January 6, 2014

VIA FEDERAL EXPRESS

Honorable Joan D. Klein, Presiding Justice
and Honorable Associate Justices
California Court of Appeal
Second Appellate District, Division 3
300 S. Spring Street
2nd Floor, North Tower
Los Angeles, California 90013

Re: Amicus Letter Brief of the California Medical Association in Support of
Petition for Writ of Mandate in Alwin Lewis, M.D. v. Superior Court of the
State of California, County of Los Angeles (Medical Board of California, Real
Party in Interest) - Case No. B252032

Dear Presiding Justice Klein and Associate Justices:

The California Medical Association (CMA) respectfully submits this amicus curiae letter in support Dr. Alwin Lewis, M.D.'s pending Petition for Writ of Mandate in the above-mentioned case.

I. Interest of the California Medical Association.

CMA is a non-profit, incorporated professional association for physicians with approximately 38,000 members throughout the state of California. For more than 150 years, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA's physician members practice medicine in all specialties and settings. CMA and its physician members are committed to the protection of the patient's right to medical privacy and confidentiality which is the foundation of the patient-physician relationship and is essential to the ability of a physician to provide quality and effective care. Physicians accordingly invest substantial resources into maintaining and protecting the confidentiality and security of patient health information. CMA and its physician members have a strong interest in ensuring that the disclosure of California's Controlled Substance Utilization Review and Evaluation System (CURES) data to third-party government agencies be subject to clear and consistent regulations and procedures that properly balance patient privacy with the governmental interest.

For the reasons stated in the petition for writ of mandate, CMA believes that the current laws governing CURES and the manner in which patient prescription drug data is disclosed are inconsistent with the broad scheme of federal and state laws protecting the confidentiality and privacy of patient medical information. By this amicus letter brief, CMA wishes to impress upon the Court the importance of confidentiality of medical information as an indispensable
component of quality medical care and provide a broad perspective on patient privacy matters around prescription drug monitoring programs (PDMPs) such as CURES. CMA asks this Court to give meaningful protection to confidential medical information, including prescription information collected in CURES.

II. The Petition for a Writ of Mandate Should Be Granted.

This case highlights the importance of protecting patient privacy rights in the digital age while balancing the government interest in regulating and preventing prescription drug abuse. A patient's prescription drug information, particularly for drugs that are approved for treatment of specific medical conditions, can reveal a patient's underlying medical condition. The Real Party in Interest Medical Board's Return and Memorandum of Points and Authorities in Opposition to Petition for Extraordinary Writ of Mandate (MBC Opposition) argues that patients have no expectation of privacy in their prescription records and therefore, the government can freely mine and access data in PDMPs without a warrant, any showing of reasonable cause to access the information, restrictions as to the scope of the data, or limits on the discretion of the inspecting officers. While CMA supports CURES as a "valuable preventative, investigative and educational tool for health care providers, regulatory agencies...and law enforcement[.]" Health and Safety Code section 11165 does not adequately protect patient privacy. In today's digital age, PDMPs like CURES allow the government to easily and efficiently store a patient's prescription data and mine it for information indefinitely. Given this Orwellian-esque technology, it is more important than ever that there are clear guidelines on the use of CURES data by law enforcement and regulatory agencies such as the Medical Board.

A. Confidentiality of Medical Information Is An Essential Component Of Quality Medical Care.

Patients have a high expectation of privacy in the provision of medical services. The duty of physicians to protect patient privacy lies at the very core of the medical profession. Confidentiality is one of the most enduring ethical tenets in the practice of medicine, and is essential to the patient-physician relationship. It is the cornerstone of the patient's trust, successful medical information gathering for accurate diagnosis and treatment, an effective physician-patient relationship, good medicine and quality care.

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1 Senate Bill 809, 2013 Stats. Ch. 400. In 2013, the California Legislature enacted S.B. 809 to allocate funding through licensing fees to CURES for the reasonable cost of operating and maintaining CURES.

2 Tuscon Woman's Clinic v. Eden, 379 F.3d, 531, 550 (9th Cir. 2004); see also Board of Medical Quality Assurance v. Gherardini, 93 Cal.App.3d 669, 678 (1979) ("A person's medical profile is an area of privacy infinitely more intimate, more personal in quality and nature").

3 See Privacy in the Context of Health Care Report 2-I-01, American Medical Association, Council on Ethical and Judicial Affairs at 2, available at www.ama-assn.org/amallpub/upload/mm/369/ceja_2i01.pdf ("Confidentiality is one of the oldest medical ethical precepts, dating back to the Hippocratic Oath").

