THE OPIOID EPIDEMIC IS NOT NEW: TIME TO CHANGE THE PRACTICE OF MEDICINE

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On August 11, 2017, during a press conference, President Donald J. Trump proclaimed, "[t]he opioid crisis is an emergency."[1] No one doubts that the United States is currently in an opioid epidemic with substantive concerns about abuse, dependence, addiction, and overdose deaths. It is a complex problem, involving issues of abuse with both licit (such prescription drugs as oxycodone and fentanyl) and illicit drugs (such as heroin).[2] It involves inappropriate and criminal behaviors by both physicians and patients. To date, this matter has been addressed primarily by policy makers as a legal issue, with the creation of more legislation and regulation. However, it is at its heart and core a medical issue, since prescribing opioids is an almost essential component of the practice of medicine,[3] and it must be addressed as one. Adding more and more burdensome requirements may be only repeating the same mistakes regulators have made in the past.

This paper focuses on four interventions that are most likely to facilitate change in the practice of medicine: prescription drug monitoring, restricting prescribing practices, targeted prescriber education, and dedicated enforcement by state medical boards.[4] We begin with a recent case report, upholding the right of medical

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[1] Wayne Drash & Dan Merica, *Trump: 'The opioid crisis is an emergency,'* CNN, http://www.cnn.com/2017/08/10/health/trump-opioid-emergency-declaration-bn/index.html (last updated Aug. 11, 2017).

[2] *See America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse (May 14, 2014).

[3] *See* Bruce Psaty & Joseph O. Merrill, *Addressing the Opioid Epidemic – Opportunities in the Postmarketing Setting*, 376 NEW ENG. J. MED 1502, 1502–03 (2017).

[4] These tools are recognized by the Office of National Drug Control Policy (ONDCP) as key interventions as well. *See* A. Travis Manasco et al., *Characteristics of State Prescription Drug Monitoring Programs: A State-by-State Survey*, 25 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 847, 847 (2016).

boards to access and use information readily accessible from California's prescription drug monitoring program (PDMP). Part I further focuses on three specific efforts: (1) prescription monitoring programs; (2) training requirements for health care professionals; and (3) restrictions on prescriptions, including an explanation of past statutory history. Part II explores the discipline of health care professionals for misconduct and incompetency as an additional measure for enforcement. This section begins by recounting the story of Elvis Presley and the disciplinary actions taken against his physician and pharmacist. The paper concludes with some reflections on the current authority of state medical boards and the need for professional organizations to self-police.

I. GOVERNMENT AGENCY EFFORTS TO COMBAT THE OPIOID EPIDEMIC

A. Prescription Drug Monitoring Programs

1. Dr. Lewis v. California Medical Board

The recent California Supreme Court case, *Lewis v. Superior Court*,[5] is illustrative of how prescription drug monitoring programs ("PDMPs") are used at the medical board level to enforce standards. PDMPs record information about controlled substance prescriptions using state-based systems.[6] They were created as a means for physicians to review the medication patterns of their patients in order to avoid improper prescribing.[7] Additionally, PDMPs are used by state agencies to monitor not only patients but provider prescribing patterns as well.[8] Forty-nine states and the District of Columbia have PDMPs.[9] They began as early as 1939 in California and 1972 in Pennsylvania, though the majority were established in the last decade.[10] Currently, there is no uniform

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[5] *See* Lewis v. Superior Court, 3 Cal. 5th 561, 566–67 (2017).

[6] Manasco et al., *supra* note 4.

[7] *See* Michael A. Ashburn, *The Evolution of Prescription Drug Monitoring Programs*, 25 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 852, 852 (2016).

[8] *See id.*

[9] *See* Lynn Webster & Martin Grabois, *Current Regulations Related to Opioid Prescribing*, 7 PHYSICAL MED. & REHABILITATION J. 236, 242 (2015).

[10] *See* Erin P. Finley et al., *Evaluating the Impact of Prescription Drug Monitoring Program Implementation: A Scoping Review*, BMC HEALTH SERVS. RES. 1, 1–2 (2017).

model for PDMPs and their use is highly variable among the providers in different states.[11] *Lewis v. Superior Court,* is just one example of how they are likely to be used.

The key issue in *Lewis v. Superior Court* was whether patients' privacy was violated when medical boards obtained information from the monitoring program database.[12] In this case, the California Supreme Court ruled that the Medical Board of California ("the Board") was sufficiently justified in obtaining data from its PDMP without good cause, warrant, subpoena, or consent.[13]

California's PDMP—called CURES (Controlled Substance Utilization Review and Evaluation System)—is an online program maintained by the California Department of Justice[14] and is a good example of a standard state PDMP.

Created in 1996, this specific program is designed to accomplish two goals: (1) "'assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances,'" and (2) "to help 'law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of [certain] controlled substances.'"[15] The program monitors prescribing by requiring any pharmacy or dispenser to report specific information (including patient name, contact information, amount of drug dispensed, and number of refills) for every Schedule II, III, and IV controlled substances prescription.[16] The program can create individual reports on physicians' prescribing activity. To gain access to the records, one must be a registered user of the program,[17] though the

[11] *See id.* One should note that the National Association of Boards of Pharmacy has made one national PDMP called NABP PMP InterConnect that allows for interstate data sharing available online since 2011 and it is currently being used by 42 states. *See PMP InterConnect*, NAT'L ASS'N BDS. PHARMACY, https://nabp.pharmacy/initiatives/pmp-interconnect/ (last visited Sept. 28, 2017).

[12] *See* Lewis v. Superior Court, 3 Cal. 5th 561, 565 (2017).

[13] *See id. See also* Brian Melley, *Court: California med board justified in prescription probe*, ASSOCIATED PRESS NEWS (July 18, 2017), https://www.apnews.com/9a5f6296440446d991d2b28dad741961/Court:-California-med-board-justified-in-prescription-probe.

[14] *See CURES 2.0*, CAL. DEP'T JUSTICE, https://oag.ca.gov/cures (last visited Sept. 28, 2017).

[15] *Lewis*, 3 Cal. 5th at 566.

[16] *Id.* (quoting the statute). This program monitors more drugs than most programs monitor, as most focus on Schedule II drugs. *See* Manasco et al., *supra* note 4, at 849.

