Case No. S219811

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

ALWIN CARL LEWIS, M.D.,
Petitioner,

v.

SUPERIOR COURT FOR THE STATE OF CALIFORNIA,
COUNTY OF LOS ANGELES,
Respondent,

MEDICAL BOARD OF CALIFORNIA,
Real Party in Interest.

On Review From the Court of Appeal,
Second Appellate District, Division Three, No. B252032
After an Appeal from the Superior Court of Los Angeles County,
Honorable Joanne B. O'Donnell, No. BS139289

AMICUS CURIAE BRIEF OF ELECTRONIC FRONTIER FOUNDATION IN SUPPORT OF PETITIONER ALWIN LEWIS

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CORPORATE DISCLOSURE STATEMENT

Amicus Curiae Electronic Frontier Foundation states that it does not have a parent corporation and that no publicly held company owns 10 percent or more of its stock.

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INTRODUCTION AND SUMMARY OF ARGUMENT

The decision of the lower court—which permits law enforcement to access patients' controlled substance prescription records from California's Controlled Substance Utilization Review and Evaluation System ("CURES") without a warrant or any showing of cause for why such access is needed—conflicts with the privacy guarantees of both the Fourth Amendment and the California Constitution. The court recognized that patients have a legally protected privacy interest in their prescription records, but in ruling that law enforcement can access controlled substance prescription records without a warrant on the ground that patients have a low expectation of privacy in such records, the court erred dramatically. The court should have found the expectation of privacy in such records to be heightened—just as in the case of "ordinary" medical records. And consistent with the Fourth Amendment and the California Constitution, it should have required a warrant before law enforcement can gain access to patients' CURES records.

The lower court's conclusion that patients have a diminished expectation of privacy in their controlled substance prescription records is flawed in two respects:

First, the information contained within prescription records is just as sensitive as the information contained elsewhere in a patient's medical file, and prescription records are thus due the same heightened protection afforded to medical records—that they "will not be shared with nonmedical personnel without . . . consent." *Ferguson v. City of Charleston*, 532 U.S. 67, 78 (2001). A reasonable patient does not expect law enforcement to have easier access to their prescription records than the rest of their medical records.

Second, the court erred in presuming that the business of prescribing controlled substances is a closely regulated industry for purposes of the

administrative search exception to the Fourth Amendment's warrant requirement. The U.S. Supreme Court has only found four industries to fall within this narrow exception, and the prescription of controlled substances is not one of them. *City of Los Angeles v. Patel*, __ U.S. __, 135 S. Ct. 2443, 2454 (2015). Even assuming that controlled substance prescriptions were a closely regulated industry, the court erred in concluding that close regulation of the business of *prescribing* controlled substances would reduce *patients'* expectation of privacy in their personal prescription records.

If permitted to stand, the lower court's decision will permit law enforcement entities to gain access to extremely sensitive medical records without any judicial oversight. This Court should reverse the lower court's holding, recognize that prescription records are due the same heightened expectation of privacy as any other medical records, and require law enforcement to obtain a warrant supported by probable cause—and provide patient notice—prior to accessing CURES records. This Court need not decide the standard applicable in an investigation that could have only civil or administrative consequences, but in a case with even the potential for criminal charges—like Dr. Lewis's case—the U.S. Constitution and the California Constitution require both a warrant and patient notice.

ARGUMENT

I. THE LOWER COURT'S DECISION CONTRAVENES THE PRIVACY GUARANTEES OF BOTH THE FOURTH AMENDMENT AND THE CALIFORNIA CONSTITUTION.

By statute, every prescription of a Schedule II, III, or IV controlled substance must be logged within the CURES database, along with a patient's name, address, telephone number, gender and date of birth, the drug name, drug form, quantity, number of refills, whether the drug was dispensed as a refill or first-time request, and information about the

prescribing physician and pharmacy. Health & Safety Code § 11165(d). CURES data may be "provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil or criminal actions." *Id.* § 11165(c)(2).

Although the statute does not explicitly require law enforcement agencies to obtain a warrant to access CURES records, it does require the CURES program to comply with federal and state privacy laws and to safeguard the privacy and confidentiality of patients.[2] *Id.* § 11165(c)(1)–(2). The lower court nonetheless upheld the Medical Board of California's access to patients' controlled substance prescription records from CURES without a warrant, let alone any showing of cause for why such access is needed.[3] Such unfettered access contravenes the privacy protections of both the Fourth Amendment and the California Constitution. For any investigation such as the one at issue here—*i.e.*, with the potential to lead to criminal charges—a warrant must be required before law enforcement can access patients' CURES records.

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[2] The statute provides that "(1) [t]he operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations" and "(2) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients." Health & Safety Code § 11165(c)(1)–(2).

[3] In this case, the Medical Board searched Dr. Lewis' patients' prescription records despite not having any ground to believe that Dr. Lewis had committed misconduct with respect to his prescribing practices. *See Lewis v. Superior Court*, 226 Cal. App. 4th 933, 938–39 (2014) (indicating that a Board investigator obtained CURES reports for Dr. Lewis' prescribing practices from November 1, 2005 through November 25, 2008 based on a single patient's complaint that Dr. Lewis had "recommend[ed] that she lose weight and start a diet that [she] considered to be unhealthful").

A. The Fourth Amendment Protects Against Unreasonable Searches and Seizures.

The Fourth Amendment provides protection against "unreasonable searches and seizures." U.S. Const., amend. IV. A "search" for purposes of the Fourth Amendment occurs "when an expectation of privacy that society is prepared to consider reasonable is infringed." *United States v. Jacobsen*, 466 U.S. 109, 113 (1984). The Fourth Amendment thus guards against searches and seizures of items or places in which a person has a reasonable expectation of privacy. *United States v. Ziegler*, 474 F.3d 1184, 1189 (9th Cir. 2007). "'[S]earches conducted outside the judicial process, without prior approval by judge or magistrate,'" like the search at issue here, "'are *per se* unreasonable under the Fourth Amendment—subject only to a few specifically established and well-delineated exceptions.'" *Arizona v. Gant*, 556 U.S. 332, 338 (2009) (citing *Katz v. United States*, 389 U.S. 347, 357 (1967)).

