THE BEST OF BOTH WORLDS: APPLYING FEDERAL COMMERCE AND STATE POLICE POWERS TO REDUCE PRESCRIPTION DRUG ABUSE

Stacey L. Sklaver
The Best of Both Worlds: 
Applying Federal Commerce and State Police Powers 
To Reduce Prescription Drug Abuse

By Michael C. Barnes and Gretchen Arndt*

INTRODUCTION

Prescription drug¹ abuse is the fastest growing drug problem in the United States.²

Although public perception sees prescription medications as inherently safer than illicit

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¹ Noteworthy prescription medications that are often abused include opioids (hydrocodone, oxycodone), stimulants (dextroamphetamine, methylphenidate), and benzodiazepines (alprazolam, diazepam). These medications are all classed as controlled substances under federal and most states’ laws. Controlled substances are drugs, substances, or immediate precursors of drugs that the government has determined it must regulate because of their potentially dangerous effects. See 21 U.S.C. § 802 (6) (for the statutory definition of controlled substances), 21 C.F.R. §§ 1308.11-15 (for the current list of controlled substances in Schedules I-V). This Article addresses a federal Controlled Substances Act amendment applicable to controlled substances in Schedules II-V. 21 U.S.C. § 801 et. seq. This Article often focuses on opioid pain medications because these pain relievers are the most commonly abused controlled substances.

Nevertheless, solutions to prescription drug abuse must also apply to stimulants and benzodiazepines.

² CDC Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic, Morbidity and Mortality Report Weekly, CENTERS FOR DISEASE CONTROL AND PREVENTION (January 13, 2012) / 61(01):10 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm. Consistent with the National Prescription Drug Abuse Prevention Strategy, this Article “regards as imprecise the Substance Abuse and Mental Health Services Administration’s National Survey on Drug Use and Health (NSDUH) definition of nonmedical use of prescription medications, which is ‘use without a prescription of the individual’s own or simply for the experience or feeling the drugs caused.’ This definition of nonmedical use does not differentiate between misuse and abuse. Katz et al.’s definition[s] of misuse and abuse are more precise. Katz et al. define misuse as ‘use of medication (for a medical purpose) other than as directed or as indicated, whether willful or unintentional, and whether harm results or not.’ They define abuse as . . . the intentional self-administration of a medication for a nonmedical purpose such as altering one’s state of consciousness, e.g., getting high.’ Katz et al.’s well-delineated definitions should be used when describing misuse and abuse.

* Michael C. Barnes is the managing partner at DCBA Law & Policy LLP in Washington, DC. Gretchen Arndt is a 2013 J.D. candidate at George Mason University School of Law and a member of the George Mason University Civil Rights Law Journal. The authors would like to thank Stacey L. Sklaver for her research and editing contributions.
street drugs, prescription opioids caused 14,800 deaths in 2008, which is more than cocaine and heroin combined. Prescription drug abuse is even more prevalent than most illicit drug use, and prescription drug-related deaths have increased over 300-fold from 1999 to 2008. These staggering figures have prompted the U.S. Centers for Disease Control and Prevention to call prescription drug abuse a national epidemic, have prompted the presidential administration to respond to the problem with a prescription drug abuse prevention plan, and have prompted state governors and attorneys general to develop state-specific task forces and plans.

Yet, one hundred million patients in the U.S. suffer from chronic pain; many are worried about access to medications that have become a vital part of their palliative

For the general purposes of this article, however, we will often use the phrase ‘prescription drug abuse’ to encompass these various related definitions.”

3 Prescription Drug Abuse, OFFICE OF NATIONAL DRUG CONTROL POLICY http://www.whitehouse.gov/ondcp/prescription-drug-abuse Accessed August 14, 2012 (“Some individuals who [abuse] prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a healthcare professional and dispensed by a pharmacist.”).


5 Id.

6 Id (reporting that “drug poisoning deaths involving opioid analgesics more than tripled from about 4,000 in 1999 to 14,800 in 2008.”).


care.10 State-licensed healthcare providers serve as the gatekeepers for federally regulated medications.11 These practitioners12 face the conflict of treating patients in pain—an invisible symptom—and fearing discipline for improperly prescribing pain medication.13 Even more disturbing is the fact that many physicians have never received the proper education or training to understand the consequences of prescribing controlled substances or how to take steps to prevent serious harm to their patients who are taking such medications.14 Through mandatory education, physicians can learn how to adequately treat their patients while preventing abuse.15

While some state legislatures have taken proactive steps to prevent prescription drug abuse by requiring mandatory prescriber education, many have not.16 Prescriber education is needed on a national level. Moreover, the solution to the prescription drug abuse problem must address patient health, safety, and welfare under the purview of the states’ plenary police powers, and movement of controlled substances through federally governed interstate commerce. This Article proposes action that harnesses the state and federal systems to provide a comprehensive, effective solution: the Controlled Substances Act (“CSA”)17 must require prescribers to obtain education and training on safe prescribing and abuse prevention methods before they may register to prescribe

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10 See, e.g., Jeffrey Fudin, Label Changes for Opioids, FOR or AGAINST, BLOG (August 3, 2012), http://paindr.com/blog/.
12 “Practitioners” and “prescribers” refer to prescribing health care practitioners, including physicians, physician assistants, nurse practitioners, and dentists.
15 See id.
16 Supra Section IV. A. California, Massachusetts, Michigan, Oregon, and Tennessee require some pain management or prescribing training for licensure.
controlled substances. By establishing mandatory education for every controlled substance prescriber nationwide pursuant to the CSA, the federal government is not encroaching on states’ plenary police power because such action is authorized under the Commerce Clause of the United States Constitution.

