

Medical Marijuana Legislation: What We Know - and Don't

Linda Simoni-Wastila

Francis B. Palumbo

Follow this and additional works at: <http://digitalcommons.law.umaryland.edu/jhclp>

 Part of the [Chemicals and Drugs Commons](#), [Health Law Commons](#), [Medicinal and Pharmaceutical Chemistry Commons](#), and the [Public Health Commons](#)

Recommended Citation

Linda Simoni-Wastila, & Francis B. Palumbo, *Medical Marijuana Legislation: What We Know - and Don't*, 16 J. Health Care L. & Pol'y 59 (2013).

Available at: <http://digitalcommons.law.umaryland.edu/jhclp/vol16/iss1/4>

This Conference is brought to you for free and open access by DigitalCommons@UM Carey Law. It has been accepted for inclusion in Journal of Health Care Law and Policy by an authorized administrator of DigitalCommons@UM Carey Law. For more information, please contact smccarty@law.umaryland.edu.

MEDICAL MARIJUANA LEGISLATION: WHAT WE KNOW— AND DON'T

LINDA SIMONI-WASTILA*

FRANCIS B. PALUMBO**

I. INTRODUCTION

The use of marijuana as a medicinal agent available to individuals suffering from pain, glaucoma, wasting syndromes associated with HIV and AIDS, nausea from chemotherapy, and a host of other medical conditions and symptoms has become more widely accepted.¹ Over the past decade, eighteen states and the District of Columbia have adopted medical marijuana legislation (MML) that allows citizens to register, cultivate, and/or otherwise procure marijuana for personal medical use.² Additionally, the Maryland Legislature has passed a bill that, if signed by the Governor, would provide for distribution of medical

Copyright © 2013 by Linda Simoni-Wastila & Francis B. Palumbo.

* Linda Simoni-Wastila, BSPHarm, MSPH, PhD, is a professor and Vice Chair of Research at the University of Maryland School of Pharmacy, Department of Pharmaceutical Health Services Research. I thank my former graduate student Dr. Jingjing Qian for assistance in literature review in earlier work.

** Francis B. Palumbo, PhD, JD, is Professor of Pharmaceutical Health Services Research and Executive Director, Center on Drugs and Public Policy, University of Maryland School of Pharmacy.

1. See, e.g., JANET E. JOY ET AL., MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE 22–24 (1999) (listing different disorders treated with marijuana at two California Cannabis Cultivators Clubs); Sunil K. Aggarwal et al., *Medicinal Use of Cannabis in the United States: Historical Perspectives, Current Trends, and Future Directions*, 5 J. OPIOID MGMT. 153, 156 (2009) (explaining that studies show the therapeutic potential of cannabinoids).

2. Alaska, Arizona, California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Maine, Massachusetts, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, and Washington have all adopted MML. ALASKA STAT. § 17.37 (2010); ARIZ. REV. STAT. ANN. §§ 36-2801–19 (Supp. 2012); CAL. HEALTH & SAFETY CODE § 11362.5 (West 2007), § 11362.7–9; COLO. CONST. art. XVIII, § 14; COLO. REV. STAT. ANN. §§ 12-43.3-101–106 (West 2012), § 18-18-406.3 (West 2012), § 25-1.5-106 (West 2012); 2012 Conn. Acts 55 (Reg. Sess.); DEL. CODE ANN. tit. 16, §§ 4901a–4926a (2011); D.C. CODE §§ 7-1671 (Supp. 2012); HAW. REV. STAT. ANN. §§ 329-121–128 (LexisNexis 2008 & Supp. 2011); ME. REV. STAT. ANN. tit. 22, §§ 2421–2430-B (Supp. 2011); 2012 Mass. Legis. Serv. 369 (West); MICH. COMP. LAWS ANN. §§ 333.26421–.26430 (West Supp. 2012); MONT. CODE ANN. §§ 50-46-301–344 (2011); NEV. CONST. art IV, § 38; NEV. REV. STAT. ANN. §§ 453A.010–810 (LexisNexis Supp. 2011); N.J. STAT. ANN. §§ 24:6I-1–16 (West Supp. 2012); N.M. STAT. ANN. §§ 26-2B-1–7 (LexisNexis Supp. 2011); OR. REV. STAT. ANN. §§ 475.300–.346 (2011); R.I. GEN. LAWS §§ 21-28.6-1–12 (2011); VT. STAT. ANN. tit. 18, §§ 4472–741 (LexisNexis Supp. 2012); WASH. REV. CODE ANN. §§ 69.51A.005–.903 (West 2012).

marijuana through academic medical centers,³ The popularity of medical marijuana legislation continues, with an additional eleven states considering ballot initiatives.⁴

In response to the widespread acceptance of marijuana as a medical aide and the subsequent adoption of MML, a 2009 American Medical Association Council on Science and Public Health Report noted that the patchwork of state-based systems that have been established for medical marijuana is “woefully inadequate” to establish even rudimentary safeguards including patient information handouts that normally would be applied to the appropriate clinical use of psychoactive substances.⁵ The unwieldy patchwork of varying MML is negatively compounded by the lack of research on both utilization and health outcomes, as well as patterns or emerging trends in state with such legislation or regulations.⁶ Even basic information, such as the number of patients who use marijuana in states that have removed state-level penalties, has not been clearly established.⁷ To date, research relating to medical marijuana has focused on the historical use of cannabis as medicine,⁸ current scientific and medical understanding of marijuana’s role in human health,⁹ and the safety and efficacy of medical marijuana.¹⁰ Even clinical research is hampered by the reluctance of federal funders to sponsor such research, as well as the difficulty in obtaining government-approved strains for research purposes.¹¹ From a policy perspective, there remains a paucity of research evaluating the efficacy of decriminalization

3. H.B. 1101, 433rd Leg., 1st Sess. (Md. 2013).

4. PROCON.ORG, 11 States with Pending Legislation to Legalize Medical Marijuana. <http://medicalmarijuana.procon.org/view.resource.php?resourceID=002481> (last modified March 6, 2013) (Noting that as of March 2013, Alabama, Florida, Illinois, Iowa, Kansas, Kentucky, Maryland, Missouri, New Hampshire, New York, and West Virginia all have pending legislation proposing to legalize Medical Marijuana).

5. COUNCIL ON SCI. & PUB. HEALTH, AM. MED. ASS’N, REPORT NO. 3, USE OF CANNABIS FOR MEDICINAL PURPOSES 15 (2009).

6. *Id.*

7. *Id.* at 6.

8. See JOY ET AL., *supra* note 1, at 19 (noting marijuana’s use as an herbal remedy before the 20th century); Aggarwal et al., *supra* note 1, at 157 (calling the medicinal use of marijuana a “rediscovery” rather than “a novel medical practice”).

9. See AM. COLL. OF PHYSICIANS, SUPPORTING RESEARCH INTO THE THERAPEUTIC ROLE OF MARIJUANA 5, 9 (2008) (noting that side effects, methods of administration, and the availability of alternatives are all factors used to assess the medicinal value of marijuana); see also Mohamed Ben Amar, *Cannabinoids in Medicine: A Review of their Therapeutic Potential*, 105 J. ETHNOPHARMACOLOGY 1, 3 (2006) (describing various adverse effects of medical marijuana on certain illnesses).