B. The California Constitution Protects Individuals' Informational Privacy Rights.

Not only does Article I, Section 1 of the California Constitution explicitly list privacy as an inalienable right of all people,[4] but as this Court has recognized, "[i]nformational privacy is the core value furthered by" the

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[4] The California Constitution provides, "All people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, *and privacy*." Cal. Const., art. I, § 1 (emphasis added). The phrase "and privacy" was added by an initiative adopted by California voters on November 7, 1972, commonly referred to as the "Privacy Initiative" or "Privacy Amendment." *Hill v. National Collegiate Athletic Assn.*, 7 Cal. 4th 1, 15 (1994); *see also* Civ. Code § 1798.1 ("The Legislature declares that the right to privacy is a personal and fundamental right protected by Section 1 of Article I of the Constitution of California and by the United States Constitution and that all individuals have a right of privacy in information pertaining to them.").

explicit inclusion of the right to privacy in that section. *Hill v. National Collegiate Athletic Assn.*, 7 Cal. 4th 1, 35 (1994); *see also Los Angeles Gay & Lesbian Ctr. v. Superior Court*, 194 Cal. App. 4th 288, 307 (2011) (citation and internal quotations omitted) ("[T]he privacy right protects the individual's reasonable expectation of privacy against a serious invasion."). The right of privacy not only "'prevents government and business interests from collecting and stockpiling unnecessary information about us[,]'" but also "'from misusing information gathered for one purpose in order to serve other purposes[.]'" *Hill*, 7 Cal. 4th at 17 (citation omitted). A particular class of information is private, and thus protected, "when well-established social norms recognize the need to maximize individual control over its dissemination and use to prevent unjustified embarrassment or indignity." *Id.* at 35. Any incursion into individual privacy "must be justified by a compelling interest." *White v. Davis*, 13 Cal. 3d 757, 775 (1975).

In *White*, this Court explained that "the moving force" behind California's constitutional right to privacy was concern over "the accelerating encroachment on personal freedom and security caused by increased surveillance and data collection activity in contemporary society[.]" *Id.* at 774. Inclusion of the right to privacy recognizes that "[t]he proliferation of government . . . records over which we have no control limits our ability to control our personal lives." *Id.* Among the "principal 'mischiefs'" targeted by the right is "the improper use of information properly obtained for a specific purpose, for example, the use of it for another purpose or the disclosure of it to some third party." *Id.* at 775.[5] Such improper use of private date was implicated in this case.

[5] The words of this Court were prescient—and recently amplified by the U.S. Supreme Court in *Riley v. California*, __ U.S. __, 134 S. Ct. 2473 (2014). In *Riley*, the Court held that electronic searches with the potential

Namely, the legislative purpose underlying the collection of patients' prescription records for CURES is to assist doctors and pharmacies in making better prescribing decisions and to reduce prescription drug abuse. *See* Health & Safety Code § 11165(a). But the Board used CURES records to investigate a specific doctor—a very different purpose.

C. Both the Fourth Amendment and the California Constitution Recognize a Heightened Privacy Interest in Medical Records.

The U.S. Supreme Court has specifically recognized that patients have a reasonable expectation of privacy in their medical records—and that "an intrusion on that expectation may have adverse consequences because it may deter patients from receiving needed medical care." *Ferguson*, 532 U.S. at 78, n.14 (citing *Whalen v. Roe,* 429 U.S. 589, 599–600 (1977)); *id.* at 78 ("The reasonable expectation of privacy enjoyed by the typical patient undergoing diagnostic tests in a hospital is that the results of those tests will not be shared with nonmedical personnel without her consent."); *see also In re Search Warrant (Sealed)*, 810 F.2d 67, 71 (3d Cir. 1987) ("[M]edical records are clearly within this constitutionally protected sphere.").

And unsurprisingly, the right of privacy under Article I, Section 1 of the California Constitution likewise "extends to . . . medical records." *John B. v. Superior Court*, 38 Cal. 4th 1177, 1198 (2006) (citing *Hill*, 7 Cal.4th at 41); *see also Bd. of Med. Quality Assurance v. Gherardini*, 93 Cal. App.

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to give law enforcement access to large amounts of information about a person must be limited by warrant protections. *Id.* at 2489–91. Despite the long history of the Fourth Amendment's "search incident to arrest" doctrine, the Court had no difficulty requiring law enforcement to get a search warrant in order to search a cellphone that had been lawfully obtained during an arrest. The Court was wary of the immense storage capacity of a cell phone, which could give law enforcement access to much more information than it would otherwise be able to collect. *Id.* at 2489.

3d 669, 679 (1979) (holding that protection of the privacy of medical records "falls squarely within the protected ambit, the expressed objectives of article I, section 1"); *Davis v. Superior Court*, 7 Cal. App. 4th 1008, 1019 (1992) ("[A] person's medical profile is an area of privacy which cannot be compromised except upon good cause."); *Bearman v. Superior Court*, 117 Cal. App. 4th 463, 468 (2004), *as modified on denial of reh'g* (May 3, 2004) (The Medical Board "cannot delve into an area of reasonably expected privacy simply because it wants assurance the law is not violated or a doctor is not negligent in treatment of his or her patient.").[6]

It also extends to mental health records. *See Long Beach City Employees Assn. v. City of Long Beach*, 41 Cal. 3d 937, 944 (1986) ("If there is a quintessential zone of human privacy it is the mind. Our ability to exclude others from our mental processes is intrinsic to the human personality."); *Pettus v. Cole*, 49 Cal. App. 4th 402, 440 (1996), *as modified on denial of reh'g* (Oct. 15, 1996) (determining as a matter of law that an employee had a legally cognizable privacy interest in detailed psychiatric information conveyed in the course of psychiatric evaluations arranged and paid for by his employer after he requested disability leave).