Part I of this Article discusses changes in prescribing practices and the need to educate prescribers, the gatekeepers of the supply of controlled substances. Part II discusses states’ authority to regulate the practice of medicine, providing an overview of states’ plenary police power. Part III discusses federal authority to regulate controlled substances. This includes an overview of the Commerce Clause, an overview of the CSA, and relevant case law that establishes the federal government’s authority to mandate prescriber education pursuant to the Commerce Clause. Part IV looks at other attempts to impose a prescriber education requirement. Part V proposes how such an education requirement should work and uses Massachusetts and Virginia as models to show how a prescriber education mandate would fit into current state systems. Part VI discusses how the prescriber requirement will empower healthcare providers to prescribe appropriately, improve patient treatment, and reduce liability. This national effort will be successful because it will reach all controlled substance prescribers, and because it provides a way for the federal government to enhance its regulation of commerce without encroaching on states’ plenary police powers.

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19 U.S. Const. art. I, § 8, cl. 3.
I. INTERRUPTING SUPPLY BY EDUCATING PRESCRIBERS

Over the past two decades, prescribers have generally been more willing to treat patients using controlled substances.20 Given the current prescription drug abuse epidemic, prescribers must be more cautious in treating people with pain and other conditions for which controlled substances may be prescribed. This Part discusses those changes in controlled substance prescribing, highlights the problem that practitioners are receiving inadequate training on how to safely prescribe, and establishes the need for an education requirement.

A. Changes in Prescribing Opioids

Opioid medications relieve pain by reducing the effects of a painful stimulus in the part of the brain that feels emotions.21 Until about fifteen years ago, opioids were routinely prescribed only for end-of-life care, for cancer, and after surgery.22 Since then, pain care experts and organizations at the state and national level began emphasizing the importance of pain management.23 These experts and organizations have made a case for using opioids also to treat chronic pain because some patients experience a reduction in

20 See infra Note 23.
pain with long-term opioid use.\textsuperscript{24} Although many healthcare professionals now prescribe opioids to treat chronic pain, studies suggest that physicians may prescribe opioids too quickly, that opioids may ultimately be ineffective for chronic pain, and that such medication may pose serious health risks.\textsuperscript{25} For instance, researchers have linked opioid use to increased sensitivity to pain, negative immune effects, sleep apnea, suppression of sexual hormone production, increased elderly falls and hip fractures, and overdose deaths.\textsuperscript{26} Additionally, opioids can be addictive and can lead to psychological dependence,\textsuperscript{27} leading many pain-care physicians to question the legitimacy of opioid use for treatment of chronic pain.\textsuperscript{28} In fact, medical journals report that between 4\% and 26\% of those who take opioids for long-term pain treatment become addicted.\textsuperscript{29}

Prompted by recent investigative journalism revealing strong ties between pharmaceutical companies and both medical professionals and organizations that have promoted expanded uses of opioids for pain treatment, in May 2012, the U.S. Senate Finance Committee began an investigation into ties between industry funding and the


\textsuperscript{25} See CDC Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic, Morbidity and Mortality Report Weekly, CENTERS FOR DISEASE CONTROL AND PREVENTION (January 13, 2012) / 61(01):10 \url{http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm}. (“In a prospective, population-based study of injured workers with compensable low back pain, 38 percent of the workers received an opioid early in their care, most at the first doctor visit. Among the 6 percent who went on to receive opioids for chronic pain for 1 year, most did not report clinically meaningful improvement in pain and function, even though their opioid dose rose significantly over the year.”)


\textsuperscript{29} Cautious, Evidence-Based Opioid Prescribing, PHYSICIANS FOR RESPONSIBLE OPIOID PRESCRIBING \url{http://www.supportprop.org/educational/PROP_OpioidPrescribing.pdf} (Accessed June 28, 2012).
groups backing the increased prescribing of opioid pain relievers. The investigative reporting, senate inquiries, and other recent events suggest that prescribing standards may be in flux. As such, there is a need to properly educate and train physicians on how to properly prescribe controlled substances.

B. The Need to Educate Prescribers

Practitioners are gatekeepers to the supply of prescription medications, including controlled substances. Both legitimate and illicit users cannot gain access to these medications until practitioners write prescriptions. Consequently, approximately 90% of the supply for non-medical users comes directly from prescribers. Yet, studies show that physicians typically receive little to no education or training in medical school on how to create proper pain management treatment plans, and on how to recognize signs of prescription drug diversion, misuse, and abuse. Although many general practitioners prescribe controlled substances, typically only practitioners who specialize in addiction


33 See Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658 p. 25 (2011) available at http://www.samhsa.gov/data/NSDUH/2k10ResultsRev/NSDUHresultsRev2010.pdf. Seventy percent of prescription pain drug abusers obtained the drug from a friend or relative, and the friend or relative presumably obtained the drug through a valid prescription. Another 19% of non-medical users obtained their prescriptions from one physician. Id.

treatment and other similar specialties receive training in opioid prescribing and substance abuse prevention and detection.35

Medical malpractice decisions are often conditioned on the practitioner’s adherence or non-adherence to common law standards of care and treatment guidelines.36 Prescribers may oppose mandatory training requirements or guidelines for fear of the threat of malpractice liability that may result from failing to adhere to such standards and guidelines.37 Furthermore, they may perceive legal rules and guidelines as a threat to their ability to use professional discretion.38 However, such fear shows an even greater need for in-depth education, not only on how to properly prescribe controlled substances, but on the realistic repercussions that practitioners may face for improperly prescribing.