Confidentiality is a necessary precondition for any patient to willingly share sensitive personal information with a physician. Patients are routinely required to disclose private and even embarrassing information to physicians who are entrusted to protect this information from unwarranted disclosures. Only within this trusting relationship can physicians provide effective treatment and preserve the basic human dignity and privacy rights of the patient.

Indeed, the very nature of the health care delivery process – which begins with a physician listening to the patient’s complaints and concerns, performing physical examinations, and diagnosing the problem – requires the patient to be completely open and candid with the physician in order for the physician to gain an accurate understanding of the patient’s medical problem and medical history and determine the best course of treatment. Thus, if patients are not completely open and frank with their health care provider, the result could be the "improper diagnosis and treatment of important health conditions.”

A patient will fully and candidly disclose his or her full medical history only if the patient believes that the physician will assertively guard the privacy of such information. By contrast, if a patient believes that such information cannot or will not be protected, he or she may withhold important facts from the physician. Without full disclosure of the patient’s symptoms and medical history, physicians may not be able to provide the patient with effective care and advice. Worse, the patient may decline to seek medical care at all, thereby allowing a potentially reversible condition to deteriorate or a communicable disease to go unrecognized and untreated. Thus, maintaining patient privacy is "essential to the effective functioning of the health and public health systems.”

B. Prescription Records In CURES Are Medical Records And Should Be Subject To Privacy Protections Under The Law.

The idea that a patient’s prescription information is not afforded the same protections as the rest of the medical record is contrary to the extensive state and federal laws governing the confidentiality of medical information. Both California’s Confidentiality of Medical Information Act (CMIA) and the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) define medical information broadly. "Medical information" is defined under the CMIA as "any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient’s medical history, mental or physical condition, or treatment." Moreover, the statute specifies that prescription data released to a physician or pharmacist from

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6 See United States v. Chase, 340 F.3d 978, 990 (9th Cir. 2003) (explaining that candor is essential to the psychotherapist-patient relationship "because patients will be more reluctant to divulge unsavory thoughts or urges" if they know that their information will not be kept confidential and may be disclosed without their consent).
8 Civil Code §56.05(j) (emphasis added).
the CURES database is considered medical information subject to the CMIA. In this light, to accept the Medical Board's arguments would lead to the absurd result that patient prescription records may be subject to different privacy protections, and patients should have a different expectation of privacy, in the same records depending on whether the information is housed in CURES or with a health care provider.

Similarly, HIPAA defines "protected health information" (PHI) as individually identifiable health information that is transmitted or maintained in electronic media or any other form or medium. Health information means any information that is created or received by a health care provider and relates to the past, present or future physical or mental health or condition of an individual, the provision of health care or payments for the provision of health care to an individual. In certain circumstances, the disclosure of the patient's name can trigger privacy protections. For example, for certain health care providers that specialize in the treatment of specific medical conditions such as oncology, HIV/AIDS, eating disorders, and gender identity disorders, even the mere disclosure that an individual is a patient at a certain physician practice can reveal their underlying medical condition.

Health & Safety section 11165(d) requires dispensing pharmacies to report identifying patient information including name, address and date of birth, identifying information for the prescriber and dispensing pharmacy, the National Drug Code number of the dispensed drug, quantity, International Classification of Diseases (ICD) diagnostic code if available, number of refills, whether the drug was dispensed as a refill or first time request, date the drug was prescribed, and date the prescription was dispensed. This information not only includes personal identifying information, it can contain a diagnostic code identifying the patient's medical condition. Such information clearly falls within the definitions of "medical information" under CMIA and "protected health information" under HIPAA.

Even absent a diagnostic code, specific prescription drug information is likely to reveal information that society deems is entitled to privacy protections. Prescription records reveal sensitive, intimate and potentially stigmatizing details about a patient's health. Controlled substances are prescribed for a wide range of serious medical conditions including testosterone deficiency, seizure disorders, chronic pain, narcolepsy, obesity, weight loss and nausea associated with AIDS and patients undergoing chemotherapy, attention deficit hyperactivity disorder, anxiety and panic disorders, post-traumatic stress disorder, gender identity disorder, and heroin addiction treatment. Since many medications are approved for use to treat specific

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9 Health & Safety Code §11165.1(d).
10 45 C.F.R. §160.103.
11 Id.
medical conditions, prescription information for schedule II, III and IV controlled substances as reported to CURES can divulge sensitive medical information about an individual.