[17] *See Frequently Asked Questions: About CURES 2.0*, ST. OF CAL. DEP'T OF JUST. OFF. OF THE ATT'Y GEN., https://oag.ca.gov/cures/faqs (last visited Sept. 26,

program is intended for health care professionals to use in practice and for law enforcement officers to use for monitoring prescribing activities. Registration is not limited to pharmacists who report this information, but also includes licensed dentists, physicians (MDs and DOs), optometrists, physician assistants, podiatrists, certified nurse midwifes, nurse practitioners, and veterinarians.[18] The health care professionals are furthermore required to be registered with the federal Drug Enforcement Administration ("DEA").[19] In 2009, the program changed to allow preregistered users (including law enforcement and regulatory boards) to gain access to these prescription records more quickly through an electronic real-time system without having to request information through mail, phone, or fax.[20]

This case began in 2008 with the Board's investigation of Dr. Alwin Carl Lewis in response to a patient complaint that Dr. Lewis recommended a curious five-bite diet for weight loss.[21] This diet would consistent only of "five bites" of food for both lunch and dinner with no breakfast.[22] Clearly, the Board's duties include protecting the public from incompetent health care professionals, and disciplining health care professionals for failing to meet the standard of care.[23] As part of this investigation, the Board's investigators obtained a CURES prescription report on Dr. Lewis' controlled substances prescribing for hundreds of patients without a subpoena or consent from these patients.[24] Based on this CURES information, the Board decided to file professional misconduct charges relating to practices for an additional five patients. The misconduct charges were "unprofessional conduct, prescribing dangerous drugs without an appropriate examination, excessive prescribing, and failure to maintain adequate and accurate medical records."[25]

Dr. Lewis filed a motion to dismiss during the administrative process stating that the Board violated his patients' privacy by

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2017) (see section about who has access and who is required to register).

[18] *Id.*

[19] *Id.*

[20] *Lewis*, 3 Cal. 5th at 566.

[21] *Id.* at 567.

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *Id.* at 568.

obtaining the CURES information without legal authorization.[26] This motion was denied and Dr. Lewis was found to have "engaged in unprofessional conduct, engaged in negligent acts, and failed to maintain adequate records."[27] Dr. Lewis was placed on probation for three years.[28] Dr. Lewis appealed this determination through the California State court appeals system using the same argument.[29]

Ultimately, the California Supreme Court agreed with the Court of Appeal's decision and held that the Board's duty to protect the public health justified any invasion of patients' privacy for this purpose.[30] After establishing that Dr. Lewis did have standing to assert his patients' constitutional rights under the state constitution,[31] the California Supreme Court implicitly assumed that he had met the three constitutional threshold elements[32] by directly addressing the successful affirmative defense of the Board, holding that there were countervailing interests[33] which justified any invasion of privacy. These justifiable interests were "protecting the public from the unlawful use and diversion of a particularly dangerous class of prescription drugs and protecting patients from negligent or incompetent physicians."[34] The Court further explained that having "a good cause requirement[35] would compromise the Board's ability to identify and address potentially dangerous prescribing practices" since the investigation "could result in protracted legal battles that effectively derail those investigations."[36] The Court also believed that there were sufficient regulatory safeguards in place to protect the confidentiality and privacy of individual patients.[37]

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[26] *Lewis*, 3 Cal. 5th at 568.
[27] *Id.*
[28] *Id.*
[29] *See id.*
[30] *See id.* at 578.
[31] *See id.* at 569–71.
[32] These elements are the following: 1) there was a legally protected privacy interest; 2) there was a reasonable expectation of privacy in the circumstances; and 3) the conduct by the accuser constituted a serious invasion of privacy. *See Lewis*, 3 Cal. 5th at 571.
[33] The Court rejected the argument that a compelling interest test needed to be applied based on the notion that that test is limited to "[an] obvious invasion of an interest's fundamental to personal autonomy." *Lewis*, 3 Cal. 5th at 572.
[34] *Lewis*, 3 Cal. 5th at 572.
[35] Good cause requirement would require the investigator to have some initial reason/evidence to warrant pulling the records. *Id.* at 575.
[36] *Id.*
[37] *Id.* at 576–77.

One of the major concerns with monitoring systems is the possible chilling effect they might have on patient treatment. This is based on the notion that patients know that they may be "watched" by a monitoring program, which is connected to the government, and that patients will not seek treatment because of this surveillance. Interestingly, the California Court, in Dr. Lewis' case, did not believe a prescription monitoring system would affect the physician-patient relationship. The Court stated:

> It is true that the disclosure of information from the CURES database may chill patients' willingness to pursue treatment. But it cannot 'be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication. Although the State no doubt could prohibit entirely the use of [Schedule II, III, or IV] drugs, it has not done so. This case is therefore unlike those in which the Court has held that a total prohibition of certain conduct was an impermissible deprivation of liberty.' The disclosure of information from CURES may be one consideration affecting a patient's choice to pursue treatment, but it does not significantly impair the patient's ultimate ability to make that choice on his or her own.[38]

The Court's logic assumes that patients have substantial decision-making power in the physician-patient relationship. The California Court furthermore found that "although patients retain a reasonable expectation of privacy in their prescription records, that [any] privacy interest is less robust than the privacy interest associated with medical records," because (1) "medical records contain far more sensitive information than do prescription records," and (2) "a reasonable patient would know or should know that the government monitors the sale and distribution of controlled substances, and that prescription records are routinely reviewed by pharmacists and insurance companies."[39] If a reasonable patient knows that the prescription information is being monitored by the government, there is a far more compelling argument that the patient-physician relationship may be impaired

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[38] *Id.* at 573.
[39] *Id.* at 575.

by this monitoring than this Court seems to think. Part of the patient-physician relationship is the trust that information shared in the relationship will be kept confidential. The Court did acknowledge that there could have been an alternative method, such as anonymizing patients' prescription information, which would lessen the potential impact to patients' privacy.[40]

2. Strategies to Improve PDMPs

Of course, there are ways to improve current prescription monitoring systems beyond protecting patient privacy more broadly. One major improvement would be to reduce the variability between state programs and have one national standardized system. Currently, there is remarkable variability between state programs, including those who may access and use the programs, what information is reported, and when the programs are to be used.[41] Most track Schedule II drugs, but the programs are not consistent in listing Schedule II drugs to be monitored.[42] These differences render the PDMPs less effective than they could be.[43] PDMPs track provider prescribing patterns by linking the DEA identification number of the provider, however, this information may not be as accurate if the physician is sharing his/her login information with other providers.[44] The states also have different definitions of what qualifies as high risk and when providers should be reporting or checking the program.[45] Frequency in reporting affects the timeliness and accuracy of the information in the program.[46] As one study found, "reporting frequency is the only regulatory mechanism that is associated significantly with reduced OPR [opioid pain relievers] overdose deaths"[47] and a national standard could include a higher frequency of reporting to achieve this goal.

Most PDMPs (forty percent) are administered by professional authorities associated with licensing, such as pharmacy and

[40] *See Lewis*, 3 Cal. 5th at 576.

[41] *See* Manasco et al., *supra* note 4, at 849; Bryce Pardo, *Do More Robust Prescription Drug Monitoring Programs Reduce Prescription Opioid Overdose?,* ADDICTION 1, 2 (2016).