10. See Sean M. Bagshaw & Neil A. Hagen, *Medical Efficacy of Cannabinoids and Marijuana: A Comprehensive Review of the Literature*, 18 J. PALLIATIVE CARE 111, 111 (2002) (noting that scientific data on the safety and efficacy of medical marijuana is currently “inconclusive”); Tongtong Wang et al., *Adverse Effects of Medical Cannabinoids: A Systematic Review*, 178 CAN. MED. ASS’N J. 1669, 1671 (2008) (stating that published randomized controlled trials suggest the efficacy of medical marijuana).

11. See Gardiner Harris, *Researchers Find Study of Medical Marijuana Discouraged*, N.Y. TIMES, Jan. 19, 2010, at A14 (describing how the federal government has stalled efforts to conduct marijuana research).

efforts in states and other jurisdictions.¹² Indeed, the general lack of knowledge of the impact of MML on use and consequences presents a critical barrier to designing state laws and regulations optimal for balancing treatment with desired social and public health outcomes. The purpose of this paper is twofold: 1) to review the state of knowledge regarding key policy and legal aspects of MML;¹³ and 2) to offer potential frameworks for implementing and/or evaluating MML.¹⁴ In Part II, the current knowledge, or lack thereof, of important components of health outcomes and policies is discussed. These key knowledge gaps exist in a) social and health outcomes,¹⁵ b) means of data collection,¹⁶ c) medical boards' reaction to MML,¹⁷ and d) dispensary models and their successes).¹⁸ In Part III, we address potential models for addressing these gaps and implementing solutions.

II. MEDICAL MARIJUANA AND STATE LEGISLATION: WHAT WE KNOW AND WHAT WE DO NOT

A. Little research has studied differences in social and public health outcomes based on variations in state and jurisdictional Medical Marijuana Legislation

Despite the growing adoption of MML, little is known about the influence of MML on consumption of marijuana, consumption of other controlled substances or alcohol, and consequent health outcomes. The few studies conducted to date present mixed and/or inconclusive findings, with some analyses finding MML increases recreational demand¹⁹ and others noting inconclusive evidence of such an effect.²⁰ Some organizations argue that as medical marijuana becomes more

12. See Diane E. Hoffmann & Ellen Weber, *Medical Marijuana and the Law*, 362 NEW ENG. J. MED. 1453, 1456 (2010) (citing a lack of research as contributing to a lack of consistency in state medical marijuana laws).

13. See *infra* Part II.

14. See *infra* Part III.

15. See *infra* Part II.A.

16. See *infra* Part II.B.

17. See *infra* Part II.C.

18. See *infra* Part II.D.

19. See Jerald G. Bachman et al., *Explaining Recent Increases in Students' Marijuana Use: Impacts of Perceived Risks and Disapproval, 1976 through 1996*, 88 AM. J. PUB. HEALTH 887, 889 (1998) (acknowledging that recent increases in marijuana use may be attributable to declines in disapproval and perceptions of potential risk); Rosalie Liccardo Pacula et al., *Marijuana and Youth, in RISKY BEHAVIOR AMONG YOUTHS: AN ECONOMIC ANALYSIS* 271, 274–75 (Jonathan Gruber ed., 2001) (offering several explanations for fluctuations in recreational demand of marijuana such as perceived harm and marijuana availability).

20. See Dennis M. Gorman & J. Charles Huber Jr., *Do Medical Cannabis Laws Encourage Cannabis Use?*, 18 INT'L J. DRUG POL'Y 160, 164, 166 (2007) (finding no affirmative evidence that medical marijuana laws increase use of the drug); D. MARK ANDERSON & DANIEL I. REES, INST. FOR THE STUDY OF LABOR, DISCUSSION PAPER NO. 6112, MEDICAL MARIJUANA LAWS, TRAFFIC FATALITIES, AND ALCOHOL CONSUMPTION 6 (2011) (explaining that MML does not necessarily increase marijuana use, but may convert illicit users to becoming card-carrying patients).

normative, the reduction in perceived risk will spill over into the use of recreational marijuana.²¹ Indeed, the proportion of youth aged twelve to seventeen who perceived great risk of smoking marijuana once a week declined from 54.6% in 2007 to 44.8% in 2011.²² A recent study using the 1999–2008 National Survey on Drug Use and Health (NSDUH) found MML passage associated with decreased perceived risk of marijuana’s abuse potential.²³

The effect of marijuana on driving functions is unclear. Marijuana has been associated with impaired driving functions,²⁴ but there also is evidence that such impairments do not lead to increased risk of collision.²⁵ Although no evidence links the use of medical marijuana to impaired driving, a small body of literature suggests states with MML experience reductions in alcohol use and, consequently, alcohol-related fatalities, because increased use of medical and illicit marijuana serve as alcohol substitutes.²⁶ That is, while alcohol has a well-accepted negative impact on driving function, marijuana’s impact remains less clear. Indeed, analysis of Fatal Accident Reporting System (FARS) data suggests states with MML have experienced an 8.7% reduction in total fatal accidents and a 12.0% reduction in alcohol-related fatalities.²⁷ The authors surmise their findings are due to: 1) increased use of marijuana (medical and illicit) in MML states (i.e., the substitution effect);²⁸ 2) reduced consumption of alcohol by marijuana users;²⁹ and 3) an increased tendency of marijuana users to use the substance in the privacy of their homes, thereby reducing the risk of fatalities by reducing their exposure to impaired driving.³⁰

21. See *Effects of Medical Marijuana Legalization*, COMMUNITY ANTI-DRUG COALITIONS AM., 1, http://www.cadca.org/files/policy_priorities/effectsmedicalmarijuana.pdf (last visited Apr. 1, 2013) (arguing that legalization of medical marijuana leads to decreases in perceived harm and increases in drug use).

22. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., RESULTS FROM THE 2011 NATIONAL SURVEY ON DRUG USE AND HEALTH 5 (2012).

23. See ANDERSON & REES, *supra* note 20, at 9 (finding that medical marijuana legalization in Vermont and Rhode Island led to increased use among youth between eighteen and twenty-five years old in those states).

24. See generally R. Andrew Sewell et al., *The Effect of Cannabis Compared with Alcohol on Driving*, 18 AM. J. ON ADDICTIONS 185, 187 (2009).

25. See *id.* at 186; Erin Kelly et al., *A Review of Drug Use and Driving: Epidemiology, Impairment, Risk Factors and Risk Perceptions*, 23 DRUG & ALCOHOL REV. 319, 326 (2004).

26. See ANDERSON & REES, *supra* note 20, at 6 (citing a study concluding that marijuana and alcohol are substitutes, and another finding they were complements). See generally Frank J. Chaloupka & Adit Laixuthai, *Do Youths Substitute Alcohol and Marijuana? Some Economic Evidence*, 23 E. ECON. J. 253 (2011) (discussing the effects of marijuana legislation on rates of youth alcohol abuse); John DiNardo & Thomas Lemieux, *Alcohol, Marijuana, and American Youth: The Unintended Consequences of Government Regulation*, 20 J. HEALTH ECON. 991, 1005 (2001) (finding that marijuana and alcohol are substitutes).

27. ANDERSON & REES, *supra* note 20, at 13–14.

28. *Id.* at 13.

29. *Id.* at 42 tbl.14 (illustrating a decrease in alcohol sales after legalization of medical marijuana).

30. *Id.* at 21.