In fact, due to the sensitivity of medical and mental health information, courts afford both medical records and mental health records a

[6] While California courts have applied a "good cause" standard in the context of Medical Board subpoenas, *see Gherardini*, 93 Cal. App. 3d. at 680, *Bearman*, 117 Cal. App. 4th at 469, good cause does not satisfy the Fourth Amendment—particularly, as here, where an investigation has the potential to lead to criminal charges. As such, as explained herein, the Fourth Amendment requires a warrant supported by probable cause—not merely good cause—to access patients' CURES records in any such investigation by the Board, law enforcement, or any government agency.

heightened expectation of privacy.[7] *See Gherardini*, 93 Cal. App. 3d at 678 ("A person's medical profile is an area of privacy *infinitely more intimate*, more personal in quality and nature than many areas already judicially recognized and protected.") (emphasis added); *id.* at 679 ("The matters disclosed to the physician arise in most sensitive areas often difficult to reveal even to the doctor" and "[t]heir unauthorized disclosure can provoke more than just simple humiliation in a fragile personality."); *McDonnell v. United States*, 4 F.3d 1227, 1253 (3d Cir. 1993) ("It is beyond dispute that an individual has a substantial privacy interest in his or her medical records."); *In re Search Warrant (Sealed)*, 810 F.2d at 70 ("[A]ny privacy interests the patients may have are immediately threatened by the government having obtained such highly sensitive personal information as may be contained in their medical files[.]"); *State v. Nelson*, 283 Mont. 231, 242 (1997) ("Medical records are quintessentially 'private' and deserve the utmost constitutional protection."); *Commonwealth v. Riedel*, 539 Pa. 172, 178 (1994) ("'[A]n individual has a substantial privacy interest in his or her medical records.'") (citation omitted).[8] The heightened sensitivity of such

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[7] The court in *Gherardini* reasoned that medical information was due the same heightened expectation of privacy as mental health records. *See* 93 Cal. App. 3d at 679 ("The reasonable expectation that such personal matters will remain with the physician are no less in a patient-physician relationship than between the patient and psychotherapist. The individual's right to privacy encompasses not only the state of his mind, but also his viscera, detailed complaints of physical ills, and their emotional overtones.").

[8] In addition, the California Confidentiality of Medical Information Act provides heightened protection for medical information, placing limitations on the unauthorized disclosure of personal medical information by "a provider of health care, a health care service plan, or a contractor[.]" Civ. Code § 56.10; *see, e.g.*, § 56.10(b)(2),(4) (providing that disclosure of medical information can be compelled "[b]y a board, commission, or administrative agency" only "for purposes of adjudication pursuant to its

information is what necessitates the patient-physician privilege, which "creates a zone of privacy whose purposes are (1) to preclude the humiliation of the patient that might follow disclosure of his ailments and (2) to encourage the patient's full disclosure to the physician of all information necessary for effective diagnosis and treatment of the patient."[9] *Gherardini*, 93 Cal. App. 3d at 678–79 (internal citations and quotations omitted).

D. Pursuant to the Fourth Amendment and the California Constitution, a Warrant Supported by Probable Cause Is Required Before Law Enforcement Can Access Patient Medical Information—Including Controlled Substance Prescription Records.

The lower court's ruling permitting law enforcement agencies—or agencies with the power to conduct investigations that can lead to criminal charges—to access patients' controlled substance prescriptions drug records without first obtaining a warrant supported by probable cause is

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lawful authority" or "pursuant to an investigative subpoena issued under Article 2"). And in the case of law enforcement access to personal medical records, the Confidentiality Act generally requires a "search warrant lawfully issued to a governmental law enforcement agency," *see* Civ. Code § 56.10(b)(6), whereas the HIPAA Privacy Rule permits the police to use an administrative subpoena or other written request with no court involvement so long as (i) the information is relevant and material to a legitimate law enforcement inquiry, (ii) the request is specific and limited in scope, and (iii) de-identified information is insufficient. *See* 45 C.F.R § 164.512(f)(1)(ii)(C).

[9] Individuals suffering from legitimate mental health conditions could also be susceptible to discrimination if information about their conditions were to become public—and patients would thus be deterred from seeking necessary medical treatment if such information were not adequately protected. *See State Dep't of Pub. Health v. Superior Court*, 60 Cal. 4th 940, 953 (2015) ("[Welf. & Inst. Code §] 5328's confidentiality protections are designed 'to encourage persons with mental or alcoholic problems to seek treatment on a voluntary basis.'") (citation omitted).

fundamentally at odds with the aforementioned privacy protections. Indeed, none of the exceptions to the Fourth Amendment's warrant requirement apply here—including, as outlined below, the closely regulated industry exception. *See Gant*, 556 U.S. at 338 (requiring a warrant except in "a few specifically established and well-delineated exceptions"); *see infra* at 19–28. And as the *Gherardini* court made clear, a governmental administrative agency, such as the Board, "is not in a special or privileged category, exempt from the right of privacy requirements which must be met and honored generally by law enforcement officials"—and to hold otherwise would be to "ignore the federal and state constitutional commands as well as the numerous and persuasive judicial decisions in analogous areas." 93 Cal. App. 3d at 679–80. Rather, the Board should be held to the same standards as any other law enforcement officials before invading a patient's medical records. *Id.* at 680.