Even though practitioners may find it unfavorable, mandatory education and training for all who prescribe controlled substances is vital. Practitioners set the standard of care in their field because the test for liability looks to, among other facts, whether a practitioner followed an objectively reasonable standard of care in the community at


36 See infra note 44.

37 Sandra H. Johnson, Regulating Physician Behavior: Taking Doctors’ “Bad Law” Claims Seriously, 53 STLULJ 973, 1001-03 (2009) (suggesting that alleged malpractice, even if a physician is later exonerated, can chill prescribing), See also Diane E. Hoffmann and Anita J. Tarzian, Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: the Role of State Medical Boards, 31 J.L. Med. & Ethics 21, 21 (2003); Courts usually use a four-pronged test, where following a reasonable standard of care is part of the duty and breach of duty elements. See, e.g., Conrad-Hutsell v. Colturi, No. L-01-1227, 2002 WL 1290844 (Ohio Ct. App. May 24, 2003) (using a medical malpractice test comprised of 1) duty, 2) breach of duty, 3) proximate cause; and 4) damages); McCarroll v. Reed, 679 P.2d 851 (Okla. Civ. App. 1983) (using a medical malpractice test of duty, including the physician’s obligation to “use reasonable professional skill, care and diligence to prevent his patients from becoming drug addicts;” breach of duty; and injury caused by the breach).

issue. With millions of Americans reporting suffering from chronic pain and being prescribed controlled substances, and approximately 15,000 deaths resulting from opioid abuse per year, now more than ever, physicians need education on standards of care in controlled substance prescribing. Mandatory education will equip good-intentioned prescribers with the knowledge to properly treat patients while recognizing and preventing diversion, misuse, and abuse.

Practitioners can be held criminally or civilly liable if they fail to properly exercise a reasonable standard of care. To meet the standard of care, practitioners must “possess [a] reasonable degree of learning and skill which is ordinarily possessed by others of the profession.” Reasonable care includes maintaining a familiarity with appropriate treatment standards articulated by laws and guidelines, properly assessing a patient’s medical history, especially when prescribing controlled substances, which

39 Complying with the objective standard of care in the medical community in which the practitioner practices is important to assessing reasonableness, and therefore, non-negligence. Schaefer v. Larsen, 688 S.W.2d 430 (Tenn. Ct. App. 1984); Hamilton v. Hardy, 549 P.2d 1099 (Colo. App. 1976).
42 State statutes and tort law govern medical malpractice cases. See supra note 53 for discussion of state controlled substance acts.
are riskier by definition;\textsuperscript{47} and prescribing medications appropriately.\textsuperscript{48} Courts look to practice guidelines, expert opinion,\textsuperscript{49} state laws and regulations,\textsuperscript{50} and medical drug reference books\textsuperscript{51} to determine whether a practitioner’s treatment is in accordance with the standard of care. Therefore, prescribers must obtain a proper education and training on prescribing guidelines, laws, and standards.

Without the proper education and training, practitioners are more likely to breach the standard of care because they are not fully aware of the duties imposed up on them. They are more likely to improperly prescribe medications, which can result in diversion, misuse, and abuse, and also result in actions against the practitioner for medical malpractice or criminal liability.

With the proper training and education, practitioners can improve their controlled substance prescribing behaviors, protect patients and communities, and avoid liability. As such, mandatory prescriber education is necessary. Yet, advocates of prescriber education must also get over the hurdle of proving that such a requirement under the CSA does not

\textsuperscript{47} See 21 U.S.C. § 801(2) (suggesting that, if unregulated, the use of controlled substances could have a “substantial and detrimental effect on the health and general welfare of the American people”).

\textsuperscript{48} Conrad-Hutsell v. Colturi, No. L-01-1227, 2002 WL 1290844, 6 (Ohio Ct. App. May 24, 2003) (listing the duties required of all physicians when prescribing narcotics, including an inquiry into whether the practitioner was aware of the characteristics of the drug; knew the patient’s medical history and current condition; warned the patient of risk and side effects of the drug; and prescribed drugs in the correct dose, for correct durations, and administered the drug properly; and monitored the patient); see also Ballenger v. Crowell, 247 S.E.2d 287 (N.C. Ct. App. 1978) (finding against a physician in a negligence case in which the patient became strongly addicted to drugs prescribed to treat his neurological condition in reliance on his doctor’s advice that he would always just have to take the addictive drugs).

\textsuperscript{49} See Lauren Krohn, Cause of Action Against Physician for Negligence in Prescribing Drugs or Medicines § 25 (last updated July 2012) (stating that it is generally necessary to rely on expert practitioners to determine the standard of care in medical malpractice cases).

\textsuperscript{50} See infra note 44.

encroach on states’ plenary police power—a hurdle that this Article establishes can be overcome.

II. STATE AUTHORITY TO REGULATE THE PRACTICE OF MEDICINE

Controlled substances are regulated, both at the federal level through the CSA, and at the state level through state controlled substances acts, which can lead to differences in regulation from state to state. Regulating the use of controlled substances is arguably activity that falls under states’ plenary police power because it pertains to states’ rights to regulate the health, safety, and welfare of their citizens. Therefore, it would appear that a conflict exists between states’ rights and the purview of the federal government. To understand this conflict, it is important to understand states’ rights first. This Part provides an overview of constitutional doctrine of states’ plenary police power.