B. Data Limitations

Evaluation of MML is hampered mostly by lack of data. There is no single available dataset that allows thorough examination of medical marijuana legislation and its influence on social and public health outcomes.³¹ Indeed, there are no data routinely collected on medical marijuana use across the nation or within states with MML.³² An ideal database would allow analyses of medical marijuana policy on medical, social, criminal, and public health-relevant outcomes at the individual level; however, due to privacy and cost constraints, such person-level data are prohibitively expensive to collect and analyze.³³

Because medical marijuana is not reimbursable under public or private insurance programs, administrative health claims data are useless.³⁴ Data collected by law enforcement do not discriminate between marijuana used for medicinal or recreational purposes.³⁵ Similarly, data collected in national surveys, such as the NSDUH and Monitoring the Future, only capture information on marijuana use and perceptions or risk, but not the reason for use.³⁶ Thus, researchers cannot currently determine the prevalence of medical marijuana use for medical indications, nor examine the efficacy of medical marijuana and its impact on important public health and economic outcomes.³⁷

31. *See id.* at 20.

32. *See id.* at 7–8 (discussing drawbacks to available data on marijuana use in states, including states that have passed MML).

33. *See* Lisa N. Pealer et al., *The Feasibility of a Web-Based Surveillance System to Collect Health Risk Behavior Data from College Students*, 28 HEALTH EDUC. & BEHAV. 547, 548 (discussing the difficulties methodological problems posed by traditional personal survey methods).

34. *See* Jeremy Smerd, *Marijuana Reimbursement Claims Highlight How Pot Could be Gold for Employers*, WORKFORCE (Sept. 7, 2011), <http://www.workforce.com/article/20090714/NEWS02/307149995/marijuana-reimbursement-claims-highlight-how-pot-could-be-gold-for-employers#> (noting that health insurance companies do not reimburse patients for drugs, such as medical marijuana, that are not FDA-approved).

35. *See, e.g.*, FED. BUREAU OF INVESTIGATION, U.S. DEP'T OF JUSTICE, *Arrests, CRIME IN THE UNITED STATES*, <http://www.fbi.gov/about-us/cjis/ucr/crime-in-the-u.s/2010/crime-in-the-u.s.-2010/persons-arrested> (follow "Download Arrest Table Excel" hyperlink) (last visited Apr. 1, 2013) (failing to distinguish between marijuana possession arrests for medicinal and recreational use).

36. *See generally* SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 22, at 1 (noting that marijuana was considered an illicit drug for the purposes of the survey without distinguishing the purpose of its use); LLOYD D. JOHNSTON ET AL., U.S. DEP'T OF HEALTH & HUMAN SERVS., NATIONAL SURVEY RESULTS ON DRUG USE FROM THE MONITORING THE FUTURE STUDY, 1975–1997 6 (1998) (noting that marijuana use increased among secondary school students without specifying the purpose of that use).

37. *See generally* Paul Armentano, *Behind the Lack of Medical Marijuana Research: Feds Disallowing Initiatives*, HUFFPOST POLITICS: THE BLOG (Jan. 28, 2010, 2:21 PM), http://www.huffingtonpost.com/paul-armentano/behind-the-lack-of-medica_b_439415.html (explaining that the federal government must approve all clinical and preclinical research of marijuana, but thus far, only funds research on the negative impacts of marijuana use).

C. No research exists on the reaction of state medical boards to decriminalization statutes

To date, no research has been conducted that examines the actions of state medical boards in jurisdictions that have decriminalized medical marijuana.³⁸ This lack of knowledge regarding medical board practices, guidelines, policies, and standards of care relating to physicians who recommend medical marijuana creates a vacuum in understanding the role that medical boards can, and possibly should, play in ensuring that physicians recommend medical marijuana appropriately. In their role as the entities that license and discipline physicians within a state, state medical boards influence physician behavior by selecting which cases to investigate and prosecute.³⁹ Medical boards also have the authority to issue guidance or recommendations to update physicians about state law, assist physicians in their practice, or warn against certain practices.⁴⁰ Without such research, however, it is difficult to know what effect MML actually has on doctors' prescription habits and practices.

D. The significance of differing laws relating to marijuana dispensaries is unknown

Some MML authorizes the creation of a system of licensed dispensaries to distribute marijuana.⁴¹ Dispensaries are not licensed pharmacies that operate under the control of state boards of pharmacy, although apparently in California the state board of pharmacy has been given the responsibility of inspecting dispensaries.⁴² A licensed pharmacy would need a DEA permit to dispense controlled substances and DEA would not issue a permit to a pharmacy to distribute medical marijuana.⁴³ Dispensaries are a relatively novel concept and not comparable to other health care delivery centers.⁴⁴ There are few guidelines regarding how best to run a dispensary,

38. See ANDERSON & REES, *supra* note 20, at 19 (commenting on the lack of research on the impact of state MML).

39. See, e.g., CAL. BUS. & PROF. CODE § 2220 (2013) (authorizing the California medical board to enforce the provisions within the chapter against physicians and surgeons); *Medical Marijuana*, THE MED. BD. CAL., http://www.mbc.ca.gov/medical_marijuana.html (last visited Apr. 1, 2013) (providing the California Medical Board's recommendations on points for physicians to consider before recommending medical marijuana in order to avoid disciplinary action).

40. See generally Drew Carlson & James N. Thompson, *The Role of State Medical Boards*, 7 VIRTUAL ETHICS 1 (2005), <http://virtualmentor.ama-assn.org/2005/04/pdf/pfor1-0504.pdf> (discussing the role of state medical boards and how they are responsible for establishing standards and guidelines for physicians).

41. See Hoffmann & Weber, *supra* note 12, at 1456 tbl.2 (listing states that have enacted MML that allow for establishment of dispensaries in various forms).

42. CAL. BD. OF PHARMACY, 2013 LAWBOOK FOR PHARMACY 14 (2009).

43. 21 U.S.C. § 822 (1999).

44. See generally LEIYU SHI & DOUGLAS A. SINGH, ESSENTIALS OF THE U.S. HEALTH CARE SYSTEM 24 (2d ed. 2010) (describing the various subsystems that provide the framework for health care delivery in the United States).

although private citizens and organizations have promulgated some best practice guidelines.⁴⁵ To date, no research has compared or contrasted the practices and characteristics of dispensaries in different states, although there is one study of dispensary policies within California.⁴⁶

While a handful of studies compare and contrast different MML,⁴⁷ no attempt has been made to analyze the components of the different legal frameworks in order to place them on a continuum so that the impact of different legal structures can be compared against specific outcome measures.⁴⁸ In Part III, potential models for gathering information on differing policies and outcomes are proposed.

III. POTENTIAL MODELS: DISPENSARIES, REMS, AND PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

While each state's MML is designed to meet similar goals, the laws vary in many important ways, including limits on the quantity of marijuana that may be possessed or cultivated,⁴⁹ authorization to sell marijuana through dispensaries,⁵⁰ regulation of dispensaries,⁵¹ approved conditions of use,⁵² regulation of use,⁵³

45. See, e.g., Eric Markowitz, *How to Open a Medical Marijuana Dispensary*, INC. (May 27, 2011), <http://www.inc.com/guides/201105/how-to-open-a-medical-marijuana-dispensary.html> (offering insight on expected costs and revenues to opening a medical marijuana dispensary).