The lower court justified its ruling by concluding that patients have a diminished expectation of privacy in their controlled substance prescription drug records. But as outlined below, the court dramatically erred in its reasoning. Patients' prescription drug records—whether controlled or uncontrolled—are entitled to the same degree of protection as any other medical records. And considering the appropriately *high* expectation of privacy that patients reasonably have in their prescription drug records, permitting law enforcement to access sensitive personal information stored within CURES without a warrant supported by probable cause violates the guarantees of both the Fourth Amendment and the California Constitution.[10]

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[10] As noted in the *Amicus* Brief of *Amici Curiae* the American Civil Liberties Union ("ACLU") of Southern California, ACLU of Northern California, and ACLU of San Diego and Imperial Counties in Support of

Furthermore, as the government acknowledged in its brief, the Board provided patients for whom it sought complete medical records an opportunity to consent, then notice and an opportunity to object, before obtaining the records via subpoena. *See* Attorney General's Answer Brief on the Merits, at 23. But notice was not provided to patients whose prescription records were sought. The lower court found that "[t]hese deficiencies [are] not pertinent to our resolution of the issue presented here, and these concerns are better directed to the Legislature." *Lewis*, 226 Cal. App. 4th at 949 n.13. But lack of notice and due process in a search is exactly what the court was responsible for evaluating. Given the sensitivity of prescription records, the Board should be required to follow the same notice procedures it follows with regard to ordinary medical records when it seeks CURES prescription records.

Requiring a warrant and patient notice before accessing CURES records will not cause undue delay or in any way thwart the legislative purpose of CURES—*i.e.*, assisting doctors and pharmacies in making better prescribing decisions and reducing prescription drug abuse. *See* Health & Safety Code § 11165(a). But it will ensure that the privacy rights of California patients are protected. This Court should reverse the lower court's holding and require law enforcement to obtain a warrant—and provide patient notice—before accessing CURES records in any investigation with the potential to lead to criminal charges.

Petitioner, at 41–42, enforcing the constitutional safeguard of a warrant requirement will only bring California in line with a number of other states. California patients should enjoy the same protections for the privacy of their prescription drug records as patients in other states.

II. THE COURT OF APPEALS ERRED IN CONCLUDING THAT PATIENTS HAVE A DIMINISHED EXPECTATION OF PRIVACY IN PRESCRIPTION RECORDS.

The lower court recognized that "[l]ike medical records, prescription records contain identifying information and sensitive information related to drugs used to treat a person's medical condition and also reveal medical decisions concerning the course of treatment." *Lewis*, 226 Cal. App. 4th at 947. And California law expressly recognizes that patient information based on CURES data provided to licensed health care practitioners and pharmacists is "medical information subject to the provisions of the Confidentiality of Medical Information Act[.]" Health & Safety Code § 11165.1(d).

The court nonetheless distinguished patients' expectation of privacy in their controlled substance prescription records from patients' expectation of privacy in their "ordinary" medical records, reasoning that "[a] reasonable patient filling a prescription for a controlled substance knows or should know that the state, which prohibits the distribution and use of such drugs without a prescription, will monitor the flow of these drugs from pharmacies to patients." *Lewis*, 226 Cal. App. 4th at 948. This rationale, if accurate, would apply to all prescription records, not just controlled substances, since the distribution of all prescription drugs is limited by their very nature.

But the court's reasoning is flawed in two other respects. First, it fails to appreciate that the information contained within prescription records—whether controlled or uncontrolled—is just as sensitive as the information contained elsewhere in a patient's medical file. Second, it erroneously presumes that the business of prescribing controlled substances constitutes a "closely regulated" industry for purposes of the administrative search exception to the Fourth Amendment's warrant requirement, and that

the close regulation of *physicians* somehow impacts *patients'* expectation of privacy in their personal prescription records.

A. Prescription Records Contain Information Just as Sensitive As "Ordinary" Medical Records and Are Due the Same Heightened Expectation of Privacy.

The privacy of patients' prescription records—whether controlled or uncontrolled—should be protected as much as any other medical information. Prescription records are an indispensable part of a patient's medical file, and they contain information about a patient and their medical conditions and medical history that is just as sensitive in nature as information contained within that patient's "ordinary" medical records. *See Douglas v. Dobbs*, 419 F.3d 1097, 1102 (10th Cir. 2005), *cert. denied*, 546 U.S. 1138 (2006) ("Information contained in prescription records not only may reveal other facts about what illnesses a person has, but may reveal information relating to procreation—whether a woman is taking fertility medication for example—as well as information relating to contraception."); *id.* ("[W]e have no difficulty concluding that protection of a right to privacy in a person's prescription drug records, which contain intimate facts of a personal nature, is sufficiently similar to other areas already protected within the ambit of privacy."); *see also Loder v. City of Glendale*, 14 Cal. 4th 846, 894 (1997) (noting that a drug testing program impacted student athletes' "interest in 'informational privacy' insofar as the urinalysis provided the NCAA with personal and confidential information regarding the student's medical condition *and the student was required to disclose the medications that he or she currently was taking*") (emphasis added) (citing *Hill*, 7 Cal. 4th at 40–41).

Indeed, "[i]t is now possible from looking at an individual's prescription records to determine that person's illnesses, or even to ascertain such private facts as whether a woman is attempting to conceive a

child through the use of fertility drugs." *Doe v. Se. Pa. Transp. Auth. (SEPTA)*, 72 F.3d 1133, 1138 (3d Cir. 1995). As such, courts have recognized that the "privacy in prescription records falls within a protected 'zone of privacy' and is thus protected as a personal right either 'fundamental' to or 'implicit in the concept of ordered liberty.'" *Douglas*, 419 F.3d at 1102 (citation omitted); *see also SEPTA*, 72 F.3d at 1138 ("An individual using prescription drugs has a right to expect that such information will customarily remain private."); *State v. Skinner*, 10 So. 3d 1212, 1218 (La. 2009) ("[T]he right to privacy in one's medical and prescription records is an expectation of privacy that society is prepared to recognize as reasonable.").[11]

The federal District Court of Oregon recently rejected an attempt to distinguish between medical records and prescription information for purposes of a patient's reasonable expectation of privacy—stating that any such distinction "is very nearly meaningless." *Oregon Prescription Drug Monitoring Program v. U.S. Drug Enforcement Admin.*, 998 F. Supp. 2d 957, 966 (D. Or. 2014), *appeal docketed*, Case No. 14-35402 (9th Cir. May 9, 2014). In that case, the Oregon Prescription Drug Monitoring Program

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[11] In *Skinner*, the Louisiana Supreme Court held that a warrantless search of a criminal defendant's pharmacy records violated the defendant's Fourth Amendment privacy interests and the state constitutional right to privacy. 10 So. 3d at 1218. The lower court here distinguished *Skinner* on the grounds that it involved a criminal investigation and the court therefore did not engage in a balancing test to assess whether the invasion of privacy was justified. *See Lewis*, 226 Cal. App. 4th at 952. The fact that *Skinner* did not balance the privacy intrusion against the government's interest in accessing the records is irrelevant to *Skinner*'s overall evaluation of an individual's reasonable expectation of privacy in prescription records. Indeed, although Dr. Lewis' case is not criminal, it implicates the standard law enforcement must satisfy to gain access to prescription records for purposes of an individualized investigation—one that could lead to criminal charges.