Under the Tenth Amendment of the U. S. Constitution, powers not specifically granted to the federal government or prohibited to the states are reserved to the states. States have an inherent authority to impose regulations on the private rights of their citizens in order to protect their citizens’ health, safety, and welfare. This authority is referred to as “state plenary police power.”

\[54\] Barsky v. Board of Regents, 347 U.S. 442, 449 (1954) (stating that “It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power. The state's discretion in that field extends naturally to the regulation of all professions concerned with health.”)
\[55\] U.S. CONST. amend. X.
\[56\] United States v. E. C. Knight Co., 156 U.S. 1, 11 (1895) (“the power of a State to protect the lives, health, and property of its citizens, and to preserve good order and the public morals . . . is a power originally and always belonging to the States, not surrendered by them to the general government, nor directly restrained by the Constitution of the United States, and essentially exclusive.”)
The authority to regulate the practice of medicine, in particular, falls under the purview of states’ plenary police power rather than under the authority of the federal government.58 For example, in *State v. Gee*,59 William R. Gee was an aspiring chiropractor in Arizona who practiced chiropractic science without first complying with the requirements under state law.60 In order to practice, Mr. Gee needed a certificate in basic sciences and a license from the State Board of Chiropractic Examiners.61 Of note, Mr. Gee claimed that the technical requirements prescribed by the Arizona Basic Science Act62 were unconstitutional because they violated the due process clauses of the Fourteenth Amendment of the U.S. Constitution and the Constitution of Arizona.63 He took issue with the vagueness of the term “practice of healing” in the Act, and the discretion given to the State Board of Examiners in determining who passed the exam.64 The United States Supreme Court ruled in favor of the state, concluding that it is unquestioned that the legislature “has the power and duty to control and regulate such professions and practices affecting the public health and welfare.”65 The Court established that states regulate the practice of healthcare professions under their plenary police powers.

III. **FEDERAL AUTHORITY TO REGULATE CONTROLLED SUBSTANCES**

Although states have the authority to regulate the practice of medicine, the federal government has concurrent authority to regulate some aspects of the practice of medicine as well. The federal government derives this power from the Commerce Clause. This Part

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59 236 P.2d 1029 (Ariz. 1951).
61 *Id.*
62 A.R.S §§ 32-401-02 (1939)
63 *Id.* (regarding U.S. CONST. amend. IV. and A.Z. CONST. art. 2, § 3)
64 *Id.* at 1032.
65 *Id.* at 1033.
provides an overview of the Commerce Clause and discusses how the federal government derives its authority to regulate controlled substances pursuant to the Controlled Substances Act and its relevant case law. It also discusses recent restrictions and their practical impact on the CSA.

A. The Controlled Substances Act and Federal Authority Under the Commerce Clause

The federal government regulates controlled substances pursuant to the CSA. This authority is derived from the Commerce Clause. Before discussing the Commerce Clause, it is important to have an understanding of what the CSA entails.

1. The Controlled Substances Act

In 1970, Congress enacted the Controlled Substances Act, a federal law controlling the manufacture and distribution of controlled substances. It requires adherence to registration, storage, and record-keeping requirements for those who manufacture, distribute, dispense, import, or export controlled substances. The CSA attempts to ensure that records are kept of the handling of controlled substances as they move down the supply chain from the manufacturer to the end user.

In 1973, Congress created the Drug Enforcement Administration (“DEA”) under the CSA, and gave the agency the authority to schedule and regulate controlled substances. Under the CSA, the DEA is responsible for preventing, detecting, and investigating diversion of controlled substances, while ensuring the availability of these drugs for legitimate use. The Act classifies controlled substances using five schedules

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67 Id.
68 United States v. Rosenberg 515 F.2d 190, 193 (9th Cir. 1975).
69 Id. at 263-64.
based on each drug’s medical uses and potential for abuse. The most dangerous controlled substances, such as heroin and synthetic “bath salts,” are classified in Schedule I. Schedule I substances cannot be prescribed under the CSA because, by definition, they have no accepted medical use. Schedules II through V contain drugs with medical uses, but also have the potential for abuse.

Prescribers licensed to practice in a state must register with the DEA every three years in order to prescribe controlled substances in Schedules II through V. When prescribing controlled substances, registered practitioners must follow the prescription-writing, order form, and record-keeping provisions of the CSA or face penalties. Regulations under the CSA require that a controlled substance prescription be dated and signed as of the date of issue. The prescription must include the patient’s and practitioner’s names and addresses; the practitioner’s DEA registration number; the drug’s name, strength, and dosage form; the quantity prescribed; the directions for use; and the number of refills.

In addition to civil and criminal liability at common law, under the CSA, practitioners face criminal charges, including fines, revocation of licenses to practice medicine, and imprisonment, for improperly prescribing controlled substances. In order

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72 Id.
80 Id.
81 Id.
to avoid penalties, “a prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” When a practitioner commits a violation, the DEA can prosecute the practitioner under the CSA, or the practitioner may be prosecuted under state laws. Tension exists between medical practitioners and federal drug enforcement efforts because healthcare practitioners see DEA interventions as a threat to their autonomy to practice medicine in a way that best serves their patients.

Since the creation of the federal prescriber registration requirement, the government’s commerce power has expanded. During the expansion, petitioners seized the opportunity to challenge the CSA’s provisions that allow the federal government to regulate medications in commerce. However, the Supreme Court has solidified the DEA’s authority under the CSA to regulate controlled substances in the stream of commerce. Even those who believe that the expansion of Commerce Clause has gone too far can find that the federal government has the authority to mandate a prescriber education requirement under the CSA.