46. NANCY J. WILLIAMS, ET AL., CAL. CTR. FOR POPULATION RESEARCH, *EVALUATING MEDICAL MARIJUANA DISPENSARY POLICIES: SPATIAL METHODS FOR THE STUDY OF ENVIRONMENTALLY-BASED INTERVENTIONS* (2011).

47. See Robert MacCoun & Peter Reuter, Keynote Address at the Michigan State University Journal of Medicine & Law Symposium: Exploring Drug Depenalization: The Next Step After Proposal 1 (Apr. 10, 2009) (distinguishing Michigan's medical marijuana law from California's law); Hoffmann & Weber, *supra* note 12, at 1453–56 (discussing variations in state medical marijuana laws, including differences in covered medical conditions and allowable quantities).

48. See *infra* Part III (discussing potential models to accomplish this goal).

49. See *18 Legal Medical Marijuana States and DC: Laws, Fees, and Possession Limits*, PROCON, <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881> (last updated Feb. 22, 2013, 5:21 PM) (comparing medical marijuana state laws in terms of the year passed, fee, and possession limit); Hoffmann & Weber, *supra* note 12, at 1454, 1456 tbl.2 (reporting that most states regulate the amount of marijuana that patients or caretakers may possess and giving examples of variations in state amount requirements).

50. See Hoffmann & Weber, *supra* note 12, at 1456 tbl.2 (demonstrating that while California, Maine, Rhode Island, and New Jersey allow marijuana dispensaries, other states including Alaska, Oregon, and Washington do not).

51. See *id.* at 1454 (reporting that most state laws do not have specific provisions regulating dispensaries, whereas California allows dispensing of medical marijuana through cooperatives or collectives).

52. See *id.* at 1454, 1455 tbl.1 (reporting that different states allow use of medical marijuana for different diseases and conditions; for instance, Michigan and Rhode Island allow marijuana use for Hepatitis C while California and New Jersey do not allow such use).

53. Compare CAL. HEALTH & SAFETY CODE § 11362.79 (West 2007 & Supp. 2013) (providing that California prohibits a qualified patient from smoking medical marijuana in certain places including where smoking is illegal, in or within 1,000 feet of school, or on a school bus), with ALASKA STAT. § 17.37.040 (2012) (noting that in Alaska, medical use of marijuana is prohibited in any place of

including location of use, responsibilities of physicians (e.g., whether alternative treatment was attempted),⁵⁴ regulation of caregivers,⁵⁵ ability of local governments to set additional controls on cultivation and distribution,⁵⁶ establishment of registries,⁵⁷ and whether qualified users are protected from arrest and/or prosecution.⁵⁸ In broader terms, MML creates legal frameworks that vary in the balance each jurisdiction creates between access and restrictiveness.

A. The Role of Dispensaries: A New Kind of Pharmacy?

Marijuana, including medical marijuana, is a Schedule I controlled dangerous substance.⁵⁹ As such, its possession and/or use in the United States is illegal.⁶⁰ As far as the federal government, through the Drug Enforcement Administration (DEA) is concerned, it has no acceptable medical use, thus maintaining marijuana's Schedule I status.⁶¹ Residents in states with medical marijuana decriminalization statutes cannot use the U.S. Constitution, principally the Commerce Clause, as a shield.⁶² In 2009, the Department of Justice issued a memorandum to U.S. Attorneys that federal resources should not be used to prosecute people whose actions are in compliance with state laws

employment, in any medical facility monitored by the department or the Department of Administration, on or within 500 feet of school grounds, or on a school bus).

54. See MARIJUANA POLICY PROJECT, STATE-BY-STATE MEDICAL MARIJUANA LAWS: HOW TO REMOVE THE TREAT OF ARREST app. H (2011), available at <http://www.mpp.org/assets/pdfs/library/State-by-State-Laws-Report-2011.pdf> (noting that when physicians issue a recommendation or certification to patients authorizing use of medical marijuana, some states require that physicians discuss the risks and benefits of medical marijuana use and to include in the certification that the patient has an approved condition).

55. Compare CAL. HEALTH & SAFETY CODE § 11362.7(e) (West 2007 & Supp. 2013) (requiring a primary caregiver to be at least 18 years old in California), with ALASKA STAT. § 17.37.010(d) (2012) (requiring a primary caregiver in Alaska to be at least 21 years old).

56. Compare CAL. HEALTH & SAFETY CODE § 11362.83 (West 2007 & Supp. 2013) (allowing cities or local counties in California to enact other laws consistent with the state medical marijuana law), with ALASKA STAT. §§ 17.37.010–080 (2012) (providing no provisions giving local governments authority to enact additional controls).

57. See Hoffmann & Weber, *supra* note 12, at 1454, 1456 tbl.2.

58. See *id.*

59. *Controlled Substances*, U.S. Dep't of Justice, 3 (Sept. 6, 2012), http://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf.

60. See *id.* See also Marsha N. Cohen, *Breaking the Federal/State Impasse Over Medical Marijuana: A Proposal*, 11 *Hastings Women's L.J.* 59, 60–61 (2000) (discussing the prohibition of use and possession of Schedule I controlled substances).

61. See OFFICE OF DIVERSION CONTROL, *Controlled Substance Schedules*, U.S. DEP'T OF JUSTICE, <http://www.deadiversion.usdoj.gov/schedules/> (last visited Apr. 1, 2013) (noting that marijuana, as a Schedule I Controlled Substance, has no accepted medical use and a high likelihood for abuse).

62. See *Gonzales v. Raich*, 545 U.S. 1, 22 (2005) (holding that application of the Controlled Substance Act to intrastate growers and users of medical marijuana was within Congress's Commerce Clause powers, meaning it cannot be used as a shield to prevent criminal liability for marijuana manufacturing).

providing for use of medical marijuana.⁶³ It is important to note that this memorandum did not change the law, was not binding on the U.S. Attorneys, and that the Administration could easily reverse its position.⁶⁴

In fact, despite the policy stated above, there appears to be a lessening of the federal tolerance for medical marijuana at least as it relates to dispensaries. A number of states allow these dispensaries, California having the largest number, but dispensaries were not necessarily included in the federal government's tolerance of state medical marijuana decriminalization laws.⁶⁵ In October 2011, California's four U.S. Attorneys, including Sacramento's U.S. Attorney, held a press conference to announce the federal government's intention to crack down on medical marijuana dispensaries.⁶⁶ The federal government sent out letters to dispensaries and their landlords in San Francisco, San Diego, and Marin County that dispensaries were in violation of federal law.⁶⁷ The letters instructed the landlords to evict their dispensary tenants.⁶⁸ They also directed the dispensaries to close up shop within forty-five days; otherwise, both the dispensary owners and the landlords would be arrested and prosecuted.⁶⁹ The government noted that it was focusing only on those dispensaries that were "clearly profiteering" from the medical marijuana industry.⁷⁰ However, by December 2011, in Sacramento, California, ninety-one dispensaries were shut down, leaving only eight.⁷¹ In Montana, in March 2011, federal agents raided medical marijuana dispensaries around the state.⁷² More recently, in July 2012, the Department of Justice served Harborside Health Center's property owners with commercial property forfeiture

63. Memorandum from James M. Cole, Deputy Att'y Gen., to U.S. Att'ys (June 29, 2011), available at <http://www.justice.gov/oip/docs/dag-guidance-2011-for-medical-marijuana-use.pdf>.

64. See *id.* (emphasizing that enforcement of the Controlled Substances Act "remains a core priority" and that the Ogden Memo is only meant to guide U.S. Attorneys in exercising their "broad discretion" in prosecuting federal criminal matters).