[42] *See* Manasco et al., *supra* note 4, at 849.

[43] *See id.* at 850.

[44] *Id.* (this also raises concerns about unauthorized practice of medicine as some health care professionals are not supposed to be prescribing at all).

[45] *Id.*

[46] Finley et al., *supra* note 10, at 6.

[47] Pardo, *supra* note 41, at 8.

medical boards.[48] However, those administrated by law enforcement agencies appear more effective in reducing opioid overdoses, though many of these programs were older and so this association may be based on experience.[49] Some of the PDMPs are voluntary as well. Only twenty-one states mandate the use of PDMPs for opioid prescribers,[50] which is less than half of the programs in use. Three states mandate use of the PDMP based on a subjective judgment of inappropriate use, while some are only used when prescribing or dispensing narcotics, such as methadone.[51] Mandated programs are more effective[52] and mandatory enrollment in programs has been one suggestion for enhancing their benefits[53] but governments may lack resources to have an effective mandatory program.[54] Requiring these programs nationally would make them a more effective tool in tracking physician behaviors. In addition, not all state programs can share information between each other,[55] although there have been recent efforts to start interstate data sharing.[56]

Another difference between state programs is the expressed legislative purpose. The stated purpose may be helpful in program efficiency, because often courts consider legislative intent or purpose in determining how to interpret and in turn, how to enforce the laws.[57] Of the forty-nine states, only twenty-fives states have explicit purpose statements in their laws[58] and none of these stated purposes included reducing or preventing overdoses.[59] The most common purpose was "relate[d] to reducing the diversion, misuse, and abuse of prescription medications, the investigation and prevention of illegal activity, and benefits to practitioners."[60]

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48 *Id.* at 4.

49 *Id.* at 8–9.

50 Webster & Grabois, *supra* note 9, at 242.

51 Finley et al., *supra* note 10, at 2.

52 *Integrating and Expanding Prescription Drug Monitoring Program Data: Lessons from Nine States,* CTR. FOR DISEASE CONTROL (2017), https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf.

53 Ashburn, *supra* note 7.

54 *Id.* at 853.

55 Manasco et al., *supra* note 4, at 850.

56 CTR. FOR DISEASE CONTROL, *supra* note 52.

57 Corey S. Davis et al., *Overdose Epidemic, Prescription Monitoring Programs, and Public Health: A Review of State Laws*, 105 AM. J. OF PUB. HEALTH e9, e10 (2015).

58 *Id.* at e9.

59 *Id.* at e10.

60 *Id.*

One improvement for the programs could be to include the goal of reducing overdose and reducing harm as a way to encourage usage of PDMPs.[61] This goal is more public health-focused rather than criminally-focused.[62]

Another aspect of these programs that can be improved is physician usage. Indeed, there needs to be buy-in from the appropriate parties, particularly prescribers, that they will use the system and improved effective ongoing real-time management of information flow.[63] Physicians may only use PDMPs when they have perceived that a patient is at risk, instead as a default every time they prescribe an opioid.[64] In some states, PDMPs are not used by physicians as often. For example, in Florida, one study reported that emergency medicine physicians used it only fifty percent of time when prescribing opioids.[65] In another study that evaluated when providers used the PDMP, their "findings raise[d] concern that clinicians may overestimate their ability to detect aberrant drug use."[66] The study found there was a difference across specialties for how often the PDMP was used. Short-term prescribers such as emergency medicine physicians, dentists, and surgeons were less likely to use a PDMP in prescribing than a practitioner who prescribes opioids for chronic pain.[67] This study investigated physician decision making about using a PDMP. The major influencing factor on physician decision making was perceived patient intent or honesty, which is a subjective determination and was not always reliable.[68] Patients looking to divert drugs deceive physicians and physicians cannot always identify diversion risk based on perception of intent.[69] Some other reasons why physicians may not be using these programs include lack of knowledge about the program, and the state may not

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61 *Id.*; Pardo, *supra* note 41, at 9.

62 Davis et al., *supra* note 57, at e10.

63 *See Integrating & Expanding Prescription Drug Monitoring Program Data: Lessons from Nine States*, NAT'L CTR. FOR INJURY PREVENTION & CONTROL 11 (Feb. 2017), https://www.cdc.gov/drugoverdose/pdf/pehriie_report-a.pdf.

64 *See* Henry W. Young III et al., *The Current Utilization and Perceptions of Prescription Drug Monitoring Programs Among Emergency Medicine Providers in Florida,*10:16 INT'L J. OF EMERGENCY MED. 1, 3 (2017).

65 *See id.*

66 Gillian J. Leichtling et. al., *Clinicians' Use of Prescription Drug Monitoring Programs in Clinical Practice and Decision-Making*, 18 PAIN MED. 1063, 1066 (2017).

67 *Id.* at 1065.

68 *See id.* at 1065–66.

69 *See* Beth Jung & Marcus M. Reidenburg, *Physicians Being Deceived*, 8 PAIN MED. 433, 433–37 (2007).

require that particular type of provider to register.[70] Ways to better encourage physician use would be to integrate routines into the clinical setting, allowing ease of access and interpretability (particularly integration into electronic medical records).[71] Moreover, having real-time data collection and access would increase the benefit the programs could provide for physicians.[72] Having a standardized model, including interstate data sharing allowing for real-time usage would probably dramatically increase the impact.[73]

3. Benefits of PDMPs

There are a number of benefits that PDMPs can provide for physicians, patients, and the community. PDMPs increase detailed reporting and monitoring of controlled substances, reduce prescriptions by providers, reduce opportunities for diversion and misuse, all of which result in lowering the potential for negative outcomes, such as overdoses.[74] They can positively impact four major opioid domains affected: (1) opioid prescribing, (2) opioid diversion and supply, (3) opioid misuse, and (4) opioid-related poisonings morbidity and mortality.[75] They can help reduce misuse or inappropriate use of prescription medications by patients and inappropriate prescribing by physicians.[76] They can help with diversion, abuse, and illegal activity, and may be used both as a prevention tool and investigation tool.[77] PDMPs can assist law enforcement and regulators identify patterns, address public health and safety concerns, with the goal of hopefully lowering overdose potential and improving the community's health.[78] They can be used to identify the criteria for what is considered "risky behavior" both for providers and patients.[79] They

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[70] Dora H. Lin et al., *Physician Attitudes and Experiences with Maryland's Prescription Drug Monitoring Program (PDMP)*, 112 ADDICTION 311, 315 (2016).

[71] Leichtling et al., *supra* note 66, at 1066.

[72] *Id.*; Manasco et al., *supra* note 4, at 850.

[73] *See* Finley et al., *supra* note 10, at 7. It should be noted that one of the goals of the 2016 Comprehensive Addiction and Recovery Act was to strength PDMPs, demonstrating that our national legislature also acknowledges that these programs need to be improved. *See* Pardo, *supra* note 41, at 8.