("PDMP") brought an action against the Drug Enforcement Administration ("DEA") seeking a declaration of its rights and obligations in complying with administrative subpoenas issued by the federal agency. Several patients—who were each taking scheduled drugs to treat extreme pain conditions, gender identity disorders, or post-traumatic stress disorders—intervened, along with a doctor and the American Civil Liberties Union. *Id.* at 959, 961. The court recognized that prescription records contain highly sensitive information for which patient intervenors had a subjective—and objectively reasonable—expectation of privacy. *Id.* at 964 ("[E]ach of the patient intervenors has a subjective expectation of privacy in his prescription information, as would nearly any person who has used prescription drugs."); *id.* at 966 ("[T]he court easily concludes that intervenors' subjective expectation of privacy in their prescription information is objectively reasonable.").

As the court stated, "[t]he prescription information maintained by PDMP is intensely private as it connects a person's identifying information with the prescription drugs they use." *Id.* By obtaining prescription records, a person could discover that a patient used testosterone in particular quantities and, by extension, that they had a gender identity disorder being treated via hormone therapy; "[i]t is difficult to conceive of information that is more private or more deserving of Fourth Amendment protection." *Id.* "Although there is not an absolute right to privacy in prescription information, as patients must expect that physicians, pharmacists, and other medical personnel can and must access their records, it is more than reasonable for patients to believe that law enforcement agencies will not have unfettered access to their records." *Id.* Thus, due to patients' "heightened privacy interest" in prescription records, "the DEA's use of administrative subpoenas to obtain prescription records from the

PDMP"—rather than a warrant or court order supported by probable cause—"violates the Fourth Amendment[.]" *Id.* at 967.

Oregon Prescription illustrates the types of sensitive situations that the lower court's ruling implicates, and it appropriately determined both the expectation of privacy due to patient prescription records—whether controlled or uncontrolled—and the corresponding standard that should govern law enforcement access to such records.

The lower court, however, distinguished *Oregon Prescription* on the ground that (i) the "statutory scheme" was not similar to the CURES statute and (ii) the case dealt with the right of a federal agency to obtain records via an administrative subpoena rather than a warrant. *See Lewis*, 226 Cal. App. 4th at 952, n.16. But for the purposes here, these details are not meaningful. That the statutory scheme at issue in *Oregon Prescription* differed from the statute underlying the CURES database is irrelevant to the Oregon court's over-arching evaluation of patients' expectation of privacy in their prescription records. And that *Oregon Prescription* involved a challenge to the use of an administrative subpoena—rather than a challenge to the lack of any legal process whatsoever, as here—does not render the court's high-level conclusion that patients have a heightened expectation of privacy in their prescription records unpersuasive.

What is critical is that both *Oregon Prescription* and this case require deciding the question of what level of privacy patients can reasonably expect with regard to their personal prescription records. And as *Oregon Prescription* correctly recognized, disclosure of patients' prescription records implicates the very same concerns as the disclosure of ordinary medical records: that individuals who require treatment with

scheduled drugs covered by CURES[12] could become stigmatized, lose their jobs, or otherwise be susceptible to discrimination if information about their medical conditions gleaned from their prescription records were disclosed. For example, CURES requires reporting of common drugs used to treat anxiety and panic disorders, such as Xanax (Alprazolam) and Valium (Diazepam), as well as drugs used to treat insomnia (*e.g.*, Camazepam) and alcohol dependency (*e.g.*, Buprenorphine or Paraldehyde.)[13] *See* 21 C.F.R. §§ 1308.13, 1308.14. These are legitimate medical conditions that an individual would understandably seek to keep private—and for which patients may be deterred from seeking treatment if they felt the privacy of their prescription records would not be adequately protected.[14]

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[12] CURES applies to Schedule II, Schedule III, and Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations. *See* Health & Safety Code § 11165(d).

[13] The federal Public Health Service Act provides specific protection against the disclosure of medical records relating to the treatment of drug and alcohol abuse patients in federally funded treatment programs, recognizing the heightened sensitivity of such records. *See* 42 U.S.C. § 290dd-2. For instance, the law mandates that "[e]xcept as authorized by a court order" upon a showing of good cause, including the need to avert a substantial risk of death or serious bodily harm, "no [substance abuse] record . . . may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient." 42 U.S.C. § 290dd-2(c), (b)(2)(C).

[14] *See* Letter from the National Committee on Vital and Health Statistics to the U.S. Department of Health and Human Services, Re: Individual control of sensitive health information accessible via the Nationwide Health Information Network for purposes of treatment (Feb. 20, 2008) (available at http://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/080220lt.pdf) (last viewed Oct. 5, 2015) (noting that "there is a strong public interest in encouraging individuals to seek prompt treatment for sensitive health conditions, such as domestic violence, sexually transmitted diseases, *substance abuse*, and *mental illness*") (emphasis added).

The lower court's decision to downgrade patients' privacy expectations in their controlled substance prescription records relative to their "ordinary" medical records was thus unwarranted. Indeed, as *Oregon Prescription* held, the distinction drawn by the lower court between prescription records and any other medical records—at least insofar as a patient's reasonable expectation of privacy is concerned—is "very nearly meaningless." *See* 998 F. Supp. 2d at 966.