65. See *id.* (noting that state-authorized dispensaries are not shielded from federal prosecution or enforcement actions).

66. See Peter Hecht, *U.S. Attorneys: Marijuana Dispensaries in California Aren't Legal*, SACRAMENTO BEE, Oct. 7, 2011, <http://blogs.sacbee.com/crime/archives/2011/10/us-attorneys-marijuana-dispensaries-in-california-arent-legal.html> (reporting that federal prosecutors would be bringing criminal complaints and forfeiture actions against numerous California medical marijuana dispensaries).

67. See Alexander Leach, *The Federal Government is Cracking Down on Medical Marijuana*, EXAMINER, Oct. 8, 2011, <http://www.examiner.com/liberal-in-sacramento/the-federal-government-is-cracking-down-on-medical-marijuana>.

68. See *id.*

69. See *id.*

70. See *id.*

71. See Alexander Leach, *Medical Marijuana Dispensaries are Closing Up Shop*, EXAMINER, Dec. 5, 2011, <http://www.examiner.com/article/medical-marijuana-dispensaries-are-closing-up-shop>.

72. See Gwen Florio, *Feds Raid Medical Marijuana Operations in Missoula, Statewide*, MISSOULIAN, Mar. 14, 2011, http://missoulian.com/news/local/feds-raid-medical-marijuana-operations-in-missoula-statewide/article_eae07e58-4e7d-11e0-aa23-001cc4c03286.html.

proceedings because it violates federal law.⁷³ Harborside Health Center serves over 100,000 cannabis patients in two northern California cities.⁷⁴

B. FDA Approval and Risk Evaluation and Mitigation Strategies (REMS)

The use of marijuana for medical purposes is prohibited at the federal level because of the status of marijuana as a Schedule I drug under the Controlled Substances Act.⁷⁵ Thus, unlike other drugs in the United States, medical marijuana has not undergone approval as a new drug by the Food and Drug Administration (FDA) and has not been subject to the same level of rigorous clinical trials that is true for approved drugs.⁷⁶ Nor has marijuana been subject to the establishment of safety standards that FDA may establish for drugs with a profile of side effects or potentially harmful public health effects.⁷⁷

The FDA, for example, has developed Risk Evaluation and Mitigation Strategies (REMS) for prescription opioid analgesics due to growing concerns about their abuse and diversion. Over the past decade, the medical use of opioid analgesics (OAs) have markedly increased, with OA prescriptions rising at twice the rate of non-OA prescriptions.⁷⁸ Parallel increases in OA abuse and diversion have accompanied the rise in medical OA use.⁷⁹ In 2010, 12.2 million United States citizens aged twelve and older reported past-year non-medical use of prescription OAs, a ten percent increase from 2002, making OAs the most abused drugs after marijuana.⁸⁰ Consequences of OA abuse include death from poisoning and

73. See Malia Wollan, *Oakland Files Suit Against U.S. to Prevent Closing of Marijuana Dispensary*, N.Y. TIMES, Oct. 12, 2012, at A18 (reporting that U.S. Attorney Melinda Haag issued a forfeiture notice on two of Harborside's properties).

74. See Carly Schwartz, *Harborside Health Center Community Suffers Under Federal Cannabis Crackdown*, HUFFINGTON POST (Sept. 4, 2012, 4:02 PM), http://www.huffingtonpost.com/2012/09/04/harborside-health-center-_n_1853344.html.

75. See *supra* notes 59–61 and accompanying text.

76. See JOY ET AL., *supra* note 1, at 196 fig.5.1, 202 (displaying the various stages of testing that drugs must undergo before receiving approval for marketing in the United States).

77. See 21 C.F.R. § 201.57(c)(6) (2012) (authorizing FDA to revise a drug's labeling when there is "reasonable evidence of a causal association" between the drug and a potentially harmful health effect).

78. See Bridget M. Kuehn, *Opioid Prescriptions Soar: Increase in Legitimate Use as Well as Abuse*, 297 JAMA 249, 249 (2007) (noting that opioid analgesics are now "among the most prescribed drugs" in the United States and providing evidence of the rise of OA prescriptions).

79. See *id.* at 249–50 (noting a simultaneous rise in legitimate medical OA use and illicit OA abuse); see also SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., RESULTS FROM THE 2007 NATIONAL SURVEY ON DRUG USE AND HEALTH 250 tbl.G.1 (2008) (illustrating the rise in illicit use of prescription pain relievers from 2002 to 2007).

80. Compare SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., RESULTS FROM THE 2002 NATIONAL SURVEY ON DRUG USE AND HEALTH: DETAILED TABLES tbl.1.1A (2005) (finding that 10,992,000 persons aged twelve or older reported past-year non-medical use pain relievers in 2002), with SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., RESULTS FROM THE 2010 NATIONAL SURVEY ON DRUG USE AND HEALTH: DETAILED TABLES tbl.1.54A (2012) (finding that 12,213,000 persons aged twelve or older reported past-year non-medical use pain relievers in 2010).

overdose,⁸¹ increases in an already overburdened treatment system, with non-heroin OA abuse treatment admissions increasing from 22,600 admissions in 1999 to over 142,000 in 2009.⁸² The economic burden of OA abuse and dependence remains substantial, with total societal costs estimated at \$55 billion.⁸³ It would be difficult if not impossible to develop REMS for medical marijuana due in part to the inability to clearly identify the plant a particular individual might be using.⁸⁴ There is obviously no standardization since it is not even acknowledged by the federal government as having an accepted medical use.⁸⁵ That is not to say that a medical body might be able to develop some guidelines for its safe use and publish those in some standard form.

Although FDA-approved products that contain cannabis (e.g., Marinol®) exist, there has been a sustained push for states to decriminalize medical marijuana.⁸⁶ FDA approval of medical marijuana as it currently exists, even if allowed under the federal Food Drug and Cosmetic Act, is impractical—marijuana used for medical purposes is not a single plant variety or strain.⁸⁷ Indeed, it is the variability in plant differences in potency and effects, as well as the flexibility in dosage and administration, that lead many patients to prefer plant-sourced cannabis

81. See Leonard Paulozzi et al., *CDC Grand Rounds: Prescription Drug Overdoses – a U.S. Epidemic*, 61 *Morbidity & Mortality Wkly. Rep.* (Ctrs. for Disease Control & Prevention, Atlanta, Ga.), Jan. 13, 2012, at 10, 10 (commenting that OAs are responsible for an increasing number of unintentional overdose deaths); Margaret Warner et al., *Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999–2006*, 22 *NCHS DATA BRIEF* (Nat'l Ctr. for Health Statistics, Hyattsville, Md.), Sept. 2009, at 1, 1 (finding OA-related deaths are responsible for an increasing percentage of drug poisoning deaths); Leonard Paulozzi et al., *Increasing Deaths from Opioid Analgesics in the United States*, 15 *Pharmacoepidemiology & Drug Safety* 618, 621–22 (2006) (noting that OA poisoning is the most rapidly increasing category of poisoning death of any major drug).