[74] Finley et al., *supra* note 10, at 6.

[75] *Id.*

[76] Davis et al., *supra* note 57, at e10 tbl.1.

[77] *Id.*

[78] *Id.*

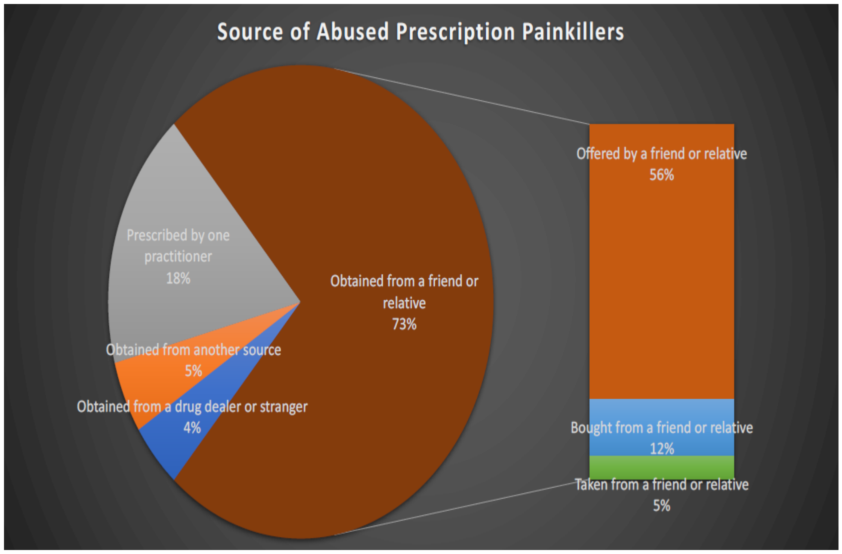
[79] Ashburn, *supra* note 7, at 852.

also help providers identify the patients that need assistance with addiction and provide more appropriate care.[80] It benefits all categories of health care providers, both prescribers and pharmacists, allowing a bridge across disciplines.[81] Electronic PDMPs are low-cost and convenient for users. They are furthermore a tool for gathering data in research and surveillance.[82] There is growing evidence of their success. New York's mandated program shows some success in stopping the rise of prescription opioid morbidity.[83] Physicians reported prescribing opioids less and their comfort with prescribing opioids increasing in Maryland.[84] Along with proper physician education and restricting prescriptions, PDMPs have the potential to dramatically impact the opioid disaster.

B. Restricting Prescribing Practices

The mandated use of PMDPs impacts prescribing practices. Moreover, recently some states have enacted or promulgated new standards further restricting opioid prescribing. For example, now, New York requires that new opioid prescriptions for acute pain be limited to a seven-day supply.[85] Several other states such as Massachusetts, Maine, Connecticut, and Vermont have crafted different approaches but with the same objective to limit the initial supply to immediate patient needs, and hopefully curb the availability of the drug.[86] The basis for this approach is that the clear majority of persons abusing prescription opioids obtain the drugs indirectly from doctors.

[80] Davis et al., *supra* note 57, at e10.
[81] *See id.*
[82] *Id.* at e10 tbl.1.
[83] *See* Richard Brown et al., *Impact of New York Prescription Drug Monitoring Program, I-STOP, on Statewide Overdose Morbidity*, 178 DRUG & ALCOHOL DEPENDENCE 348, 350 (2017).
[84] Lin et al., *supra* note 70, at 318.
[85] *Frequently Asked Questions Limited Initial Opioid Prescribing*, N.Y. ST. DEP'T OF HEALTH, https://www.health.ny.gov/professionals/narcotic/laws_and_regulations/docs/combat_heroin_legislation_faq.pdf (last visited Oct. 4, 2017).
[86] Charlotte Huff, *States Aim to Limit Opioid Prescriptions*, ACP INTERNIST (Oct. 2016), https://acpinternist.org/archives/2016/10/laws.htm.



Caption: Self-Reported Sources of Abused Prescription Painkillers[87]

Moreover, the Prescription Behavior Surveillance System found that the "top [ten percent] (decile) of [all opioid] prescribers wrote half or more of the opioid prescriptions in all states . . . In general, the more prescriptions a prescriber wrote, the higher the daily dosage they specified."[88] This shows how bad prescribing practices have complicated the epidemic. For example, California has the lowest opioid prescription rate[89] which may suggest that its robust PDMP is having an impact, particularly with its expansion to include more than just Schedule II drugs.[90] Limiting the number of dosage units that practitioners can prescribe appears to be a reasonable approach given the data available. However, one should recall that restricting prescribers' patterns has been attempted in the past at several critical points in our history, but with relatively limited success.[91]

In the United States during the early 1900s, there was an opioid crisis of a different sort than the one today. At that time, opioid

[87] Jane Hoback, *Overdosed on Opioids*, 42 NAT'L CONF. OF ST. LEGISLATURES 1, 13 (Apr. 2016).

[88] Leonard J. Paulozzi et al., *Controlled Substance Prescribing Patterns – Prescription Behavior Surveillance System, Eight States, 2013*, 64 MORBIDITY & MORTALITY WKLY. REP. 1, 7 (2015).

[89] *Id.* at 4, 10.

[90] *Id.* at 11.

[91] *See* Finley et al., *supra* note 10, at 2, 7.

products and cocaine were available without a prescription (it is reported that the first Coca-Cola recipe as concocted by an Atlanta druggist included cocaine).[92] These medicines were readily available from physicians, druggists, and traveling salesmen. The victims then were addicted adults who were legally purchasing nonprescription opioid products and children who were being overdosed. Sadly, it may have been the opioid poisoning of babies and infants and the stories of their distraught parents appearing in crusading national magazines like *Ladies Home Journal*, *Good Housekeeping*, and *The Independent* that turned the tide of public opinion toward tighter control and regulation of narcotics.[93]

One might say the first national effort to limit availability of the opioid supply centered on restricting the drugs to prescription only. The Harrison Narcotic Act was enacted by the Congress in 1914 and become effective March 1, 1915.[94] Rather than prohibit the availability of opioids outright, the law was directed toward the licensing of importers, manufacturers, physicians, and pharmacists who produced and marketed, prescribed, and dispensed narcotics.[95] The statute was administered and enforced by the Treasury Department.[96] The law required every registered physician to have a unique identifying number to prescribe the narcotics and to use their full name and identifying number on each prescription form.[97] Additionally, the doctor was obligated to write the patient's name, age, and address on each prescription order.[98] Even so, some over-the-counter ("OTC") or nonprescription opioids could still be purchased without a physician order if the amount in each dose was below a specific amount.[99] Of course, the Harrison Narcotic Act was not totally effective with respect to controlling the access to narcotics. The number of addicts continued to grow.[100] A joint legislative committee in New York estimated that the number of addicts in

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92 *See* James Hamblin, *Why We Took Cocaine Out of Soda*, THE ATLANTIC (Jan. 31, 2013), https://www.theatlantic.com/health/archive/2013/01/why-we-took-cocaine-out-of-soda/272694/.