C. CURES Does Not Adequately Protect Patient Privacy in Prescription Records.

On its face, Health & Safety Code section 11165 gives the Department of Justice (DOJ), the law enforcement agency that administers CURES, too much discretion in its disclosure of confidential patient prescription information. The law allows the DOJ to disclose confidential identifiable patient prescription data to any "state, local, and federal public agencies for disciplinary, civil or criminal purposes." This results in law enforcement and investigatory agencies accessing patient prescription records for investigations that do not relate to prescription drug abuse or diversion and in many cases, where the patient is not the subject of the investigation. It also gives the DOJ broad discretion as to which specific individuals at a law enforcement or investigatory agency can directly access the database, and where there is a request for CURES data, whether to release requested information and how much of the data should be disclosed.

Generally, for the Medical Board to seek judicial enforcement of an investigative subpoena for a physician's medical records, "it must demonstrate through competent evidence that the particular records it seeks are relevant and material to its inquiry sufficient for a trial court to independently make a finding of good cause" to order the disclosure. This requirement for a showing of good cause is founded in the patient's right of privacy guaranteed by the California Constitution. In this case, in response to a complaint by a patient who had only seen Dr. Lewis one time for an initial assessment and did not raise any issues with Dr. Lewis's prescribing practices, the Medical Board investigator accessed the prescribing records of all of Dr. Lewis's patients during a four year period from CURES. The investigator testified that it was "common practice" to obtain CURES data on the subjects of all Medical Board investigations.

In other words, the Medical Board readily admits that it employs a policy of widespread mining of sensitive prescription drug data in CURES to the greatest extent possible.

In addition, the Medical Board obtained confidential prescription records from the pharmacy pursuant to its authority to inspect pharmacy records pursuant to Business & Professions Code section 4081. While this statute was enacted to regulate pharmacists, wholesalers and manufacturers of dangerous drugs, it is now being used broadly, in conjunction with CURES data, to circumvent the requirement to show good cause prior to accessing patient medical information. This is particularly concerning in light of recent practices by pharmacies to request additional medical information from the prescriber before filling controlled substances prescriptions. The information requested by pharmacies are above and beyond what has been

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13 Health & Safety Code § 11165(c).
15 Id.
16 The Real Party in Interest Medical Board's Return and Memorandum of Points and Authorities in Opposition to Petition for Extraordinary Writ of Mandate (MBC Opposition) at 8.
traditionally transmitted to pharmacies and includes information from the patient's medical record to support the diagnosis including physician notes, ICD diagnostic codes, expected length of therapy, and previous medications tried and failed.\(^\text{17}\) Thus, the Medical Board is routinely accessing, and privy to, confidential health information of California patients without the consent of the patient, warrant, subpoena or showing of good cause.

i. **CURES Data May Not Be Protected By State and Federal Privacy and Security Laws.**

Both California law and HIPAA contain provisions that detail when and how health care providers can disclose patient information, provide for a patient's right to access their health information, receive an accounting of disclosures, and require the implementation of administrative, physical and technical safeguards to ensure the security, integrity and confidentiality of electronic health records.\(^\text{18}\) Health care providers are subject to steep civil penalties that can reach millions of dollars and, in some cases, criminal liability for violations of CMIA and HIPAA provisions.\(^\text{19}\) The DOJ's position, however, is that these protections in the law do not apply to the DOJ in their maintenance of CURES.\(^\text{20}\)

Although recent amendments made by Senate Bill 809\(^\text{21}\) state that "the operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations,"\(^\text{22}\) California's laws protecting patient privacy and security apply only to health care providers, health plans, or contractors.\(^\text{23}\) Similarly, HIPAA only applies to health care providers, health plans and health care clearinghouses that use electronic means to transmit health information. Thus, these laws protecting the confidentiality of patient health information may be inapplicable to CURES.\(^\text{24}\)


\(^{18}\) See Civil Code §§ 56 et seq. and 45 C.F.R §§164.500 et seq.; Health & Safety Code §§123100 et seq. and 45 C.F.R. §164.524 (patient access to health records); 45 C.F.R. §164.528 (accounting of disclosures); Health & Safety Code §130203; 45 C.F.R. §§164.302 et seq. (security safeguards to protect privacy of patient information).