82. Compare CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *1999 Substance Abuse Treatment Admissions by Primary Substance of Abuse According to Sex, Age Group, Race, and Ethnicity*, TREATMENT EPISODE DATA SET, <http://www.dasis.samhsa.gov/webt/quicklink/US99.htm> (last visited Mar. 30, 2013) (citing 22,637 non-heroin OA abuse treatment admissions in 1999), with CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *2009 Substance Abuse Treatment Admissions by Primary Substance of Abuse According to Sex, Age Group, Race, and Ethnicity*, TREATMENT EPISODE DATA SET, <http://www.dasis.samhsa.gov/webt/quicklink/US09.htm> (last visited Apr. 1, 2013) (citing 143,564 non-heroin OA abuse treatment admissions in 2009).

83. Howard Birnbaum et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 *Pain Med.* 657, 661 (2011) (estimating the total societal costs of OA abuse to be 55.7 billion dollars in 2007 and providing a breakdown of those costs).

84. See Shannon L. Datwyler & George D. Weiblen, *Genetic Variation in Hemp and Marijuana (Cannabis sativa L.) According to Amplified Fragment Length Polymorphisms*, 51 *J. FORENSIC SCI.* 371, 371 (2006) (noting the substantial variation in drug content among cannabis plants).

85. See *supra* notes 59–61 and accompanying text.

86. See PROCON, *supra* note 3.

87. See JOY ET AL., *supra* note 1, at 215–16 (outlining the regulatory hurdles medical marijuana cultivators would face in seeking FDA approval even if it were allowed under the Food Drug and Cosmetic Act, such as difficulties meeting the safety and efficacy standards as both a botanical product and as a drug delivered through smoke inhalation).

over Marinol® and other synthetic prescription products.⁸⁸ Cannabis plants have psychoactive properties, produced from the over eighty phenols and flavonoids in the plants; many of these compounds are thought to have medicinal properties.⁸⁹ In particular, cannabis plants produce a unique family of terpenophenolic compounds called cannabinoids.⁹⁰ Two cannabinoids of particular medical utility include Delta-9-tetrahydrocannabinol (THC), which has psychoactive properties, and Cannabidiol (CBD), which does not.⁹¹ Marinol® only includes THC, and does not include cannabidiol or other phenolic or flavonoid compounds.⁹²

Medical marijuana would be a prime candidate for a REM if approved by FDA as a new drug because there would likely be an authorized source such as the University of Mississippi where the plant variety/species would be standardized and appropriate information about its use and potential risks could be developed with some level of confidence.⁹³ Even without FDA-approval, however, states could adapt REMS-like requirements as part of their MML.⁹⁴ To date, no state has implemented such safeguards.⁹⁵

C. Prescription Drug Monitoring Programs

In response to the growing epidemic of prescription drug abuse, states have implemented prescription drug monitoring programs (PDMPs), state-level registries that monitor the prescribing, dispensing, and purchase of prescribed

88. See generally Ernest Small & H.D. Beckstead, *Common Cannabinoid Phenotypes in 350 Stocks of Cannabis*, 36 *Lloydia* 144 (1973) (analyzing variances in content among 350 unique strains of cannabis); Cohen, *supra* note 60, at 71–72 (noting that Marinol® fails to satisfy patient due to its inflexible dosage and administration, adverse side-effects, and high cost).

89. Geraint B. Osborne & Curtis Fogel, *Understanding the Motivations for Recreational Marijuana Use Among Adult Canadians*, 43 *SUBSTANCE USE & MISUSE* 539, 551 (2008).

90. *Id.*

91. See Teresa Iuvone et al., *Neuroprotective Effect of Cannabidiol, a Non-psychoactive Component from Cannabis sativa, on β -amyloid-induced Toxicity in PC12 cells*, 89 *J. NEUROCHEMISTRY* 134, 135 (2004).

92. PAUL ARMENTANO, *NORML, MARINOL VERSUS NATURAL CANNABIS: PROS, CONS AND OPTIONS FOR PATIENTS* 5 (2005), available at http://norml.org/pdf_files/NORML_Marinol_vs_Natural_Cannabis.pdf.

93. See *FDA Partnership*, U. MISS. SCH. PHARMACY, NAT'L CENTER FOR NAT. PRODUCTS RES., <http://www.pharmacy.olemiss.edu/ncnpr/fdapartnership.html> (last visited Apr. 1, 2013) (stating that FDA and the University of Mississippi School of Pharmacy have partnered to develop a research program to specifically study botanical supplements).

94. See *FOOD & DRUG ADMIN., DRAFT GUIDANCE: FORMAT AND CONTENT OF PROPOSED RISK EVALUATION AND MITIGATION STRATEGIES (REMS), REMS ASSESSMENTS, AND PROPOSED REMS MODIFICATIONS* 2 (2009), available at <http://www.fda.gov/downloads/Drugs/Guidances/UCM184128.pdf> (stating that FDA only requires a REMS when it needs to ensure the benefits of a drug outweigh its risks).

95. See *AM. SOC'Y OF ADDICTION MED., PUBLIC POLICY STATEMENT ON MEDICAL MARIJUANA* (2010), available at <http://www.asam.org/docs/public-policy-statements/1medical-marijuana-4-10.pdf?sfvrsn=0> (explaining that even in states that have legalized marijuana, the marijuana is not standardized or subject it to quality controls).

medications categorized as controlled substances.⁹⁶ A PDMP is defined as a “statewide electronic database which collects designated data on substances dispensed in the state.”⁹⁷ This implementation process took many years, as most states have been historically resistant to passing laws where the state itself would have access to a patient’s medical record.⁹⁸ Indeed, this issue of privacy has been a strong objection on the part of those who oppose state laws.⁹⁹

As of 2012, forty-eight states had enacted or authorized a PDMP;¹⁰⁰ and of these, at the time of publication, forty-three are operational.¹⁰¹ Despite widespread adoption, few studies have evaluated PDMP effectiveness in reducing prescription abuse or assessed their impact on patient care and outcomes.¹⁰² State variability in PDMP design, scope, operationalization, and rigor imposes unique challenges in assessing PDMP effectiveness.¹⁰³ Although all PDMPs use electronic technology to collect, transmit, and organize prescription data,¹⁰⁴ three states (New York, California, and Texas) supplement their electronic system with ‘hard copy’ serialized and/or tamper-proof paper forms, a deterrent to prescription alterations and forgeries.¹⁰⁵ Critics of PDMPs contend these forms reduce patient access to

96. See OFFICE OF DIVERSION CONTROL, *State Prescription Drug Monitoring Programs*, U.S. DEP’T OF JUSTICE, http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm (last updated Oct. 2011).

97. *Id.*

98. See KAREN BLUMENSCHIN ET AL., UNIV. OF KY., *REVIEW OF PRESCRIPTION DRUG MONITORING PROGRAMS IN THE UNITED STATES* 3–4 (2010) (recommending that PDMP programs not allow data to be open to the public or subject to open record laws amidst privacy concerns).

99. See, e.g., *California Medical Privacy Fact Sheet C4: Your Prescriptions and Your Privacy*, PRIVACY RIGHTS CLEARINGHOUSE (July 2012), <https://www.privacyrights.org/fs/fsC4/CA-medical-prescription-privacy#prescription-drug-monitoring-program> (stating that PDMPs create privacy concerns by putting users’ information into a database accessible to other people and governmental entities).

100. See *Status of State Prescription Drug Monitoring Programs*, NAT’L ALLIANCE FOR MODEL ST. DRUG LAWS, 2 (July 2, 2012), <http://www.namsdl.org/documents/PMPPProgramStatus07022012.pdf>.