93 STEVEN W. PRAY, A HISTORY OF NONPRESCRIPTION PRODUCT REGULATION 78–82 (2003).

94 David T. Courtwright, *Preventing and Treating Narcotic Addiction – A Century of Federal Drug Control*, 373 NEW ENG. J. MED. 2095, 2095–97 (2015).

95 *See* Harrison Narcotic Tax Act, 38 Stat. 785 (1914).

96 Courtwright, *supra* note 94, at 2096.

97 *See* Harrison Narcotic Tax Act at 785.

98 *See Id.* at 787.

99 *See* PRAY, *supra* note 93, at 82–86.

100 *See id.* at 88–89.

that city alone in 1916 was over 200,000.[101] The next major comprehensive national push[102] to restrict opioid prescribing practices occurred with the passage of the Controlled Substances Act ("CSA") in 1970.[103] This statute was enacted at the height of an all new drug abuse menace that was then enveloping the country.[104] The CSA attempted to create a closed system of controlled substances distribution.[105] With this law, prescription requirements for "controlled substances" were very specific and had to be ordered by a practitioner registered with the DEA, a criminal enforcement agency housed in the Department of Justice, and the prescription had to be dispensed by a pharmacy also registered with the DEA.[106] Moreover, each entity involved in the distribution chain from importer, manufacturer, wholesaler, and pharmacy had to keep such detailed and accurate records that the DEA could—if necessary—track almost each dosage unit to an ultimate user.[107] As it happens many opioids are classified as Schedule II Controlled Substances.[108]

The prescription order requirements were more restrictive than the Harrison Narcotic Act rules: (1) the registered practitioner could only order controlled substances "for a legitimate medical purpose"[109] "acting in the usual course of . . . professional practice;"[110] (2) the practitioner could not delegate the prescribing

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101 *Id.* at 88.

102 One should recall the impact of laws between 1917 and 1970.

103 Courtwright, *supra* note 94, at 2097.

104 *See* Joseph W. Spelman, *Heroin Addiction: The Epidemic of the 70's*, 21 ARCHIVES OF ENVTL. HEALTH: AN INT'L J. 589 (1970).

105 RICHARD R. ABOOD, PHARMACY PRACTICE AND THE LAW 171 (6th ed. 2011).

106 *Id.* at 177.

107 *See id.*

108 Some examples of Schedule II drugs include "[c]ombination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin." DRUG ENFORCEMENT ADMIN., *Drug Schedules*, https://www.dea.gov/druginfo/ds.shtml (last accessed Oct. 20, 2017).

109 21 C.F.R. § 1306.04 (2005); 21 U.S.C. § 829 (2012). Deference is given to providers to determine what a legitimate medical purpose may mean. James H. Ruble, *Prescriber–Pharmacist Collaboration: Re-engineering the Partnership to Optimize Pain Patient Care*, 27 J. OF PAIN & PALLIATIVE CARE PHARMACOTHERAPY 365, 365–66 (2013).

110 21 C.F.R. § 1306.04 (2005); 21 U.S.C. § 829 (2012). Usual course of professional practice would be defined by the state definition of what is the practice of medicine. *See* NY CLS EDUC. § 6521 (2017) (providing one example of one state definition); *Prescription Drug Physical Examination Requirements*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 29, 2015), https://www.cdc.gov/

authority to an agent; (3) the controlled substances prescription had to be dated as of the issuance date (that is, the order could not be pre-dated or post-dated); (4) all controlled substances prescriptions must include the patient's full name and address, the drug name, strength, dosage form, quantity, and directions for use, and the practitioner's name, address, and unique DEA registration number; and (5) prescriptions for Schedule II Controlled Substances could not be refilled and only be dispensed upon oral orders in an "emergency" and if the practitioner agreed to supply a written prescription with seventy-two hours.[111]

The CSA also added an additional safeguard: the pharmacist who dispensed the prescription had a "corresponding responsibility," and was thus equally liable with the prescriber to assure that the prescription was authorized for a legitimate medical purpose by a lawful practitioner in the usual course of professional practice.[112] In addition to the federal CSA prescription requirements, some states went even further in mandating that Schedule II Controlled Substances be written on specific triplicate prescription forms supplied by the state.[113]

Sadly, the 1970 CSA was not that much more successful in controlling the narcotic drug abuse problems of the day than the 1914 Harrison Narcotic Act had been.[114] With both acts, the authorities learned that restricting prescriber and pharmacy narcotic prescription routines had minimal impact without additional controls and enforcement actions.

C. Targeted Opioid Prescribing Education

Along with PDMPs and restricting prescription practices, targeted physician education about proper opioid prescribing is necessary to combat this catastrophe. The PDMPs and restrictions on opioid prescriptions are useless unless a physician knows about their existence, understands their role, and is taught how to effectively use these tools to better enhance the practice of medicine.[115] Education is the key to not repeating the same

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phlp/docs/pdpe-requirements.pdf (offering a comprehensive review of the state requirements needed to prescribe a medication).

[111] *See* ABOOD, *supra* note 105, at 218–220.

[112] *Id.* at 221–24.

[113] Whalen v. Roe, 429 U.S. 589, 593 (1977).

[114] *See* Lynn R. Webster & Martin Grabois, *Current Regulations Related to Opioid Prescribing*, 7 PM & R S236, S238 (2015).

[115] *See, e.g.*, Ellen Meara et al., *State Legal Restrictions and Prescription-*

mistakes of the past. Provider education has been connected to increased provider registration in PDMPs.[116] Furthermore, provider education has been associated with increased knowledge about legislation related to prescription practices.[117] Education is a long-term solution as compared to restricting prescriptions, which is only an immediate step.[118] Naturally, any education needs to be targeted, helping the providers who will be prescribing opioids most often. Not all physicians prescribe narcotics, so it is not logical to have a blanket mandate since the education may not be relevant to some providers.[119]

Education is the best way to change the practice of medicine and physician behaviors because it is grounded in the accepted medical practice as established by physicians. Standards of care are defined by medical professionals. To change that standard of care, one has to change physicians' mindsets, practice patterns, and routines. Targeted education allows prescribing physicians to become more knowledgeable about pain management in general, as learning how to properly prescribe opioids entails learning about how to better manage pain.[120] Effective pain management is not as simple as just writing a prescription, it involves understanding the differences between acute and chronic pain in an individual patient context. It involves taking the time to unpack what "pain" means to that patient, and education about proper pain management can provide physicians the means to do this efficiently. Clearly, some of the essential education must center on proper management of chronic pain.[121] Education helps improve learning skills, change attitudes of physicians, and improve self-reporting practices.[122]

Opioid Use among Disabled Adults, 375 N. ENG. J. MED. 44, 50–51 (2016) (stating that prescription restrictions and PDMPs had no impact on nonfatal prescription-opioid overdose but conceding that physician education was not included in this analysis).

