent media attention on illegal steroid use in sports, John Doe 4 believes law enforcement is more aggressively targeting steroid users. He fears that he may come under suspicion because he uses testosterone.

64. It is already difficult for transgender men to obtain prescription testosterone. Testosterone suitable for injection cannot be dispensed by most regular retail pharmacies, and John Doe 4 must travel to an inconveniently located special compounding pharmacy to obtain his prescription. Upon information and belief, there is only one compounding pharmacy in the metropolitan Portland area that fills prescriptions for injectable testosterone. John Doe 4 believes that increased scrutiny by law enforcement, including the DEA, erects another obstacle to obtaining treatment.

65. If the DEA were allowed to obtain prescription records from the PDMP without a warrant, John Doe 4 would be fearful of being investigated or harassed without reason. He would feel like he was constantly looking over his shoulder, and would experience undue mental distress.

66. Because there is currently no alternative treatment for GD that does not involve testosterone, John Doe 4 would not be able to avoid the DEA gaining easy access to his prescription information and the private medical information it reveals.

John Doe 3

67. John Doe 3 is an Oregon small business owner who has lived in Oregon for most of his life.

68. He takes two prescription medications classified as schedule III or IV drugs under the Federal Controlled Substances Act: clonazepam and Vicodin.

69. These medications are prescribed by Oregon-based physicians and he obtains refills of the prescriptions at pharmacies in Oregon. As a result, records of his prescriptions for these medications are recorded by the PDMP.

70. John Doe 3 is diagnosed with anxiety and post-traumatic stress disorders.

71. For approximately the last 20 years, he has taken clonazepam to treat these conditions.

72. Clonazepam is in the benzodiazepine group of drugs, and is classified in schedule IV under the Controlled Substances Act.

73. If John Doe 3 did not take clonazepam regularly, he would not be able to control his anxiety and his ability to function, including being able to work, would be impaired.

74. He is in the process of ending his use of clonazepam and substituting other medications, but that is a 12 to 18 month process that will not finish for at least another six months, if successful.

75. John Doe 3 also suffers from a genetic blood disorder that causes blood clots. He requires prescription blood thinners to control this condition and without them the condition would be life-threatening. He will need to continue taking blood thinners for the rest of his life.

76. Because John Doe 3 uses blood thinners, he cannot take over-the-counter pain medications such as aspirin or Tylenol. Most pain medications have blood-thinning properties, which could interact with his blood thinners in dangerous ways.

77. The only effective pain medications John Doe 3 can take that will not interact with his blood thinners are on the schedule list under the Controlled Substances Act.

78. His doctor prescribes him Vicodin for pain relief.

79. Vicodin is a trade name for a medication containing hydrocodone. It is classified in schedule III under the Controlled Substances Act.

80. John Doe 3 takes Vicodin to relieve all of the types of pain that most people are able to treat using over-the-counter medications. For example, he uses Vicodin to relieve the pain of headaches, back aches, and sore joints.

81. John Doe 3 keeps a constant supply of Vicodin on hand. His prescriptions are usually dispensed in quantities of 15 pills, and he typically refills the prescription every four to six weeks.

82. Because he cannot stop taking prescription blood thinners, he does not have the option of using an alternative pain medication that is not a schedule II, III, or IV drug.

83. John Doe 3 considers information about his prescriptions and his physical and mental health to be private, sensitive, and personal. He wants neither the government nor the public to know what medications he takes and what conditions they treat.

84. John Doe 3 has long followed public affairs in Oregon and he paid close attention to the debate over creation of the PDMP several years ago. He is not comfortable with his private medical information, including his prescription records, being fed into a government database, and he did not think the PDMP was a good idea.

85. Even though he did not think the legislature should have created the PDMP, some of his fears about the program were assuaged by the strong privacy and security protections put into place by the legislature. He considers the prohibition on law enforcement access to PDMP records without a court order based on probable cause to be a crucial part of those protections.