83 21 C.F.R. § 1306.04(a) (2012).
84 See infra note 227.
86 The controlled substance prescriber registration requirement originated under the Harrison Act, which required manufacturers and distributors of narcotics to register with a local internal revenue officer in order to control taxation of these substances. Harrison Narcotics Act, ch. 1, 38 Stat. 785 (1914) (repealed by the Comprehensive Drug Control Act of 1970).
87 U.S. CONST. art. I, § 8, cl. 3 (grants Congress the power to “regulate commerce with foreign nations, among the several States, and with the Indian tribes.”).
89 See, e.g., United States v. Rosenberg 515 F.2d 190 (9th Cir. 1975); United States v. Collier 478 F.2d 268 (1973 5th Cir).
90 See infra Part III.2.
2. The Commerce Clause

The U.S. Constitution states that “Congress shall have Power . . . to regulate commerce with foreign nations, and among the several states, and with the Indian tribes.”\(^\text{91}\) Courts have interpreted this to mean that Congress may regulate 1) the channels of interstate commerce; 2) the instrumentalities of interstate commerce, including persons and things in interstate commerce; and 3) economic activities that have a substantial effect on interstate commerce. \(^\text{92}\) Other iterations of the Commerce Clause test have been used since the first Supreme Court Commerce Clause case, *Gibbons v. Ogden*,\(^\text{93}\) in 1824. \(^\text{94}\) Beginning with the third prong of the test and moving in descending order, this section analyzes how the prescriber education requirement is compatible with Congress’s Commerce Clause power under all prongs of the test used since 1971.\(^\text{95}\)

In the seminal case *Gonzales v. Raich*,\(^\text{96}\) the Supreme Court specifically upheld section 801 of the CSA.\(^\text{97}\) This section states that intrastate distribution of controlled substances impacts interstate flow of controlled substances, and therefore, the federal government has the authority to regulate intrastate flow of controlled substances.\(^\text{98}\) *Raich* dealt with California’s Compassionate Use Act,\(^\text{99}\) which allowed individuals with serious medical conditions to use marijuana to treat that condition upon a physician’s

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\(^{91}\) U.S. Const. art. I, § 8, cl. 3.
\(^{92}\) Gonzales v. Raich, 545 U.S. 1, 16-17 (2005); Perez v. U.S., 402 U.S. 146 (1971) (first articulating this Commerce Clause test).
\(^{93}\) 22 U.S. 1 (1824).
\(^{94}\) 22 U.S. 1 (1824). In *Gibbons* the Supreme Court decided that the federal right to operate a ferry under federal law trumped a New York state ferry boat law. *Id.* The holding determined that “among the states” means that Congress can regulate intrastate waterways that have interstate effects, and that commerce includes intercourse between parts of nations, not just exchange of commodities. *Id.*
\(^{95}\) The Commerce Clause test used in *Raich* was first articulated in Perez v. U.S., 402 U.S. 146 (1971).
\(^{96}\) 545 U.S. 1 (2005).
\(^{98}\) Gonzales v. Raich, 545 U.S. 1 (2005).
determination that such treatment is appropriate. Yet, the CSA classifies marijuana as a Schedule I controlled substance, meaning that it has no legally recognized medical function and that physicians are not allowed to prescribe it. Per her physician’s instructions, Angel Raich grew marijuana at home to treat an inoperable brain tumor, severe seizures, and multiple chemical sensitivities, among other things. The DEA took the opportunity to challenge the Compassionate Use Act by seizing the doctor-prescribed marijuana from Raich’s home.

The government argued that consuming locally grown marijuana for medical purposes affects the interstate market of marijuana, and therefore, the federal government may regulate it. The Supreme Court articulated the Commerce Clause test, which empowers Congress to regulate the channels, instrumentalities, and activities with substantial effects on interstate commerce. Although the home-grown marijuana was grown and used intrastate, it was a fungible product indistinguishable from marijuana that illicitly passed through commerce, and it could have moved into the national market. Therefore, it fell under the third prong of the test, which allows the federal government to regulate activities with a substantial effect on interstate commerce. As such, the Court ruled the federal government could regulate growing medical marijuana because this activity has substantial effects on interstate commerce.

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100 Id.
102 Id. at 6-7; Amanda Jones, Gonzalez v. Raich: How the Medical Marijuana Debate Invoked Commerce Clause Confusion, 28 U. Haw. L. Rev. 261, 277 at n158 (2005-2006).
103 Id. at 7.
104 Id. at 20.
105 Id. at 16-17.
106 Id. at 17-20.
107 Id. at 20.
The federal government can also regulate prescription controlled substances under the second prong of the Commerce Clause test because these drugs are “things” in interstate commerce. In the 1969 case, Daniel v. Paul, the Supreme Court determined that the federal government could regulate a recreational facility in Arkansas pursuant to the Commerce Clause because three out of four items sold at the facility’s snack bar traveled in interstate commerce. The Court established that food is a “thing” in commerce by showing that the “principal ingredients going into the bread [as well as certain ingredients in the soft drinks] were produced and processed in other States.”

The facility’s snack bar sold hot dogs with buns, hamburgers with buns, soft drinks, and milk, and so a “substantial portion of the food served in the snack bar moved in interstate commerce.” Therefore, the snack bar food items were items in interstate commerce, and the lake facility that sold them could be regulated under Congress’s commerce power in conjunction with the Civil Rights Act of 1964.