B. The Court Erred in Applying the Closely Regulated Industry Exception to the Business of Prescribing Controlled Substances.

The *Lewis* court's determination that patients have a lowered expectation of privacy in their controlled substance prescription records assumed that the business of prescribing controlled substances is a "closely regulated" industry for purposes of the very narrow administrative search exception to the Fourth Amendment's warrant requirement. The court reasoned that because pharmacies are statutorily required to maintain records of prescriptions filled for controlled substances and present such records to authorities without a warrant as part of a routine auditing process, any reasonable expectation of privacy against the release of controlled substance prescription records to law enforcement is significantly diminished. *Lewis,* 226 Cal. App. 4th at 948–49 & n.12.[15]

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[15] That law enforcement has access to pharmacy records for purposes of routine administrative monitoring does not justify giving the government unfettered access to CURES records for individualized investigations. *See, e.g., United States v. Ganias*, 755 F.3d 125 (2d Cir. 2014), *reh'g en banc granted*, 791 F.3d 290 (2d Cir. 2015) (the government's possession of forensic mirror images of a defendants' hard drives, obtained via a warrant, did not undermine the defendant's reasonable expectation of privacy in the files contained therein that were non-responsive to the warrant); *United States v. Comprehensive Drug Testing, Inc.*, 621 F.3d 1162, 1169, 1172 (9th Cir. 2010) (en banc) (per curiam) (the government's seizure of

The court's reasoning is misguided. First, the court erroneously concluded that the business of prescribing controlled substances is a "closely regulated" industry. Second, the court incorrectly presumed that close regulation of controlled prescriptions lowers patients' expectations of privacy in their prescription records. The lower court's holding that patients have a diminished expectation of privacy in their controlled substance prescription records rests on these erroneous conclusions and should be reversed.[16]

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computer hard drives and related storage media containing electronic drug testing records, obtained during the execution of a search warrant for the records of ten baseball players, did not diminish privacy rights in the records beyond the scope of the warrant).

[16] In addition, although the lower court did not expressly cite the "third-party doctrine," it appeared to think that the privacy interest in patients' prescription records is diminished by the fact that prescription records are shared with pharmacies and do not remain with the doctor—seemingly relying on *Smith v. Maryland*, 442 U.S. 735, 744 (1979), which held that there is no reasonable expectation of privacy in the numbers dialed into a telephone system because one "voluntarily conveyed numerical information to the telephone company and 'exposed' that information to its equipment in the ordinary course of business." *See Lewis*, 226 Cal. App. 4th at 953 ("There is no greater right to privacy in controlled substances prescription record stored in CURES than the privacy rights in the same prescription records housed at CVS or Rite Aid Pharmacy."). But the lower court's reasoning is incorrect. As a preliminary matter, this Court has rejected the application of the third-party doctrine under California law. *See, e.g., People v. Blair*, 25 Cal. 3d 640, 654 (1979) (holding that telephone records are protected from warrantless disclosure, despite *Smith v. Maryland*'s holding that a warrant for a pen register was not required under the Fourth Amendment); *Burrows v. Superior Court*, 13 Cal. 3d 238, 243 (1974) (holding that bank customers retain a reasonable expectation of privacy in their bank records). And as Justice Sotomayor recognized in *United States v. Jones*, __ U.S. __, 132 S. Ct. 945, 957 (2012) (Sotomayor, J., concurring), the premise that an individual has no reasonable expectation of privacy in information voluntarily disclosed to third parties "is ill suited to

i. The court incorrectly presumed that the business of prescribing controlled substances is a "closely regulated" industry.

The administrative search exception to the Fourth Amendment's warrant requirement permits warrantless inspections—carefully limited in time, place, and scope—of the commercial premises of closely regulated businesses. *See United States v. Biswell*, 406 U.S. 311, 315 (1972) ("In the context of a regulatory inspection system of business premises that is carefully limited in time, place, and scope, the legality of the search depends not on consent but on the authority of a valid statute.").

The lower court presumed that the prescription of controlled substances is a "closely regulated" industry for purposes of the warrant exception based on the history of state regulation of prescription drugs. *See Lewis*, 226 Cal. App. 4th at 949. But as the U.S. Supreme Court recently clarified in rejecting the contention that the hotel industry is "closely regulated" for purpose of the administrative search exception, "'[t]he clear import of our cases is that the closely regulated industry . . . is the exception.'" *Patel*, 135 S. Ct. at 2455 (citation omitted). "Over the past 45 years, the Court has identified *only four* industries that 'have such a history of government oversight that no reasonable expectation of privacy . . . could exist for a proprietor over the stock of such an enterprise'": liquor sales, firearms dealing, mining, and running an automobile junk yard. *Id.* at 2454 (emphasis added; citations omitted). Prescribing controlled substances was not among these closely regulated industries, even though *Whalen*, 429 U.S. at 605, permits states to maintain records of certain controlled substance prescriptions. And the Court declined to add hotel

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the digital age, in which people reveal a great deal of information about themselves to third parties in the course of carrying out mundane tasks."

administration to the list—despite a long history of state regulation of hotels—stating: "nothing inherent in the operation of hotels poses a clear and significant risk to public welfare." *Patel*, 135 S. Ct. at 2454.