86. John Doe 3 is aware that the DEA claims the authority to obtain prescription records from the PDMP without first obtaining a court order based on probable cause. The prospect of the DEA being able to access John Doe 3's prescription records without first presenting evidence to a judge that he has done something wrong is deeply unsettling to him.

87. John Doe 3 fears that without the oversight provided by a judge and the requirement to demonstrate probable cause, the DEA will be able to place anyone under scrutiny and comb through their confidential medical information without good reason. He fears being the target of such unwarranted scrutiny.

88. Further, based on his past professional experience, John Doe 3 believes that the easier it is to access information in a large database, the more likely it is to leak to people without authorization or reason to view it.

89. John Doe 3 wants to keep information about his prescriptions private because he believes his health information is nobody else's business, but also because it would be embarrassing and potentially stigmatizing if the information were no longer confidential. In particular, clonazepam is a drug closely associated with the treatment of mental illness. John Doe 3 fears that other people, including law enforcement agents, would attach stigma to the fact that he receives mental health treatment. Losing the privacy of that information could negatively affect his personal and professional reputation.

90. If the DEA were permitted to obtain PDMP records without a court order based on probable cause, the prospect of federal law enforcement agents learning private details of his physical and mental health would cause John Doe 3 anxiety. He fears that that anxiety could increase his need for clonazepam, frustrating his efforts to taper off of that medication and forcing him to incur the expense and inconvenience of increasing his dosage.

91. John Doe 3 would take whatever steps he could to protect his privacy, including possibly filling his Vicodin and clonazepam prescriptions in another state, even though that would impose additional costs on him and would be inconvenient.

John Doe 2

92. John Doe 2 is an attorney and a resident of Oregon.

93. He takes prescription testosterone on a regular basis.

94. This medication is prescribed by his Oregon-based physician and he obtains refills of the prescription at pharmacies in Oregon. As a result, records of his testosterone prescriptions are recorded by the PDMP.

95. Although John Doe 2 was assigned female sex at birth, throughout his life he has identified strongly with a male gender identity.

96. Over ten years ago, he was diagnosed with gender identity disorder.

97. After John Doe 2 was diagnosed with GID, he began receiving medical treatment, as recommended and prescribed by his doctors, to help him transition from female to male sex. Part of that treatment involves hormone replacement therapy in the form of weekly injections of testosterone.

98. Hormone replacement therapy is a necessary part of his medical treatment and his ability to maintain his gender expression as male. John Doe 2 has consistently lived as a man since he started his transition.

99. John Doe 2 expects to continue using prescribed testosterone for the rest of his life.

100. His prescription for testosterone comes in the form of vials or bottles of the medication that he self-administers via injection once per week.

101. Normally, a bottle contains a three- or four-week supply of testosterone, meaning that he must obtain a refill or new prescription at the pharmacy after three or four weeks. Sometimes, he is dispensed larger bottles. The pharmacy recently provided him with a bottle of testosterone that contains approximately 20 weeks' worth of the medication.

102. As part of the medical treatment of GID recommended by John Doe 2's doctors, he plans to have a complete hysterectomy, involving the removal of his uterus and ovaries. After that surgery his body will produce less estrogen and, therefore, it is likely that his necessary dosage of testosterone will decrease. It is possible that he will be able to switch from testosterone injections to testosterone pills or transdermal patches.

103. John Doe 2 has not tried to hide his status as a person engaged in the transition from female to male gender identity. However, he has no interest in the public knowing the sensitive, personal, and private details about the future course of his medical treatment and the status of his transition.

104. Although John Doe 2 has not kept his status secret, there are many people who go to significant lengths to conceal their transgender identity and who would experience harm to their reputations, safety, or livelihoods if information about their statuses were publicly known.

105. John Doe 2 believes that detailed information about his ongoing testosterone dosage should remain between him and his doctor, and he does not want it shared with the public.

106. In particular, he recently started a new job. Although some of his coworkers know about his female-to-male status, they do not know the details of his hormone replacement therapy, and it is important to him that this information remains private.