116 *See* Michelle R. Lofwall et al., *Efficacy of Continuing Medical Education to Reduce the Risk of Buprenorphine Diversion*, 41 J. SUBSTANCE ABUSE TREATMENT 321, 328 (2011).

117 *Id.*

118 *See* Daniel P. Alford, *Opioid Prescribing for Chronic Pain — Achieving the Right Balance through Education*, 374 N. ENG. J. MED. 301, 301 (2016).

119 One example would be physicians who work in a laboratory and never come in contact with a patient.

120 *See* Alford, *supra* note 118, at 302.

121 *Id.*

122 Daniel P. Alford et al., *SCOPE of Pain: An Evaluation of an Opioid Risk Evaluation and Mitigation Strategy Continuing Education Program*, 17 PAIN

One way of determining if education is being effective is to test physician confidence in opioid prescribing.[123] When the United States Food & Drug Administration's ("FDA") Risk Evaluation and Mitigation Strategy ("REMS") requirement became effective in 2012, one study evaluated physician confidence level after taking a three-hour course. Physicians in this study reported improved confidence in managing patients with opioids prescriptions, including communication and monitoring skills.[124] The improved confidence continued even two months after completing the program.[125] There is evidence that giving physicians protocols can improve provider confidence in identifying at-risk patients and managing opioids in general.[126] In this case, there may be hints to suggest that education may do what it is intended to do, improve the practice of medicine.

The idea of mandatory prescriber education is not a new concept to lawmakers and regulators. During a two-day conference in July 2017,[127] the FDA announced that efforts need to be made to improve physician training.[128] As an expansion of the 2012 REMS program, the FDA now requires manufacturers of short-acting opioids to fund provider education about proper prescribing practices,[129] which means funding for these programs should not be an issue. However, these programs are still not mandatory and the FDA is still considering whether proper prescribing practice

MED. 52, 53, 60 (2016).

[123] *Id.* at 56 tbl.2 (noting that measuring physician confidence may not always be accurate as it may not account for the overly confident physician).

[124] *Id.* at 57, 59

[125] *Id.* at 54.

[126] Amy CS Pearson et al., *Provider Confidence in Opioid Prescribing and Chronic Pain Management: Results of the Opioid Therapy Provider Survey*, J. PAIN RES. 1395, 1395 (2017).

[127] *See Data and Methods for Evaluating the Impact of Opioid Formulations with Properties Designed to Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/NewsEvents/ucm540845.htm (last updated Sept. 13, 2017).

[128] Scott Gottlieb, Commissioner, U.S. Food & Drug Admin., Remarks Delivered before FDA's Scientific Meeting on Opioids (July 10, 2017), https://www.fda.gov/NewsEvents/Speeches/ucm566189.htm.

[129] Nadia Kounang, *FDA to Require Expanded Training on Opioids*, CNN, http://www.cnn.com/2017/07/11/health/fda-increases-opioid-training-bn/index.html (last updated July 11, 2017, 6:26 PM). Manufacturers of long-acting opioids were already mandated to fund provider education in 2012 when REMS was first developed. *See* Laurie Scudder, *The New Opioid REMS: The FDA View*, MEDSCAPE (Sept. 19, 2012), http://www.medscape.com/viewarticle/770644.

education should be mandatory.[130] Past advisory panels to the FDA recommended that education should be mandatory.[131] In June 2012, the FDA's REMS for extended-release and long-acting opioid analgesics required that drug manufacturer provide the funding for long-acting opioids. It was also noted at that time that strategies to implement mandatory prescriber education should be addressed.[132] This was five years ago and yet, we still do not have any national mandate requiring prescriber education for this drug category.

Some states, including New York,[133] have required mandatory prescriber education programs, and some states have made attempts at such implementation.[134] New York's free online program began in the middle of 2017[135] and requires:

> [p]rescribers licensed in New York to treat humans and who have a DEA registration number to prescribe controlled substances, as well as medical residents who prescribe controlled substances under a facility DEA registration number, must complete at least three (3) hours of course work or training in pain management, palliative care, and addiction by July 1, 2017.[136]

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130 *See* Laurie McGinley, *FDA Chief to Impose Tougher Doctor-Training Rules on Opioid Manufacturers*, WASH. POST (July 10, 2017), https://www.washingtonpost.com/news/to-your-health/wp/2017/07/10/fda-chief-to-impose-tougher-doctor-training-rules-on-opioid-manufacturers/?utm_term=.946594dd241a. *See also* Maggie Fox, *FDA Considers Forcing Doctors to Learn about Opioids*, NBC NEWS, (July 10, 2017, 3:20 PM), https://www.nbcnews.com/storyline/americas-heroin-epidemic/fda-considers-forcing-doctors-learn-about-opioids-n781376.

131 Ryan Basen, *FDA Revisits Mandatory Opioid Prescriber Training*, MEDPAGE TODAY (May 11, 2017), https://www.medpagetoday.com/publichealthpolicy/publichealth/65220.

132 *Risk Evaluation and Mitigation Strategy (REMS) for Opioid Analgesics*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm (last updated Sept. 28, 2017).

133 *Mandatory Prescriber Education*, N.Y. ST. DEP'T OF HEALTH, https://www.health.ny.gov/professionals/narcotic/mandatory_prescriber_education/ (last updated June 2017).

134 *See, e.g.*, S.B. 1202, 2016 Gen. Assemb., Reg. Sess. (Pa. 2016). *See also Governor Wolf Signs Bills to Battle Heroin and Opioid Crisis*, GOVERNOR'S OFFICE: NEWSROOM (Nov. 2, 2016), https://www.governor.pa.gov/governor-wolf-signs-bills-to-battle-heroin-and-opioid-crisis/.

135 Malcom Reid, *April 2017 Update: CME Pain Management Course Now Available!*, MED. SOC'Y ST. N.Y. (Jan. 6, 2017), http://www.mssnyenews.org/enews/cme_pain_management_course_now_available/.

136 *Mandatory Prescriber Education*, *supra* note 133.