Patel settles the question regarding the four limited categories to which the closely regulated business exception applies.[17] Moreover, the Ninth Circuit's holding in *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 550 (9th Cir. 2004), instructs that the exception cannot apply in this case. In *Tucson Woman's Clinic*, the court held that abortion clinics were not "closely regulated" for purposes of evaluating an Arizona regulation requiring abortion clinics to submit to warrantless inspections by the Arizona Department of Human Services because the exception "clearly does not apply to abortion clinics, where the expectation of privacy is *heightened*, given the fact that the clinic provides a service grounded in a fundamental constitutional liberty, and that all provision of medical

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[17] California courts have applied the closely regulated industry exception beyond the four industries identified by the U.S. Supreme Court in *Patel*. *See, e.g., People v. Firstenberg*, 92 Cal. App. 3d 570, 581 (1979) (nursing homes); *People v. Harbor Hut Restaurant*, 147 Cal. App. 3d 1151, 1155–56 (1983) (wholesale fish dealers); *Betchart v. Dep't of Fish and Game*, 158 Cal. App. 3d 1104, 1110 (1984) (preservation of fish and game); *Kim v. Dolch,* 173 Cal. App. 3d 736, 743 (1985) (massage parlors); *People v. Potter*, 128 Cal. App. 4th 611, 621–22 (2005) (automobile repair shop); *De La Cruz v. Quackenbush*, 80 Cal. App. 4th 775, 781–82 (2000) (insurance industry and brokerage businesses); *see also Rush v. Obledo*, 756 F.2d 713, 720 (9th Cir. 1985) (family day care homes). But these decisions likely do not survive *Patel.* Even assuming they did, the closely regulated industry exception remains the exception—*not the rule*. *See Pinney v. Phillips*, 230 Cal. App. 3d 1570, 1584 (1991) ("These exceptions for heavily regulated businesses are just that: exceptions."). And California courts have not extended the exception to pharmacies, hospitals, or other businesses dealing with controlled substance prescriptions. Nor is such an exception warranted given the sensitivity of such records. Indeed, none of the exceptions carved out by either the U.S. Supreme Court or California courts implicate such highly sensitive personal information.

services in private physicians' offices carries with it a high expectation of privacy for both physician and patient." 379 F.3d at 550 (emphasis in original).

The same reasoning applies here. Just as in *Tucson Woman's Clinic*, the expectation of privacy is heightened in the context of prescription drug records, which include highly sensitive information about an individual's medical history. *See id.; see supra* at 14–19. And just as in *Patel*, California's long history of regulating the dispensing and use of prescription drugs is not determinative of the question. *See* 135 S. Ct. at 2455. Here, the sensitivity of the information implicated outweighs the potential relevance of the state's history of regulation.

ii. The court conflated the business of prescribing controlled substances with the patients for whom the prescriptions are medical treatment.

Second, the court conflated the business of prescribing controlled substances with the patients for whom the prescriptions are medical treatment. As the Ninth Circuit explained in *Tucson Woman's Clinic*, "the theory behind the closely regulated industry exception is that *persons engaging in such industries*, and persons present in those workplaces, have a diminished expectation of privacy." 379 F.3d at 550 (quoting *New York v. Burger*, 482 U.S. 691, 701 (1987)) (emphasis added); *see also De La Cruz*, 80 Cal. App. 4th at 781 ("The rationale for the 'closely regulated' business exception is that *the owner or operator of such a business* has a 'reduced expectation of privacy[.]'") (emphasis added; citation omitted). In other words, "[a] closely regulated business is one where the pervasiveness and regularity of the government's regulation *reduces the owner's expectation of privacy in his business records*." *Pinney*, 230 Cal. App. 3d at 1583 (emphasis added).

The theory behind the closely regulated industry exception simply does not apply to patients' prescription records. There is no evidence that patients who are prescribed controlled substances know or should know that their private information is accessible to law enforcement. Patients are far more likely to know of the longstanding rules regarding doctor-patient confidentiality and the doctor-patient privilege. *See Oregon Prescription*, 998 F. Supp. 2d at 964 ("Medical records, of which prescription records form a not insignificant part, have long been treated with confidentiality. The Hippocratic Oath has contained provisions requiring physicians to maintain patient confidentiality since the Fourth Century B.C.E."). Indeed, a recent study shows that 97.2 percent of patients believe their health care providers have a legal and ethical responsibility to protect patients' medical records and private information.[18]

Such rules support an increased—not a decreased—expectation of privacy in prescription records. *See Hill*, 7 Cal. 4th at 36 ("[C]ustoms, practices, and physical settings surrounding particular activities may create or inhibit reasonable expectations of privacy."); *see also DeMassa v. Nunez*, 770 F.2d 1505, 1506–07 (9th Cir. 1985) (per curiam) (identifying rules of professional conduct and other sources of professional ethics as a

[18] New London Consulting, *How Privacy Considerations Drive Patient Decisions and Impact Patient Care Outcomes* 10 (2011) (available at www.fairwarning.com/whitepapers/2011-09-WP-US-PATIENT-SURVEY.pdf) (last visited Oct. 17, 2015); *see also* The Gallup Organization, *Public Attitudes Toward Medical Privacy* 2–3 (2010), (available at http://www.forhealthfreedom.org/Gallupsurvey/IHF-Gallup.pdf) (last visited Oct. 17, 2015) (noting that 92 percent of adults oppose giving government agencies access to their medical records without permission, while 88 percent oppose giving police or lawyers such access, 71 percent oppose giving other doctors such access, and 88 percent oppose having their medical records kept in a national computer database).

source of clients' reasonable expectation of privacy in client files possessed by attorneys).

The lower court relies on *Whalen v. Roe*—in which the U.S. Supreme Court upheld the constitutionality of a New York statute requiring the state to maintain records of certain controlled substance prescription—for the proposition that patients have a diminished expectation of privacy in their prescription records. *See Lewis*, 226 Cal. App. 4th at 948. But the legal analysis in *Whalen* was limited to the privacy interests implicated by the collection of centralized data by a state. *See id.*; *see also Whalen*, 429 U.S. at 599–604. *Whalen* did not address the issue presented here—whether law enforcement officials may access patient information stored within a centralized data repository for use in a disciplinary, civil, or criminal investigation without a warrant.