\(^{19}\) See Civil Code §56.36; 45 C.F.R. §§160.400 et seq.

\(^{20}\) The Medical Board cites as a reason for a patient's diminished expectation of privacy, that prescription information is "viewed by several third parties" before being reported to CURES. Although it is true that a patient's prescription information is viewed by the individuals and entities listed in the MBC Opposition, all of the listed "third parties" are subject to state and federal privacy laws as health care providers or health plans. MBC Opposition at 29.

\(^{21}\) Senate Bill 809, supra n.1.

\(^{22}\) Health & Safety Code §11165(c)(1) (emphasis added).

\(^{23}\) See Civil Code § 56.10 (disclosure of medical information); Health & Safety Code §§123100 et seq. (patient access to health records); Health & Safety Code §130203 (safeguards to protect privacy of patient information).

\(^{24}\) 45 C.F.R. §160.103. Note that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) does apply to government agencies who act as health plans in their administration of Medicare and Medicaid.
Senator Bill 809 does mandate, at CMA's urging, that the DOJ "establish policies, procedures, and regulations regarding the use, access, management, implementation, operation, storage, disclosure and security of the information within CURES" which may resolve this lack of clear and consistent guidelines regarding the privacy and security protections for CURES data. These regulations, however, have yet to be promulgated. As a result, there is currently no distinct scheme protecting patient prescription data, medical information that a health care provider would be obligated to protect under California privacy and security laws and HIPAA, in the CURES database. Based on the Petitioner's privacy arguments and those set forth in this letter brief, CMA respectfully requests this Court to provide guidance in this rule-making process by establishing the legal principles applicable to CURES that protect patient confidentiality.  

ii. PDMPs in Other States Have More Protections To Ensure Patient Privacy.

The DOJ operates with broad discretion over the disclosure of CURES data in contrast to other state PDMPs. PDMPs in other states, many of them established after CURES, provide for more privacy protections, including patient access to their own data, not allowing regulatory boards to directly access PDMP data, and placing limits on the release of prescription data to regulatory boards to requests involving drug-related investigations. Some state statutes governing PDMPs specifically state that the PDMP system shall comply with HIPAA and state privacy laws. Other state PDMPs also provide an express exemption from state public records laws for PDMP data and provide that PDMP data is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by a regulatory board. Despite these additional restrictions, with the increased sophistication of technological database tools, the protection of patient privacy in PDMPs is an emerging concern and the subject of multiple ongoing lawsuits.

26 See MASS. GEN. LAWS ch. 94C, §24A (Massachusetts PDMP provides prescription information to "individuals who request their own prescription monitoring information" and to regulatory agencies provided that the "data request is in connection with a bona fide specific controlled substance or additional drug-related investigation"); FLA. STAT. ANN. §§893.055, 893.0551 (Florida's PDMP allows patients to review their PDMP data "for the purpose of verifying the accuracy of the database information" and provides prescription information to regulatory boards who request PDMP data for "a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances"); OR. REV. STAT. §431.966 (Oregon's PDMP must provide prescription information to a patient at no cost and within 10 days of the patient's request for information. It will provide PDMP data to a "professional regulatory board that certifies in writing that the requested information is necessary for an investigation related to licensure, renewal or disciplinary action"); N.Y. PUBLIC HEALTH LAW §§3343-a, 3371 (New York's PDMP provides patient access to their own controlled substance histories and provides relevant information to the appropriate law enforcement agencies when there is a "reason to believe that a crime related to the diversion of controlled substances has been committed").
27 See FLA. STAT. ANN. §893.055(2)(a); OR. REV. STAT. §431.962(2)(d), 431.966.
28 See FLA. STAT. ANN. §893.0551; MASS. GEN. LAWS ch. 94C, §24A(d).
29 See FLA. STAT. ANN. §893.055(7)(c)(4).
30 See Michael H. Lambert v. R.J. Larizza, as State Attorney for the Seventh Judicial Circuit of the State of Florida, No. 2013-31402, Circuit Court, Seventh Judicial Circuit, Volusia County, Florida (June 12, 2013) and Oregon
Under the current statutory scheme, patients in California have no access to their information in CURES, no means to determine what information is within the database, whether it has been disclosed to a third-party, or whether the information contained within CURES is accurate. Moreover, there are no clear guidelines to inform patients of when their confidential prescription data may be accessed by law enforcement or regulatory agencies. The DOJ has sole discretion in determining whether to disclose patient prescription records, how much data should be disclosed and to whom it should be disclosed. As a result, patients in California, who generally are afforded stronger privacy protections than most states, are not afforded those same protections and transparency when it comes to their confidential medical information in the state’s PDMP database.