Again, in United States v. Sullivan, Congress found that “things” that had traveled within commerce could be regulated by the commerce power. In this case, which was tried under the Federal Food, Drug and Cosmetic Act, Jordan James Sullivan, a retail druggist, appealed misbranding charges that resulted when he moved sulfathiazole tablets

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108 Controlled substances contain components shipped in interstate commerce or are themselves shipped in interstate commerce. See Id. at 40 (O’Connor, J., dissenting) (recognizing that most substances regulated under the CSA besides marijuana contain elements that travel in interstate commerce).
111 Id.
112 Id. (According to the Court, under Title II of the Civil Rights Act of 1964 (“the Act”), 42 U.S.C.S. § 2000a et seq., any restaurant, cafeteria, lunchroom, lunch counter, or facility that serves the public and is principally engaged in selling food for consumption on the premises is a place of public accommodation within the meaning of the Act because its operations affect commerce. “The snack bar’s status as a covered establishment automatically brings the entire Lake Nixon facility within the ambit of the Act.”).
from a properly labeled container to containers without proper instructions for use.\textsuperscript{114} At issue was whether the federal government could regulate the drugs under the Commerce Clause if the drugs’ manufacturers had previously shipped the drugs in interstate commerce, even though Dr. Sullivan only held them for intrastate sale.\textsuperscript{115} The Court found that, because the drugs had previously traveled across state lines, they were considered “things” in interstate commerce under the commerce power, and therefore, the Court found Dr. Sullivan guilty of misbranding under federal law, even though the drugs were held only for local, intrastate sale.\textsuperscript{116}

The proposed CSA Amendment requiring prescriber education is valid under all three prongs of the Commerce Clause test. First, the federal government can mandate a prescriber education requirement under the third prong of the Commerce Clause, as in \textit{Raich}. Practitioners, as gatekeepers along the supply chain of prescription controlled substances, are engaging in an activity that could have a significant impact on commerce. Like the marijuana in \textit{Raich} that could travel interstate after it was grown, controlled medications can move interstate after being prescribed within a state. With the proper education, physicians may change their prescribing habits, either prescribing more or fewer controlled substances. Therefore, given the prescribers’ substantial effects on commerce, Congress may require that practitioners engage in mandatory training under the third prong of the Commerce Clause test.

Second, the federal government derives authority to issue a prescriber education requirement through the second prong of the Commerce Clause test. Almost every

\textsuperscript{114} \textit{Id.}
\textsuperscript{115} \textit{Id.}
\textsuperscript{116} \textit{Id.} at 698 (stating that it is a “constitutional power of Congress under the commerce clause to regulate the branding of articles that have completed an interstate shipment and are being held for future sales in purely local or intrastate commerce”).
controlled substance contains ingredients that move in interstate commerce, similar to the snack bar ingredients in *Paul*. And, almost every controlled substance is shipped through interstate commerce at some point before use, similar to the medication in *Sullivan*.

Therefore, like the food products sold in *Paul* and the medications held for local sale in *Sullivan*, controlled substances are things of interstate commerce that may be regulated under the second prong of the Commerce Clause test. As Justice Scalia stated in *Raich*, it is “self-evident” that items falling under the channels or instrumentalities of interstate commerce prongs fall under the commerce test because they are the “ingredients of interstate commerce itself.”

Third, the federal government can obtain authority to mandate a prescriber education requirement to regulate the gatekeepers of the supply of controlled substances through the first prong of the Commerce Clause test that provides the power to regulate the channels of interstate commerce. In *Heart of Atlanta Motel v. United States*, the Supreme Court upheld the constitutionality of the Title II of the Civil Rights Act of 1964. It held that the law was a valid exercise of congressional power to prohibit from discriminating by race when boarding travelers. Congress has this authority “to keep the channels of interstate commerce free from immoral and injurious uses.” These individuals responsible for transporting others to the motel via channels of interstate commerce, such as interstate roadways, could be regulated under the first prong of the commerce test.

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117 Gonzales v. Raich, 545 U.S. 1, 34 (2005) (Scalia, J., concurring).
120 *Id.*
Like the flow of travelers through the interstate channels of travel in *Heart of Atlanta Motel*, controlled substances pass through an interstate supply chain from manufacturer to distributor, to pharmacy, to patient. The CSA was enacted to regulate of the national supply chain of controlled substances. As stated in *United States v. Collier*, a case upholding the constitutionality of the CSA, discussed further below, the Fifth Circuit said:

...Congress fashioned the Comprehensive Drug Control Act to provide "a 'closed' system of drug distribution for legitimate handlers of such drugs. Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control."  

In keeping with this rationale for regulation under the CSA, practitioners need mandatory education to fulfill their role as gatekeepers of potentially dangerous medications in the channel of commerce. If practitioners are not allowed or are too afraid to prescribe, the channel is blocked. If practitioners overprescribe, the channel is flooded. This analysis of regulating the gatekeepers of the supply of controlled substances is consistent with the stance of those who believe that the Commerce Clause has been interpreted too broadly. Unlike the substantial effects argument under the third prong, controlling the supply of potentially injurious substances in commerce is fully within Congress’s traditional commerce power used since 1824, as held in *Gibbons v. Ogden.*

The prescriber education mandate argument can also be made under the Necessary and Proper Clause of the Constitution. Under the Necessary and Proper Clause, as forged by Justice Scalia in his concurrence to *Raich,* the federal government can obtain authority to regulate the gatekeepers of the supply of controlled substances.