101. *Id.*

102. See Jeanmarie Perrone & Lewis S. Nelson, *Medication Reconciliation for Controlled Substances—An “Ideal” Prescription-Drug Monitoring Program*, 366 NEW ENG. J. MED. 2341, 2341 (2012) (noting the limited amount of research on PDMP effectiveness is a result of differing PDMP designs across states).

103. *Id.*

104. See *id.* (discussing how PDMPs have benefited from technological advancements).

105. See N.Y. STATE DEP’T OF HEALTH, *WHAT EVERY PRACTITIONER NEEDS TO KNOW ABOUT CONTROLLED SUBSTANCE PRESCRIBING* 2 (2009), available at <http://www.health.ny.gov/publications/1477.pdf> (describing the requirement of New York practitioners to keep written records of all prescribed controlled substances); Scott M. Fishman, *Repeal of Triplicate Prescribing and the New Security Paper Prescription Requirement in California*, CSA BULLETIN (Cal. Soc’y of Anesthesiologists, San Mateo, Cal.), Jan.–Mar., 2004, at 2 (stating that California requires the use of tamper-resistant security paper for all controlled drugs prescribed); *Texas Prescription Program*, TEX. DEP’T PUB. SAFETY, http://www.txdps.state.tx.us/RegulatoryServices/prescription_program/prescriptionforms.htm (last visited Apr. 1, 2013) (stating that Texas practitioners use single or multiple copy forms issued by the state to write prescriptions for certain controlled substances).

necessary medications due to the “chilling effect” on prescribers who fear scrutiny of their practices.¹⁰⁶

Since the most comprehensive empiric work evaluating PDMPs was conducted a decade ago on the New York paper-based benzodiazepine PDMP program,¹⁰⁷ only a few single-state¹⁰⁸ and multiple-state¹⁰⁹ analyses have been conducted. This research finds PDMPs are associated with reductions in prescribing of targeted medications. Although one study found PDMP states experienced both lower OA supply and treatment admissions than non-PDMP states,¹¹⁰ another study found PDMPs that communicated with prescribers and pharmacists achieved a ten percent reduction in the use and abuse of monitored prescription drugs.¹¹¹ To date, only one has documented opioid analgesic

106. See, e.g., Jing Wang & Paul J. Christo, *The Influence of Prescription Monitoring Programs on Chronic Pain Management*, 12 PAIN PHYSICIAN 507, 510 (2009) (noting that physicians may under-treat pain in order to avoid investigations by regulatory agencies).

107. In 1989, New York State implemented regulations requiring all benzodiazepines prescriptions to be written on special triplicate prescription forms, a measure that had significant effects on benzodiazepine use. See, e.g., *Benzodiazepines: Additional Effects of The Triplicate Program*, 90 N.Y. ST. J. MED. 273, 273 (1990); *Benzodiazepines: Prescribing Declines Under Triplicate Program*, 90 N.Y. ST. J. MED. 218, 218 (1990); Michael Weintraub et al., *Consequences of The 1989 New York State Triplicate Benzodiazepine Prescription Regulations*, 266 JAMA 2392, 2392 (1991); Sallie-Anne Pearson et al., *Racial Disparities In Access Following Regulatory Surveillance of Benzodiazepines*, 166 ARCHIVES INTERNAL MED. 572, 575 (2006); Anita K. Wagner et al., *Effects of State Surveillance on New Post-Hospitalization Benzodiazepine Use*, 15 INT’L J. QUALITY HEALTH CARE 423, 426 fig.1, 427 (2003).

108. See, e.g., Aaron M. Gilson et al., *Time Series Analysis of California’s Prescription Monitoring Program: Impact On Prescribing And Multiple Provider Episodes*, 13 J. PAIN 103, 104 (2012) (analyzing California’s use of tamper-resistant prescription forms to determine whether forms affected doctors’ prescribing practices for Schedule II opioids); Katherine A. Sigler et al., *Effects of Triplicate Prescription Law On Prescribing of Schedule II Drugs*, 41 AM. J. HOSP. PHARMACY 108, 108 (1984) (studying Texas’ triplicate prescription program’s prescribing patterns for Schedule II substances); Nathaniel Katz et al., *Usefulness of Prescription Monitoring Programs For Surveillance — Analysis of Schedule II Opioid Prescription Data In Massachusetts, 1996–2006*, 19 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 115, 116 (2010) (analyzing Massachusetts’ prescription monitoring program and opioid prescribing and usage trends).

109. See e.g., Leonard J. Paulozzi et al., *Prescription Drug Monitoring Programs And Death Rates From Drug Overdose*, 12 PAIN MED. 747, 749 (2011) (comparing drug overdose mortality rates in states with PDMPs with states without PDMPs); U.S. GEN. ACCOUNTING OFFICE, GAO-02-634, *PRESCRIPTION DRUGS: STATE MONITORING PROGRAMS PROVIDE USEFUL TOOL TO REDUCE DIVERSION* 15 (2002) (reporting the success of PDMP programs in certain states, including Kentucky, Nevada, and Utah); Richard M. Reisman et al., *Prescription Opioid Usage And Abuse Relationships: An Evaluation of State Prescription Drug Monitoring Program Efficacy*, 3 SUBSTANCE ABUSE: RES. & TREATMENT 41, 43 (2009) (studying PDMP programs in several states between 1997 and 2003); Ronald Simeone & Lynn Holland, *An Evaluation of Prescription Drug Monitoring Programs*, SIMEONE ASSOCIATES, INC. 2 (Sept. 1, 2006), <http://www.simeoneassociates.com/simeone3.pdf> (studying the impact of PDMPs in curbing drug supply and abuse in the United States between 1997 and 2003).

110. Reisman et al., *supra* note 109, at 46–47.

111. Simeone & Holland, *supra* note 109, at 40.

prescribing changes associated with electronic-only PDMPs,¹¹² although another study found changing from a “triplicate” paper-based program to one requiring an electronic security form resulted in statistically significant increases in Schedule II opioid analgesics, especially short-acting oxycodone and hydrocodone.¹¹³ Other research has documented that PDMPs with paper prescription overlays experienced both lower prescription OA use and overdose mortality rates than electronic-only PDMPs.¹¹⁴ Compared to non-PDMP states, those with prescription monitoring programs utilized greater amounts of Schedule III hydrocodone and non-significantly lower amounts of Schedule II opioid analgesics.¹¹⁵ It is important to note that reductions in use of prescription medications targeted by PDMPs does not translate into a corresponding reduction in their abuse or diversion.¹¹⁶ To date, no research on PDMPs has adequately differentiated the effectiveness of PDMPs in reducing abuse and diversion versus reducing medical access to controlled prescription medications.¹¹⁷

As noted previously, the widespread acceptance of PDMPs has not resulted in a widespread understanding of their intended and unintended impacts. PDMPs remain contentious, with their supporters¹¹⁸ and detractors.¹¹⁹ The specter of a chilling effect on prescribing (and dispensing) for those patients in genuine medical need has been a prime motivator for objections.¹²⁰ Despite these concerns, the DEA

112. Linda Simoni-Wastila & Jingjing Qian, *Influence of Prescription Monitoring Programs On Analgesic Utilization By An Insured Retiree Population*, 21 PHARMACOEPIDEMOLOGY & DRUG SAFETY 1261, 1262 (2012).