There has been some resistance to the notion of mandatory prescriber education from physicians. None of this reluctance has been against the idea of education, but centers on *mandatory* education. There is disagreement about mandates in general, based on a principle of physician autonomy: physicians should not be told how to practice medicine.[137] In 2012, the American Medical Association ("AMA") and the American Academy of Family Physicians ("AAFP") opposed mandatory provider education,[138] citing concerns that this is an unwarranted expansion of government into the practice of medicine and that this will cause the public to question the competency of our physicians. The AMA opposes mandatory education, but acknowledges that there needs to be improvements in provider training.[139] However, the competency of physicians is already being questioned based on the under and over-prescribing of painkillers, and increasing provider education publicly may challenge public confidence in physicians' abilities because the public knows physicians are receiving additional education. The AAFP stated that mandating education may restrict access for legitimate treatment of pain for patients.[140] However, education only better enhances physician autonomy because it gives physicians more knowledge when asked to make an informed recommendation.[141] Moreover, there has been evidence to show that mandated prescriber education does not address the real underlying causes of prescription drug abuse,[142] such as mental illness. Targeted education may prove to better address underlying issues as it will be the providers who are most affected by this crisis that would receive the education.

One might state that the mandatory education should be for all

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137 *See* Laurie Scudder, *Is Physician Autonomy Dead?*, MEDSCAPE (July 7, 2016), http://www.medscape.com/viewarticle/865788_1.

138 Stephen Loiaconi, *Physicians Warn Mandatory Opioid Prescription Training Could Have Unintended Effects*, WJLA (May 6, 2016), http://wjla.com/news/nation-world/physicians-warn-mandatory-opioid-prescription-training-could-have-unintended-effects. *See* Am. Acad. of Family Physicians, *AAFP Position Paper Opposes Mandated CME, Other Barriers for Prescribers of Opioids*, 10 ANNALS FAM. MED. 474 (2012).

139 Loiaconi, *supra* note 138.

140 BD. OF DIRS, AM. ACAD. OF FAMILY PHYSICIANS, PAIN MANAGEMENT AND OPIOID ABUSE: A PUBLIC HEALTH CONCERN 1 (2012), http://www.aafp.org/dam/AAFP/documents/patient_care/pain_management/opioid-abuse-position-paper.pdf.

141 Alford et al., *supra* note 122, at 52.

142 Michael E Schatman & Lynn R Webster, *The Health Insurance Industry: Perpetuating the Opioid Crisis through Policies of Cost-Containment and Profitability*, 8 J. PAIN RES. 153, 154 (2015).

physicians and should not allow for exceptions. However, this may prove to be a repressive strategy since some subspecialties may not prescribe opioids at all as part of routine practice, which is why targeted education would be a better approach. The education needs to be relevant to the provider for the provider to support its implementation. Targeted education would correspondingly increase the chance that there is physician and organizational support for the programs.

From a policy point of view, prescriber education probably needs to be mandatory, at least for those who are prescribing opioids, because the opioid problem has persisted for so long and the practice of medicine appears unchanged.[143] In addition, physicians already have mandated requirements for continuing medical education ("CME"), just like many other professions.[144] The program could even be online, as there has been evidence of successful implementation of online education in the medicine.[145] Education is also relatively inexpensive compared to other public health tools. Indeed, as Dr. Daniel P. Alford stated:

> Prescriber education is a more finely tuned approach to addressing the opioid-misuse epidemic, allowing us to individualize care on the basis of a patient's needs after a careful benefit–risk assessment. That, after all, is the way we manage all chronic diseases. Education can empower clinicians to make appropriate, well-informed decisions about whether to initiate, continue, modify, or discontinue opioid treatment for each individual patient at each clinical encounter. Education has the potential to both reduce overprescribing and ensure that patients in need retain access to opioids.[146]

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143 *See* Alford et al., *supra* note 122, at 60 (stating that mandatory education may be required as the REMS program has not been as successful as originally envisioned).

144 *Compare* N.Y. COMP. CODES R. & REGS. tit. 22, § 1200.0 (2017), *with* Michael E. Schatman & Beth D. Darnall, *"Just Saying No" to Mandatory Pain CME: How Important Is Physician Autonomy?*, 14 PAIN MED. 1821 (2013).

145 *See* Liz Forbat et al., *Distance Education Methods Are Useful for Delivering Education to Palliative Caregivers: A Single-Arm Trial of an Education Package (PalliativE Caregivers Education Package)*, PALLIATIVE MED. 1, 6 (June 12, 2017).

146 Alford, *supra* note 118, at 301–02.

Coupled with restricting prescription practices and successful mandatory PDMPs, the practices of medicine that may have caused this opioid disaster can be limited.

II. ROLE OF MEDICAL BOARDS

The opioid drug crisis is not new, but over the years, it has been escalating and the number of related deaths growing more alarming. Or has it? Forty years ago, on August 16, 1977, Elvis Presley died.[147] Codeine was one of the many drugs found in his system; the blood level at autopsy was ten times the therapeutic serum concentration.[148] Among the nine other *prescription* drugs identified at autopsy were: Diazepam (Valium), methaqualone (Quaalude), phenobarbital, ethchlorvynol (Placidyl), and ethinamate (Valmid).[149] Alcohol and illegal controlled substances were not found.[150] The toxicology report opined: "[t]ogether, all this information points to a conclusion that, whatever tolerance the deceased may have acquired to the many drugs found in his system, the strong probability is that these drugs were the major contribution to his demise."[151]

In investigating the source of these prescription drugs, the Tennessee Board of Medical Examiners learned that the principal prescriber was George C. ("Dr. Nick") Nichopoulos, MD.[152] In the days before electronic medical records, pharmacy patient medication profiles, and online PDMPs, methodical drug inventory investigations were arduous and time-consuming. In this case, medical board investigators had to look at individual prescription files at separate pharmacies located relatively close to the prescriber and the patient. It was reported that the investigation team, with two secretaries, visited 153 pharmacies and were on site about 1100 hours reviewing over 6.5 million prescriptions.[153]

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[147] Forest Tennant, *Elvis Presley: Head Trauma, Autoimmunity, Pain, and Early Death*, 13 PRAC. PAIN MGMT. 44, 45 (June 2013).

[148] *Id.* at 46.

[149] *Id.*

[150] J.D. ROCKEFELLER, THE MYSTERIES SURROUNDING THE DEATH OF ELVIS PRESLEY 10 (2016).

[151] Tennant, *supra* note 147, at 46.

[152] JOEL WILLIAMSON, ELVIS PRESLEY: A SOUTHERN LIFE (2014), *as reprinted in* Joel Williamson, *The Elvis Presley Coverup: What America Didn't Hear about the Death of the King*, SALON (Nov. 16, 2014), https://www.salon.com/2014/11/16/the_elvis_presley_coverup_what_america_didnt_hear_about_the_death_of_the_king.