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123 See supra note 94.
124 Id. at 33-42 (Scalia, J., concurring).
Justice Scalia agreed that Congress has the power to regulate intrastate goods that could flow through interstate commerce. But he disagreed with the validity of the third prong of the Commerce Clause test because he thought that activities that only have a substantial effect on interstate commerce could not be justified as true things of interstate commerce. Instead, he argued that Congress’s power over things not of interstate commerce derives from the Necessary and Proper Clause of the Constitution. Justice Scalia found that the CSA’s provisions were necessary and proper in order to allow the federal government to stop diversion and oversee proper supply of controlled substances. The application of the Necessary and Proper Clause hinged on whether the CSA was an appropriate means to allow the federal government to achieve these goals. Justice Scalia suggested that preventing diversion was not a violation of sovereignty of the sort that would be inappropriate, and that it was sufficient to authorize the application of the CSA to Angel Raich. This reasoning can be extended to require prescriber education to help ensure that controlled substances stay within the appropriate chain of supply. Thus, a federal prescriber education requirement is constitutional under both the Commerce Clause and the Necessary and Proper Clause.

125 See id. at 34.
126 Id.
127 Id. (saying “when necessary to make a regulation of interstate commerce effective, Congress may regulate even those intrastate activities that do not themselves substantially affect interstate commerce.”)
128 Id. at 39.
129 Id. at 40.
130 See id. at 41.
131 Id. at 42.
B. Recent Restrictions on Commerce Power Do Not Affect the CSA’s Constitutionality

Commerce Clause jurisprudence includes a 70-year period of restriction beginning after the civil war in 1867 and continuing to 1937 when the Supreme Court largely invalidated challenged federal laws.\textsuperscript{132} From 1937\textsuperscript{133} until the mid-1990s, the commerce power was unshaken and continued to expand through Supreme Court findings.\textsuperscript{134} Then, a recent line of cases restricted the Commerce Clause power.\textsuperscript{135} \textit{United States v. Lopez}\textsuperscript{136} and \textit{United States v. Morrison}\textsuperscript{137} addressed whether noneconomic conduct can be construed as asserting substantial effects on commerce through the third prong of the Commerce Clause test. \textit{National Federation of Independent Business v. Sebelius}\textsuperscript{138} addressed whether Congress may compel commerce. The prescriber education mandate can be distinguished from the regulations that were overturned in each of these cases.

In \textit{Lopez}, Alfonso Lopez challenged the constitutionality of the federal Gun-Free School Zones Act of 1990 (the “Act”), which prohibited possessing a firearm in a school zone.\textsuperscript{139} Alfonso Lopez, Jr., a twelfth grade student, brought a concealed gun to school to deliver it to another person in exchange for money.\textsuperscript{140} After school authorities discovered

\textsuperscript{132} \textsc{Erwin Chemerinsky}, \textit{Constitutional Law Principles and Policies} 247 (4th ed. 2011).
\textsuperscript{133} The first case to begin changing the Commerce Clause doctrine was NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1 (1937).
\textsuperscript{134} \textsc{Erwin Chemerinsky}, \textit{Constitutional Law Principles and Policies} 269 (4th ed. 2011).
\textsuperscript{139} 514 U.S. 549 (1995).
\textsuperscript{140} \textit{Id.} at 551.
he was carrying the weapon, he was charged with violating the Act.141 Lopez argued that the federal statute was unconstitutional “as it is beyond the power of Congress to legislate control over our public schools.”142 The government argued that the possession of a firearm in an educational setting would substantially impact interstate commerce because it would likely lead to a violent crime, which would then affect the general economic condition by raising insurance costs and limiting the willingness to travel to an area perceived to be unsafe.143 Unlike the case of prescribed controlled substances, there was no evidence that Lopez’s gun had traveled interstate or that the law at issue would substantially affect commerce in guns because the law was specific to guns near schools.144 Therefore, the Supreme Court rejected these arguments, finding instead that the presence of a gun near a school was not economic activity.145 It held that, under the government’s reasoning, Congress’s power could extend over almost anything, including “criminal law enforcement or education where States historically have been sovereign.”146 Our case for the prescriber education regulation can be distinguished because, as described above in Section III.A., the activity of releasing a supply of controlled substances to consumers does have substantial effects on commerce, unlike the noneconomic possession of a gun near a school in *Lopez*.

In *Morrison*, the Supreme Court found the Violence Against Women Act (“VAWA”) unconstitutional based on *Lopez*.147 Christy Brzonkala alleged that she was

141 *Id.*
142 *Id.*
143 *Id.* at 563-64.
144 *Id.* at 643. “Respondent was a local student at a local school; there is no indication that he had recently moved in interstate commerce, and [under the law at issue] there is no requirement that his possession of the firearm have any concrete tie to interstate commerce.”
147 529 U.S. 598 (2000).
raped by Virginia Polytechnic Institute football players and sued for civil damages under the VAWA, which provides a federal civil remedy for victims of gender-motivated violence.\textsuperscript{148} After the defendants challenged the constitutionality of VAWA, Brzonkala and the government argued that the VAWA should be upheld under the third prong of the Commerce Clause.\textsuperscript{149} They argued that gender-motivated violence affects interstate commerce by

\begin{quote}
deterring potential victims from traveling interstate, from engaging in employment in interstate business, and from transacting with business, and in places involved in interstate commerce; . . . by diminishing national productivity, increasing medical and other costs, and decreasing the supply and demand for interstate products.\textsuperscript{150}
\end{quote}

The Supreme Court rejected Brzonkala’s and the government’s argument, and found that the VAWA was unconstitutional because the acts of violence had only an “attenuated” effect on interstate commerce rather than a substantial one.\textsuperscript{151} Moreover, the acts of violence only resulted in indirect economic consequences, and intrastate actions must be economic in nature to be viewed in aggregate by courts.\textsuperscript{152} If cumulative effects of noneconomic activity could justify such as economic activity, it would allow Congress to regulate any violent crime in the country.\textsuperscript{153} Unlike those who commit violence against women, prescribers of controlled substances do substantially affect interstate commerce by their actions. As shown in Section III.A., healthcare providers are gatekeepers of the supply of controlled substances, and both controlled substances and prescribers of controlled substances may be regulated under Congress’s Commerce Clause power.