107. John Doe 2 is aware that the DEA claims the authority to obtain prescription records from the PDMP without a warrant. He believes the privacy protections

created by Oregon law, including the requirement that law enforcement obtain a court order based on probable cause before requesting prescription records from the PDMP, are extremely important.

108. John Doe 2 does not want the DEA to access or obtain his prescription information because he takes testosterone for a legal and medically necessary purpose and he considers information about his prescriptions to be private.

109. He fears that because the quantity of testosterone dispensed to him sometimes varies widely, from small bottles containing a three- or four-week supply to large bottles containing a 20-week supply, law enforcement might think that he is using testosterone for an illicit purpose. He believes law enforcement agents should be required to prove that they have evidence of wrongdoing before they gain access to his medical records.

110. If the DEA (or the public) obtained information about John Doe 2's testosterone dosage in the future, they would be able to deduce private information about the status of his transition. For example, if his testosterone dosage decreased in the future, it could indicate that he had had his uterus and ovaries removed.

111. It would be distressing to John Doe 2 if the DEA were allowed to obtain prescription records from the PDMP without a warrant. Because there is currently no alternative treatment for his GID that does not involve testosterone, he would not be able to avoid the DEA gaining easy access to his prescription information and the private medical information it reveals.

112. However, John Doe 2 might take steps to protect his privacy by, for example, requesting that he receive only smaller supplies of testosterone from the pharmacy

in order to avoid potential suspicion and attention from law enforcement. Having to refill his prescription more frequently is inconvenient, and causes him to incur the expense of traveling to the pharmacy more frequently.

John Doe 1

113. John Doe 1 is a retired CEO and a resident of Oregon.

114. John Doe 1 currently takes four medications that are classified in schedules II or IV under the Federal Controlled Substances Act. Prescriptions for those medications are issued by doctors in Oregon and filled at pharmacies in Oregon. As a result, records of these prescriptions are recorded by the PDMP.

115. John Doe 1 suffers from frequent kidney stones, which are extraordinarily painful when they occur. Although he has a high pain threshold, he would not be able to tolerate the pain of kidney stones without medication.

116. In order to control the pain associated with kidney stones, his physician prescribes him two painkillers, oxycodone and hydrocodone.

117. Both oxycodone and hydrocodone are classified in schedule II under the Controlled Substances Act.

118. Over the course of a typical year, John Doe 1 has approximately three kidney stone episodes. When he feels a stone developing, he needs to be able to take oxycodone or hydrocodone immediately to prevent debilitating pain. Therefore, he must always have a supply of these medications on hand.

119. He also travels internationally frequently, sometimes to areas with limited health care services. When he travels it is important that he carries supplies of

oxycodone and hydrocodone with him so that he can deal with a kidney stone episode.

120. If he does not take oxycodone or hydrocodone to treat a kidney stone episode, John Doe 1 will end up in the emergency room where he will require intravenous painkillers.

121. The frequency with which he needs to fill new prescriptions for oxycodone and hydrocodone depends on the severity and frequency of kidney stones.

122. John Doe 1 also suffers from a type of restless leg syndrome that prevents him from getting adequate sleep at night. When he is unable to get adequate sleep during the night, his ability to function during the daytime is seriously impaired.

123. To treat his restless leg syndrome, John Doe 1's neurologist has prescribed two medications, Ambien and Sonata.

124. Ambien is a trade name for the drug zolpidem. It is classified in schedule IV under the Controlled Substances Act.

125. Sonata is a trade name for the drug zaleplon. It is classified in schedule IV under the Controlled Substances Act.

126. John Doe 1 usually takes Ambien at the start of the night in order to be able to fall asleep. Most nights, he wakes during the night to use the restroom and, if he can't fall back asleep after that, he takes Sonata.

127. He has been taking Ambien and Sonata for approximately the last ten years and he expects to continue taking them for the foreseeable future.

128. Ambien and Sonata are dispensed to him in 30-day supplies. Therefore, every 30 days he refills his prescriptions at his pharmacy.