Nor did *Whalen* analyze patients' reasonable expectation of privacy in prescription records in any depth. *See Skinner*, 10 So. 3d at 1218 ("[W]e do not find that *Whalen*'s upholding of a regulatory scheme for the monitoring of prescriptions for controlled substances diminishes a person's Fourth Amendment privacy interest to permit warrantless governmental intrusion during the course of a criminal investigation.").[19] The lower court's rationale to the contrary "focuses . . . only on the unquestioned right of the Medical Board to investigate the doctor" and "ignores the patient's

[19] The lower court also erroneously stated that this Court relied on *Whalen* in holding in *Hill v. National Collegiate Athletic Association* that student athletes have a diminished expectation of privacy in their urine samples and that the NCAA's drug testing program therefore did not violate the right to privacy under the California Constitution. *See Lewis*, 226 Cal. App. 4th at 948. But the *Hill* Court did not even cite *Whalen* in its analysis of students' reasonable expectation of privacy in their urine samples. *See* 7 Cal. 4th at 41–43.

constitutional and statutory rights to be left alone." *See Gherardini*, 93 Cal. App. 3d at 680.

More generally, much of the health care industry could be said to be heavily regulated by state and federal governments, but no one would reasonably think that such regulation—much of which is for the benefit of patients, including their privacy—diminishes the privacy of their medical records. That an industry is closely regulated in a colloquial sense does not, as a matter of fact or law, put patients on notice that their information may be accessed by law enforcement at any time and for any reason. Thus, even assuming *arguendo* that the business of prescribing controlled substances was "closely regulated," this cannot diminish the privacy expectations of patients who are lawfully prescribed those drugs.

iii. Warrantless searches of prescription records do not qualify for the closely regulated industry exception.

Even assuming that the business of prescribing controlled substances met the threshold requirement of being "closely regulated," the warrantless searches here do not qualify for the exception, which requires that the search be reasonable because (a) a "'substantial' government interest" underlies the inspection scheme, (b) warrantless inspections are "'necessary to further [the] regulatory scheme,'" and (c) the inspection program "'in terms of the certainty and regularity of its application, [provides] a constitutionally adequate substitute for a warrant.'" *Burger*, 482 U.S. at 702–03 (citation omitted).

Warrantless inspections of CURES data fail the *Burger* test. The government has not shown that warrantless inspections are necessary to further the purpose of CURES, *i.e.*, assisting doctors and pharmacies in making better prescribing decisions and cutting down on prescription drug abuse. Nor has the government shown that the protocols outlined in CURES for the use of prescription records by outside agencies provide a

constitutionally adequate substitute for a warrant in terms of the certainty and regularity of its application. Indeed, the CURES statute is silent regarding the specific protocols outside agencies must follow in order to use CURES records in disciplinary, criminal, or civil investigations; it states only that the operation of CURES must comply with federal and state privacy laws and safeguard the privacy and confidentiality of patients. *See supra* at 3; Health & Safety Code § 11165(c)(1)–(2). And contrary to the lower court's finding, the statute's broad and vague allowance of data sharing with state and federal agencies for civil, criminal, and disciplinary purposes does not demonstrate that physicians and patients will know who is authorized, and under what "narrow" circumstances, to receive CURES data. *See Lewis*, 226 Cal. App. 4th at 953. On its face, without its express incorporation of federal and constitutional and statutory protections, the statute would seemingly permit *unlimited* access to prescription records by outside agencies—leaving patients and physicians entirely unclear of who was accessing their records and under what circumstances.

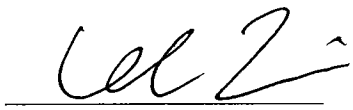
The lower court erred—in multiple ways—in applying the closely regulated industry exception, and its decision should be reversed. As the Ninth Circuit has held, "[e]veryone's interests are best served if there are clear rules to follow that strike a fair balance between the legitimate needs of law enforcement and the right of individuals and enterprises to the privacy that is at the heart of the Fourth Amendment." *Comprehensive Drug Testing*, 621 F.3d at 1177. Here, that balance requires law enforcement to obtain a warrant supported by probable cause, and provide patient notice, before gaining access to sensitive CURES records.

CONCLUSION

The decision of the Court of Appeal—permitting law enforcement to access highly sensitive prescription drug records without either a warrant or notice—is premised on an erroneous understanding of both patients' reasonable expectation of privacy in such records and the closely regulated industry exception to the Fourth Amendment's warrant requirement. This Court should overrule the lower court's decision to downgrade patients' expectation of privacy in their controlled substance prescription records and instead require law enforcement to obtain a warrant supported by probable cause—and provide patient notice—before accessing sensitive CURES records.

Dated: October 23, 2015

Respectfully submitted,

By: 

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CERTIFICATE OF COMPLIANCE

Counsel for *Amicus Curiae* hereby certifies, pursuant to Rules 8.486(a)(6) and 8.204(c)(1) of the California Rules of Court, that the foregoing brief was produced using proportionally-spaced, 13-point type, including footnotes, and contains approximately 8,143 words, excluding the cover, the tables, the signature block, the verification, and this certificate, which is less than the 14,000 words permitted by this rule. Counsel relies on the word count of the Microsoft Word word-processing program used to prepare this brief.

Dated: October 23, 2015

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PROOF OF SERVICE BY MAIL

Re: ***LEWIS v. S.C. (MEDICAL BOARD OF CALIFORNIA)***
Supreme Court of the State of California Case No. S219811

I, Stephanie Shattuck, declare that I am over the age of 18 and not a party to the within action. My business address is 815 Eddy Street, San Francisco, CA 94109.

On October 23, 2015, I served true copies of the attached APPLICATION OF ELECTRONIC FRONTIER FOUNDATION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF IN SUPPORT OF PETITIONER ALWIN LEWIS and *AMICUS CURIAE* BRIEF OF ELECTRONIC FRONTIER FOUNDATION IN SUPPORT OF PETITIONER ALWIN LEWIS on the following parties by placing copies of the document(s) listed above in an envelope, addressed to the parties listed below, which envelope was then sealed by me and deposited in the United States Mail, postage prepaid, at San Francisco, California.

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I declare under penalty of perjury that the foregoing is true and correct. Executed on October 23, 2015 at San Francisco, California.

Stephanie Shattuck