D. The Digital Age and Increased Technological Capacity to Store and Mine Data Heightens the Need for Patient Privacy Protections.

Finally, this case raises a very contemporary issue facing the courts regarding the right to privacy in the digital age. In United States v. Jones, 132 S.Ct. 945 (2012), the U.S. Supreme Court found that the warrantless use of a GPS device to track the plaintiff’s vehicle violated his reasonable expectation of privacy. In her concurring opinion, Justice Sotomayor addressed how modern technology may necessitate a reconsideration of privacy rights when personal information and history is preserved electronically and can be easily collected, maintained and mined by the government in mass quantities for years into the future. More recently, the U.S. District Court for the District of Columbia addressed the expectation of privacy of telephone metadata in the face of modern technology, ruling that the National Security Agency’s data-gathering was likely unconstitutional under the Fourth Amendment.  

Today, Medical Board investigators can easily access over 100 million individually identifiable entries of schedule II, III and IV controlled substances dispensed to patients in California sitting at their desks. Advances in technology enable the government to store and analyze mass quantities of data, including confidential medical information of millions of patients that can be stored in perpetuity and constantly updated with new data. In 2013, California dedicated almost $4 million, including over $1.6 million from physician licensing fees in the Medical Board’s Contingent Fund, towards a technological update to CURES in its Final


Budget. With this funding, CURES will receive a much needed technological upgrade after years of underfunding and understaffing that has resulted in a system that makes it difficult for physicians to access the database to assist them in making informed prescribing decisions. While this is a welcome upgrade for California physicians, it also underscores the importance of ensuring that proper privacy protections are in place for a more powerful database with increased capacity to store and aggregate data and ability to share data with other state and national PDMPs.

Gathering information in CURES is cheaper and easier in comparison to conventional information gathering techniques used by the Medical Board in the recent past. It also allows for the Medical Board to proceed surreptitiously, evading the ordinary checks that constrain abusive government practices that violate patient privacy. Furthermore, technology has greatly increased the quantity of information available to the Medical Board and facilitates its ability to correlate data from different sources. Records that once revealed only "a few scattered tiles of information about a person now reveal an entire mosaic" of a person's medical history. Such intrusions can discourage patients from fully and candidly disclosing their medical history with physicians or seek medical care at all and compromise the ability of physicians to provide quality care.

Accordingly, CMA urges the Court to grant the petition for writ of mandate.

Respectfully,

Francisco J. Silva, SBN 214773
Long X. Do, SBN 211439
Lisa Matsubara, SBN 264062
CALIFORNIA MEDICAL ASSOCIATION

By: Lisa Matsubara
Attorneys for California Medical Association

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35 Health care practitioners registering to access CURES face an onerous application process and long delays in processing their applications. Should they encounter any problems, there is currently no way to contact the program to resolve their issues. The CURES/PDMP website contains a message that says that the DOJ "cannot respond to telephone inquiries or emails to the CURES/PDMP Program due to budget-related resourcing issues." CURES/PDMP website, supra n.33.

36 Jones, 132 S.Ct. at 956 (Sotomayor, J., concurring).

37 Memorandum Opinion at 54, Klayman, supra n.32.
I, Mandeep Heer, hereby declare:

I am employed in Sacramento, California. I am over the age of eighteen years and am not a party to the above-entitled action. My business address is 1201 J Street, Sacramento, California 94814.

On January 6, 2014, I caused the document(s) to be served as indicated below:

**AMICUS CURIAE LETTER BRIEF OF THE CALIFORNIA MEDICAL ASSOCIATION IN SUPPORT OF PETITION FOR WRIT OF MANDATE**

U.S. Mail: By mailing a true copy thereof via first-class postage through the United States Postal Service, as set forth in the attached Service List.

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

Executed on January 6, 2014, at Sacramento, California.

Mandeep Heer
## SERVICE LIST

*Alwin Lewis, M.D. v. Superior Court of the State of California, County of Los Angeles (Medical Board of California, Real Party in Interest)* -
Case No. B252032

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| The Honorable Joanne O'Donnell   | The Superior Court of Los Angeles              |
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| SUPERIOR COURT OF THE STATE OF   |                                                |
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| COUNTY OF LOS ANGELES            |                                                |
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