129. John Doe 1 has tried alternative medications to help him sleep, but none of them is as effective in treating his restless leg syndrome and allowing him to sleep as the combination of Ambien and Sonata. He has also gone to a sleep clinic for assessment, and these medications are the best treatment that doctors have offered him.

130. John Doe 1 considers information about his drug prescriptions and his medical conditions to be private, and intends for them to remain between him and his health care providers.

131. John Doe 1 has followed the debate over the creation and implementation of the Oregon Prescription Drug Monitoring Program. He is generally skeptical of government databases that contain confidential information of private individuals, particularly sensitive information like medical records. In his experience, the government is not adept at maintaining good security for its records and information is sometimes released or put to uses for which it was not intended.

132. When the PDMP was created, John Doe 1 took some solace from the fact that law enforcement would not be able to obtain prescription records from it without a court order based on probable cause. The possibility that the DEA might be able to obtain John Doe 1's prescription records easily, without a warrant, is upsetting to him. He believes it would be an intrusion on his privacy for a law enforcement agent to have easy access to his medical information.

133. If the DEA is allowed to obtain prescription records from the PDMP without a warrant, it would give John Doe 1 pause the next time he visited the doctor to discuss his treatment. He relies on his physicians to decide what the best

medications are to treat his medical conditions, but he would inform his doctors of the DEA's easier access to the PDMP records and would ask their advice. At a minimum, his behavior would change each time he refilled his prescriptions and he would seriously consider whether he had other treatment options.

134. If John Doe 1 had a way to obtain prescriptions without the DEA being able to easily obtain them from the PDMP without a warrant, he would do so. However, given the frequency with which he must refill his prescriptions for Ambien and Sonata and the urgency attached to his access to adequate supplies of oxycodone or hydrocodone, it would be impractical and expensive for him to travel to a jurisdiction that does not have a prescription drug monitoring program.

James Roe, M.D.

135. Dr. James Roe is a medical doctor working as a general internist who primarily treats geriatric and hospice patients. He sues on his own behalf and on behalf of his patients with prescription records in the PDMP.

136. Dr. Roe is licensed to practice medicine in both Oregon and Washington. He has completed a pain management education program for physicians who regularly treat patients in chronic or terminal pain, as required by Oregon law. He is also a member of the Oregon Medical Association.

137. Dr. Roe holds a current controlled substance registration certificate from the DEA permitting him to prescribe medications classified in schedules II, III, IV, and V under the Controlled Substances Act.

138. Approximately half of Dr. Roe's patients are Oregon residents. He splits his time evenly between practicing medicine in Oregon and Washington.

139. Dr. Roe specialize in geriatrics and the treatment of hospice patients with terminal illnesses. Most of the hospice patients he treats survive less than six months.

140. Most of the patients he treats in Oregon are admitted to intermediate care facilities, including rehabilitation centers and nursing homes. His treatment of these patients includes prescribing them appropriate and medically necessary medications.

141. Dr. Roe frequently has patients who are discharged from hospitals or skilled care facilities. He writes prescriptions for such patients on a nearly daily basis. Those prescriptions are usually filled at retail pharmacies. For example, Dr. Roe recently treated a patient with a compound fracture who returned home after a stay in the hospital. The only effective treatment for this patient's pain was a prescription for a narcotic painkiller on the Controlled Substances Act schedule list.

142. Dr. Roe also treats patients who are not yet enrolled in hospice or skilled care programs who require prescriptions for schedule II–IV drugs. For example, Dr. Roe recently prescribed narcotic painkillers to an 86-year-old patient with a terminal illness who was waiting to be formally enrolled in a hospice program and was suffering from acute pain. If he had not prescribed the patient a painkiller on the schedule list, the patient would have had to go to the emergency room to receive pain medication.

143. In the past, Dr. Roe has treated a number of hospice patients and other patients who were receiving care at home.

144. Dr. Roe's practice deals largely with end-of-life care for people suffering from diseases such as cancer, AIDS, chronic obstructive pulmonary disease, and

emphysema. He also treats geriatric patients, including patients recovering from traumatic injuries caused by falls and patients with chronic pain.