[153] *Id.*

For the six months preceding Presley's death, January 1, 1977 through August 16, 1977, they learned that Dr. Nichopoulos wrote prescriptions for over 8800 dosage units—capsules, tablets, and injectable vials—of uppers, downers, and opioids, including the powerful narcotics Dilaudid, Percodan, and Demerol.[154] During this period, a single pharmacy, located just across the street from Dr. Nichopoulos' primary Memphis office, and one pharmacist—Jack Kirsch, DPh—dispensed more than 5600 controlled substances doses (sedatives, stimulants, and narcotics), all in Elvis Presley's name.[155] Both Drs. Kirsch and Nichopoulos were disciplined by their respective licensing boards.[156] The pharmacy board revoked Dr. Kirsch's pharmacist license; the medical board suspended Dr. Nichopoulos' medical license for the Presley case violations, and later revoked his license for other offenses involving controlled substances.[157]

As the Presley case illustrates, state medical and pharmacy boards have for many years had the regulatory responsibility and authority to discipline physicians and pharmacists when they act incompetently or unprofessionally with respect to opioid prescribing. Medical and pharmacy boards exist to assure that licensees are competent and act in a professional manner with patients.[158] In one study, the most frequent causes for disciplinary action were: (1) incompetency or negligence (thirty-four percent); (2) licensee abuse of alcohol or drugs (fourteen percent); and (3) inappropriate prescribing practices (eleven percent).[159] Perhaps state boards should not only use their "bully pulpits" more often, but also wield their "big stick" more frequently, particularly since they are already engaged in disciplinary actions for incompetency and inappropriate prescribing to the extent that they are.

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[154] *See* BRUCE D. WHITE, DRUGS, ETHICS, AND QUALITY OF LIFE: CASES AND MATERIALS ON ETHICAL, LEGAL, AND PUBLIC POLICY DILEMMAS IN MEDICINE AND PHARMACY PRACTICE 100 (2008).

[155] *See id.*

[156] *Id.*

[157] *George Nichopoulos, Elvis's doctor - obituary*, DAILY TELEGRAPH (Mar. 2, 2016), http://www.telegraph.co.uk/news/obituaries/12178962/George-Nichopoulos-Elviss-doctor-obituary.html.

[158] *See* COMM. ON THE HEALTH PROFESSIONS EDUC. SUMMIT, HEALTH PROFESSION EDUCATION: A BRIDGE TO QUALITY 98 (Ann C. Greiner & Elisa Knebel eds., 2003), https://www.ncbi.nlm.nih.gov/books/NBK221528/pdf/Bookshelf_NBK221528.pdf.

[159] James Morrison & Peter Wickersham, *Physicians Disciplined by a State Medical Board*, 279 J. AM. MED. ASS'N 1889, 1889 (1998).

Administrative proceedings undertaken by the medical and pharmacy boards to show that practitioners have engaged in incompetent or unprofessional acts are often lengthy and sometimes difficult. To discipline or sanction a licensee, the board must conclude, based on a preponderance of the evidence presented at a hearing by an attorney in support of the charges and other evidence permitted under New York Public Health Law § 230, that the licensee failed to meet a standard in practice.[160] For incompetency or inappropriate prescribing, most likely the prosecution must establish the standard by expert testimony. The expert witness called to testify about the standard will probably attempt to establish currently accepted medical practices as evidenced by commonly used guidelines[161] and best practices as reported in the literature.[162]

Perhaps as other efforts are attempted—such as requiring mandatory continuing education on optimal opioid prescribing and patient safety, improving PDMPs and techniques, and further restricting prescribers—state medical and pharmacy boards should step up surveillance and enforcement. Failure to complete education or even having a suspicious PDMP report might be evidence of incompetency. *Lewis v. Superior Court* case is one example of how the medical board might use reports and go beyond the initial compliant to discover negligent and unprofessional practices.[163] Another technique that boards could use would be mandatory review of providers who are flagged in these PDMPs. [164] All of these possibilities might help medical boards effectively use the power they already have to change and monitor the practice of medicine.

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160 N.Y PUB. HEALTH LAW § 230 (10)(f). *See also* Mayer v. Novello, 757 N.Y.S.2d 143, 145 (App. Div. 2003).

161 *See* Deborah Dowell, Tamara M. Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 MORBIDITY & MORTALITY WKLY. REP. 1, 1 (2016).

162 *See* Amy S. B. Bohnert et al., *Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths*, 305 JAMA 1315 (2011); Anuj Shah et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use - United States, 2006-2015*, 66 MORBIDITY & MORTALITY WKLY. REP. 265 (2017).

163 *See* Lewis v. Superior Court, 3 Cal. 5th 561, 567–68 (2017).

164 *See* Deborah Dowell et al., *Mandatory Provider Review and Pain Clinic Laws Reduce the Amounts of Opioids Prescribed and Overdose Death Rates*, 35 HEALTH AFF. 1876, 1881 (2016) (mentioning "previous analyses" link mandated PDMP review to reductions in opioid prescription rates).

III. CONCLUSION

The United States has only four percent of the world's population and yet it consumes approximately eighty percent of the world's narcotics.[165] Is it reasonable to assume that the pain in the United States is that vastly different from the rest of the world to require so many opioids? As stated in the *New England Journal of Medicine*:

> In this setting, the combination of aggressive marketing of prescription opioids by manufacturers, promotion by marquee professors, and endorsement by pain societies contributed to a cultural transformation. The long-standing convention of trying to avoid opioids for chronic pain gave way to a new culture in which the drugs were favored for chronic noncancer pain, despite a lack of evidence to support their use.[166]

The medical boards need to take responsibility for their role in helping change the status quo. They have the power to correct incompetent practices and should do so. The public is eager for action. Physicians and their professional organizations should take a leadership role. Medical boards are central to enhancing the public's positive perception of medicine's role in this crisis. Medical boards have the responsibility as stated in the *Dr. Lewis* case, to "[protect] the public from the unlawful use and diversion of a particularly dangerous class of prescription drugs and protecting patients from negligent or incompetent physicians."[167]

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165 Dina Gusovsky, *Americans Consume Vast Majority of the World's Opioids*, CNBC (Apr. 27, 2016, 9:13 AM), https://www.cnbc.com/2016/04/27/americans-consume-almost-all-of-the-global-opioid-supply.html. *See also* Michael Zennie, *Americans Consume Eighty Percent of the World's Pain Pills as Prescription Drug Abuse Epidemic Explodes*, DAILY MAIL (May 10, 2012, 12:15 PM), http://www.dailymail.co.uk/news/article-2142481/Americans-consume-80-percent-worlds-pain-pills-prescription-drug-abuse-epidemic-explodes.html.

166 Bruce M. Psaty & Joseph O. Merrill, *Addressing the Opioid Epidemic – Opportunities in the Postmarketing Setting*, 376 NEW ENG. J. MED. 1502, 1502 (2017).

167 *Lewis*, 3 Cal. 5th at 572.