113. Gilson et al., *supra* note 108, at 106.

114. Simoni-Wastila & Qian, *supra* note 112, at 1262 (finding that paper and/or form-based monitoring systems produced a reduction in the use of opioid analgesics); Paulozzi et al., *supra* note 109, at 752 (noting that PDMPs resulted in lower opioid overdose mortality rates in California, New York and Texas).

115. Paulozzi et al., *supra* note 109, at 751.

116. *See id.* at 750–51.

117. *See* Wang & Christo, *supra* note 106, at 510 (discussing conflicting results regarding the effects of PDMPs on doctors’ prescribing behaviors and opioid drug abuse rates).

118. *See* Amy Pavuk, *States Could Make Better Use of Prescription Data To Fight Drug Abuse, Study Finds*, ORLANDO SENTINEL Sept. 20, 2012, http://articles.orlandosentinel.com/2012-09-20/news/os-pdmp-study-florida-20120920_1_prescription-drug-prescriptions-from-multiple-doctors-florida-s-pdmp (discussing how supporters of Florida’s PDMP believe it contributes to reduced drug abuse rates).

119. *See* THOMAS CLARK ET AL., BRANDEIS UNIV., *PRESCRIPTION DRUG MONITORING PROGRAMS: AN ASSESSMENT OF THE EVIDENCE FOR BEST PRACTICES* 4 (2012), http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/PDMP%20Update%201-31-2013.pdf (noting public and private supporters, including the Drug Enforcement Agency, Department of Justice, and Purdue Pharma, the manufacturer of OxyContin); Felisa Cardone, *Lawmakers May Cancel State Database Used To Fight Prescription-Drug Abuse*, DENVER POST, Mar. 7, 2011, http://www.denverpost.com/news/ci_17553082 (discussing Colorado lawmakers’ distrust of the state PDMP amidst privacy concerns and a lack of information to the public).

120. *See* KRISTIN M. FINKLEA ET AL., CONG. RESEARCH SERV., R42593, *PRESCRIPTION DRUG MONITORING PROGRAMS* 20 (2012) (discussing various organizations’ concerns that PDMPs may limit doctors’ ability to adequately treat patient pain).

and other advocates for PDMPs have been successful in convincing states to adopt PDMPs.¹²¹ Probably the most significant tool in the DEA's recruiting repertoire is the grant money from the federal government to states for program implementation once PDMP legislation is passed.¹²²

PDMPs are not without their benefits. They may be used to authenticate prescribers, pharmacies, and patients.¹²³ They may be helpful in emergency departments and other urgent care settings to assist in the treatment of patients who present without known medical history.¹²⁴ The success of PDMPs may depend, in part, on which area of the state is responsible for tracking prescriptions.¹²⁵ Is it law enforcement, such as the Attorney General's office, or is it a health care entity, such as the state public health department? Similarities abound with medical marijuana. For instance, the Vermont Medical Marijuana Registry is housed in the state's criminal information center.¹²⁶ Thus, as with the problem of prescription opioid analgesics, such decisions are important for determining the effectiveness of medical marijuana laws in providing access when needed, and preventing diversion as possible.¹²⁷

121. See U.S. GEN. ACCOUNTING OFFICE, *supra* note 109, at 20 (noting how the DEA has been supportive of states that start PDMP programs).

122. *Id.* See, e.g., BUREAU OF JUSTICE ASSISTANCE, U.S. DEP'T OF JUSTICE, OMB NO. 1121-0329, HAROLD ROGERS PRESCRIPTION DRUG MONITORING PROGRAM FY 2012 COMPETITIVE GRANT ANNOUNCEMENT 3-4 (2012), available at <https://www.bja.gov/Funding/12PDMPsol.pdf> (describing a federal grant to assist states in starting PDMPs).

123. See IJIS INST., PMP COMMITTEE PHASE II PMIX PILOT PROJECT SURVEY OF STATE PRESCRIPTION MONITORING PROGRAMS 19-20 (2007), available at <http://www.nasca.org/News/IJISpmixPMPSurveyResults1.07.pdf>.

124. See David F. Baehren et al., *A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors*, 56 ANNALS EMERGENCY MED., 19, 22 (2010) (reporting that PDMPs are helpful in measuring patients' patterns of seeking out opiate medications).

125. See generally *State/Territory/District Contacts*, ALLIANCE STS. WITH PRESCRIPTION MONITORING PROGRAMS, <http://www.pmpalliance.org/content/stateterritorydistrict-contacts> (last visited Apr. 1, 2013) (outlining various state agencies charged with monitoring PDMPs).

126. *Medical Marijuana Registry*, VT. CRIM. INFO. CENTER, http://vcic.vermont.gov/marijuana_registry (last visited Apr. 8, 2013).

127. See Birnbaum et al., *supra* note 83, at 664 (providing that efforts to reduce prescription opioid abuse will require involvement from a variety of parties and agencies).

IV. CONCLUSION

In 2012, an election year, states continued to place proposed legislation for the medical use of marijuana on their ballots.¹²⁸ Given the inevitable expansion of MML,¹²⁹ it behooves policy-makers, prescribers, dispensers, and patients to understand the legacy of allowing increased use of marijuana for medical purposes. Such understanding requires careful evaluation of intended—and unintended—consequences. In order to conduct meaningful evaluation, usable data should be collected at the national level. Such data would include marijuana utilization, reasons for utilization, and perceptions of risk of such use. National attention also should be given to the development of model standards of practice, based on evaluation of state MML, which could then better inform states contemplating MML, as well as improve the programs in states with existing MML.

Meanwhile, individual states should consider implementing their own evaluations, considering both the medical utilization of marijuana, as well as the effects of MML on changes in recreational use (especially among youth), admissions to substance use treatment, impaired driving and consequences, changes in use of alternative therapies, and criminal activity.¹³⁰ As well, states should consider implementing safeguards for medical marijuana expansion, including the use of patient medguides, registries, and other REMS-like components.¹³¹ Expansion of legislation for medical marijuana can provide benefits, but can also involve risks. In order to best understand the tenuous balance of benefits and risks in MML, understanding and evaluating current programs should be made a top priority.

128. See Stephanie Condon, *Marijuana, Same-Sex Marriage Initiatives Are Winners*, CBS NEWS, Nov. 7, 2012, http://www.cbsnews.com/8301-250_162-57546156/marijuana-same-sex-marriage-initiatives-are-winners (discussing the outcomes of proposed marijuana legislation in Colorado, Washington, and Oregon); Chelsea Conaboy & Zachary T. Sampson, *Mass. Voters OK Marijuana For Some Medical Conditions*, BOSTON GLOBE, Nov. 7, 2012, <http://www.bostonglobe.com/metro/2012/11/07/medical-marijuana-ballot-question/OmjNOajRHvyDgcUMVusz8H/story.html> (discussing the successful outcome of Massachusetts' medical marijuana legislation).

129. See *The Expansion Of Medical Marijuana Acceptance Across The USA Progresses With Massachusetts, Montana (And Arkansas Too Close To Call) Joining 13 Other States*, PR NEWSWIRE, Nov. 7, 2012, <http://www.prnewswire.com/news-releases/the-expansion-of-medical-marijuana-acceptance-across-the-usa-progresses-with-massachusetts-montana-and-arkansas-too-close-to-call-joining-13-other-states-177642701.html> (discussing the increase in medical marijuana acceptance in the United States).

130. See *supra* Part II.A.

131. See *supra* Part III.