145. As compared with physicians in other specialties, a disproportionate number of the medications Dr. Roe prescribes are classified in schedules II–IV under the Controlled Substances Act.

146. The most common schedule II–IV medications Dr. Roe prescribes are:

146.1. Long-acting opiate painkillers, including morphine extended release, oxycodone extended and immediate release, and oral morphine solution, which can be absorbed sublingually by patients who can no longer swallow. These medications are classified in schedule II under the Controlled Substances Act.

146.2. Vicodin, which is a narcotic painkiller containing hydrocodone. Vicodin is classified in schedule III under the Controlled Substances Act.

146.3. Drugs in the benzodiazepine group, including Xanax, Ativan, Klonopin, and Valium, among others. These medications are used to treat anxiety, and are classified in schedule IV under the Controlled Substances Act.

147. Dr. Roe prescribes schedule II–IV drugs only when they are necessary for the treatment of his patients' medical conditions. For example, many of his patients in hospice experience severe pain, and opiate or narcotic painkillers are necessary to provide palliative care in the final months of their lives. For patients with severe shortness of breath caused by lung cancer or chronic obstructive pulmonary disease, he frequently prescribes drugs in the benzodiazepine group to reduce the anxiety and panic caused by the feeling of being unable to breathe.

148. The prescriptions for schedule II–IV drugs that Dr. Roe writes for Oregon patients, except for inpatients whose prescriptions are dispensed directly by the facility where they are being treated, are recorded in the PMDP.

149. The prescriptions for schedule II–V drugs that Dr. Roe writes for Washington patients, except for hospital inpatients whose prescriptions are dispensed by the hospital, are recorded in the Washington Prescription Monitoring Program ("Washington PMP").

150. The Washington PMP is less protective of the privacy of prescription records than is the Oregon PDMP. The Washington PMP will provide prescription records to any law enforcement officials "who are engaged in a bona fide specific investigation involving a designated person." Wash. Rev. Code § 70.225.040(3)(d). The Oregon PDMP, by contrast, will release prescription records to law enforcement only if presented with a valid court order based on probable cause.

151. Over the course of his medical career, Dr. Roe has seen many initiatives by state and federal governments and medical organizations that have raised the profile of prescription drug abuse and diversion. In his experience, pain management guidelines and standardized practices introduced through these initiatives have been effective in limiting drug diversion and abuse.

152. Dr. Roe believes that drug abuse and diversion is a serious public health problem, and he does not oppose law enforcement investigations into drug diversion that are supported by evidence of wrongdoing and are not overly invasive of the

doctor-patient relationship. He objects to law enforcement requests for confidential medical information not supported by a warrant and probable cause.

153. Dr. Roe has seen the scrutiny of physicians, nurse practitioners, and physician assistants by law enforcement increase steeply. He has seen a marked change in the willingness of medical professionals to prescribe schedule II, III, or IV pain medications because they fear being investigated by state or federal law enforcement, including the DEA.

154. Even in situations where patients are experiencing dire and debilitating pain, many physicians and other medical professionals with prescribing privileges have become unwilling to issue a prescription for a medically necessary narcotic painkiller because they fear scrutiny by law enforcement. This is because law enforcement investigations of physicians are time-consuming, invasive, and can seriously harm careers. If it becomes publicly known that a physician has been investigated, even if no wrongdoing was found, it can result in loss of business and sanctions by employers.

155. The increasing reluctance of physicians, including specialists, to prescribe scheduled drugs puts increased pressure on generalists and family medicine doctors and on geriatricians and hospice physicians like Dr. Roe. Dr. Roe has had a number of cases where a patient needed strong pain medications following surgery, but where the treating surgeon, internist, and pain specialist refused to incur the risk of associating their names with narcotic painkiller prescriptions. As a result, Dr. Roe functions as the last and only alternative available for patients

with acute pain, and he provides prescriptions for scheduled painkillers when necessary to treat the patients' pain.

156. Many physicians are willing to provide short-term prescriptions for schedule II or III painkillers, but insist that after four weeks patients get their prescriptions refilled at pain clinics instead. For many nursing home and hospice patients who are unable to travel, attending a pain clinic is not a realistic option because it is often not physically possible. They need to have access to prescriptions for appropriate pain medications from their treating doctors so that they can take those medications at home or in the intermediate care facility where they are being cared for.

157. Overzealous law enforcement investigations of physicians have created a climate of fear around prescribing narcotic painkillers.

158. Federal law enforcement agents recently arranged a meeting with Dr. Roe. Two FBI agents attended the interview in person. A DEA agent located in Seattle participated in the interview by phone.

159. The agents asked Dr. Roe questions about his prescribing practices. They were particularly interested in a small number of his patients to whom he had prescribed pain medications classified in schedules II and III. They had the patients' names, and asked him to provide their diagnoses, the treatment they received, and what setting he had seen them in. The agents also asked for the addresses and contact information of these patients regardless of whether or not they were deceased.

160. All of the patients were residents of Washington. Dr. Roe had treated some of them as outpatients and some in institutional settings. Two of the patients who were living at home when Dr. Roe treated them are now deceased.

161. Dr. Roe refused to provide the agents with the confidential medical information about his patients because doing so would have violated his duty of confidentiality as their treating physician. Maintaining confidentiality and privacy of patients' medical information is crucial to the doctor-patient relationship and is an ethical and professional responsibility of physicians.

162. When Dr. Roe would not turn over the requested information, the DEA agent threatened him by stating that the agent could get an administrative order that day to revoke Dr. Roe's state medical licenses and his DEA controlled substance registration certificate. Without these, Dr. Roe would not be able to practice medicine.

163. Dr. Roe asked the agents if there were any disciplinary actions or criminal charges pending against him. They told him that there were not, but they continued to pressure him. Their questions suggested that they believed Dr. Roe was prescribing medications that were being diverted to illegal uses.

164. Dr. Roe also asked how the agents had come by the names of these patients, what their source was for the names, and why they were asking about them. Specifically, he asked whether the agents had obtained Dr. Roe's prescription records from the Washington PMP. The agents refused to answer. The agents did not produce a warrant for the information they had obtained or for the information they were seeking.

165. Upon information and belief, the agents obtained Dr. Roe's prescription records for these patients from the Washington PMP. Dr. Roe treated these patients in different clinical settings and at different times and he does not know of another source from which the agents could have easily obtained information about such a disparate set of patients.

166. Upon information and belief, the agents did not obtain a probable cause warrant to search Dr. Roe's and his patients' records in the Washington PMP.

167. Although all of the patients under discussion were Washington residents, it is likely that the agents also requested Dr. Roe's prescription records for Oregon patients from the Oregon PDMP. The DEA agent who took part in the interview by phone was from the DEA's Seattle office. The Seattle office is the headquarters of the DEA's Seattle Division, which covers the states of Washington and Oregon. Further, because Dr. Roe's practice is equally divided between Washington and Oregon, an investigation by federal law enforcement officials of his Washington prescribing practices only would miss fifty percent of his prescribing activities.

168. While it is possible that the agents were only investigating Dr. Roe's Washington prescribing practices, it is equally likely that they requested his prescription records from the Oregon PDMP but that the State of Oregon refused to provide them.

169. Subsequently, the DEA served on Dr. Roe a Notice of Inspection of Controlled Premises. Federal agents met Dr. Roe at his home, where he keeps his office, and

inquired about prescriptions for controlled substances he had provided to three terminally ill patients in Washington. Dr. Roe last treated those patients in 2011 and 2012, and they are now deceased. Agents requested that Dr. Roe turn over records relating to his treatment of those patients.

170. Most recently, while Dr. Roe and his family were away from home, law enforcement agents entered his locked home pursuant to a search warrant signed by a Washington judge. The warrant authorized seizure of, inter alia, "[a]ny and all records and items relating to prescribing and distribution of controlled substances." When Dr. Roe returned home, he found a copy of the warrant and discovered that the papers in his home office had been inspected and moved. Upon information and belief, no papers or property were removed from his home.

171. Dr. Roe was shaken and intimidated by the initial interview and subsequent interactions with the DEA and FBI agents and was particularly disturbed by the ease with which the agents were apparently able to obtain his Washington prescription records and by their failure to explain a good reason for investigating him and his patients.

172. Since the interview Dr. Roe has changed his prescribing practices. He is more reticent to prescribe schedule II–IV drugs to existing patients. He has also decided to stop making house calls to patients who are not in skilled care facilities or other institutions. Dr. Roe fears that prescribing scheduled drugs to such patients opens him up to too much suspicion by law enforcement. When his patients return home from a stay in a hospital or skilled care facility, he has started requiring them to make an appointment within one week with another doctor (either a local general

practitioner or a local pain clinic) so someone else can take over prescribing any required schedule II–IV medications. These decisions have created a barrier between the doctor and patient relationship and caused Dr. Roe to lose income.

173. These changes are a reaction to the ease with which federal law enforcement can obtain Dr. Roe's prescription records and commence an investigation of him and his fear of being subjected to further unwarranted investigation.

174. Dr. Roe's prescription records reflect sensitive and confidential medical information about his patients and can reveal private details about their diagnoses and prognoses.

ACLU of Oregon

175. The ACLU of Oregon sues on behalf of its members who have prescription records in the PDMP. The ACLU of Oregon's 11,000 members include patients who fill prescriptions for schedule II–IV medications at Oregon pharmacies and physicians who issue prescriptions for schedule II–IV medications to Oregon patients.

FIRST CAUSE OF ACTION

(Fourth Amendment)

176. Intervenors hereby restate and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint in Intervention.

177. The Fourth Amendment to the United States Constitution protects against unreasonable searches.

178. Where persons have a reasonable expectation of privacy in the items or locations to be searched, a search is per se unreasonable unless conducted pursuant to a properly issued warrant based on probable cause.

179. Intervenors and other Oregon patients and physicians have a reasonable expectation of privacy in their prescription drug records, including prescription records contained in the PDMP.

180. The DEA's use of administrative subpoenas pursuant to 21 U.S.C. § 876 to compel disclosure of prescription records contained in the PDMP violates the Fourth Amendment because those subpoenas do not constitute warrants based on probable cause.

181. If the DEA obtains access to personally identifiable drug prescription records without a probable cause warrant, Intervenors and other Oregon patients and physicians will suffer irreparable injury to their constitutional right to be free from unreasonable searches.

SECOND CAUSE OF ACTION

(Unlawful Agency Action in Violation of the

Administrative Procedure Act, 5 U.S.C. §§ 702, 706)

182. The DEA's actions described herein were and are contrary to constitutional rights, power, privilege, or immunity, and should be set aside as unlawful pursuant to 5 U.S.C. § 706.

183. The DEA's use of administrative subpoenas pursuant to 21 U.S.C. § 876 to compel disclosure of prescription records contained in the PDMP violates the

APA, 5 U.S.C. § 706 because it is contrary to constitutional rights, power, privilege, or immunity.

PRAYER FOR RELIEF

WHEREFORE, Intervenors John Does 1–4, Dr. James Roe, and ACLU of Oregon respectfully ask this court for:

a. A declaration that the DEA's requests for personally identifiable prescription records from the PDMP without first obtaining and producing a warrant violate the Fourth Amendment rights of Intervenors and other individuals in Oregon, as well as the Administrative Procedure Act;

b. Appropriate injunctive relief, including, but not limited to, a permanent injunction prohibiting the DEA from obtaining prescription records from the PDMP without securing a probable cause warrant;

c. Attorneys' fees and costs; and

d. Such other and other further relief that the Court deems just and proper.

Respectfully submitted this 10th day of April, 2013.

/s/ Ben Wizner
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