\textsuperscript{148} Id.; 42 U.S.C. § 13981.
\textsuperscript{149} 529 U.S. 598, 607 (2000).
\textsuperscript{150} Id. at 615.
\textsuperscript{151} Id. at 612.
\textsuperscript{152} Id. at 628.
\textsuperscript{153} Id. at 615.
The majority opinion in the recent Supreme Court case, *Sebelius*, argued that the federal government could not mandate health insurance under the Commerce Clause.\footnote{154 132 S. Ct. 2566 (2012).} The case follows the line of cases that recognize limits of Congress’s Commerce Clause power. However, like *Lopez* and *Morrison*, which overturn legislation that can be distinguished from the proposed legislation at hand on the grounds that the regulations on guns near schools and violence against women, respectively, were *noneconomic* regulations, the regulation in *Sebelius* can be distinguished from that in the proposed CSA Amendment. In *Sebelius*, the Supreme Court held that the Affordable Care Act was not a valid embodiment of the legislature’s commerce power, and instead upheld the Act under Congress’s taxing power.\footnote{155 Nat’l Fed’n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).} The Act compels individuals to purchase health insurance or to pay a fine for not purchasing insurance.\footnote{156 Id. at 2580.} The rationale behind the law is that many seemingly healthy people unexpectedly have health events requiring costly medical care, and that these uninsured individuals raise costs for hospitals and paying health insurance customers.\footnote{157 Id. at 2585.}

Justice Roberts’ majority opinion found that the Constitution “gave Congress the power to *regulate* commerce, not to *compel* it.”\footnote{158 Id. at 2589 (italics in original).} Because this law would require those persons not currently acting in the health insurance market to engage there, this law would be compelling specific commercial activity by individuals.\footnote{159 Id. at 2590.}

The proposed prescriber education requirement does not compel commerce, and therefore, is viable after the *Sebelius* ruling. Commerce related to controlled substances...
has and will occur whether or not the proposed prescriber education requirement is
enacted. The mandate would require prescribers of controlled substances to act and be
educated in prescribing, but the regulation would only be applied to practitioners who
actively choose to act themselves, by registering to prescribe controlled substances.
Unlike the uninsured actors who will be compelled to buy health insurance or pay a tax
under the Affordable Care Act “because they are doing nothing,” the prescribers that
would be regulated under the education mandate actively make the choice to prescribe
controlled substances in commerce. And, the commerce exists outside of the proposed
regulation on prescribers. Like other areas that have safety risks that cannot adequately be
controlled without federal oversight of activity, this sort of regulation of existing
commerce is constitutional.¹⁶⁰

C. States’ Plenary Police Power vs. the Commerce Clause

The proposed federal prescriber education requirement mandates professional
training for state-licensed practitioners who prescribe controlled substances. This
requirement is permitted under the Commerce Clause, but also does not undermine the
regulation of medical practice reserved to the states because, as shown in the following
cases, core provisions of the CSA have survived challenges based on states’ plenary
police power. For instance, in United States v. Collier¹⁶¹ and United States v.

¹⁶⁰ For example, state police powers traditionally include regulation of motor vehicles. But, in 1986, the
federal government passed the Commercial Motor Vehicle Safety Act to ensure that drivers of large
vehicles are qualified to do so, and to remove from highways unsafe large-vehicle drivers. Because states
had varying rules regarding drivers of large trucks and buses, it was necessary for the federal government
to involve itself. States themselves could not adequately regulate large vehicles moving between states.
Repeat criminal offenders were deterred through federal commercial drivers’ license requirements under
the Act. Like the CSA Amendment proposed in this Article, the federal commercial drivers’ license
retained the states’ authority to issue drivers licenses, but required that states meet minimum requirements.
Federal Motor Carrier Safety Administration, U.S. DEPARTMENT OF TRANSPORTATION,
Rosenberg, the Fifth and Ninth circuits, respectively, established the constitutionality of regulations under the CSA and asserted that such regulations do not invalidate the states’ police powers to regulate medicine. In Collier, Dr. Henry M. Collier appealed his conviction under the CSA for distributing methadone outside of the usual course of his professional practice based on his improper prescribing of methadone, which is a synthetic opioid. He specifically attacked § 841(a)(1) of the CSA, which applies criminal sanctions to physicians for unlawfully prescribing and dispensing controlled substances. He argued that the provision violated the Tenth Amendment by invading the state’s residual police power to control medical practice because the provision does not require a showing that the conduct of individual acts affected interstate commerce. The court held that § 801 constituted a permissible exercise of Congress’s powers under the Commerce Clause because Congress itself had already specifically determined that local distribution and possession of controlled substances have a substantial and direct effect upon interstate commerce. Therefore, the only issue on appeal was whether the CSA allowed the federal government to regulate activity without encroaching on states’ authority. The court found that the CSA was directly targeted at physicians, such as Dr. Collier, who legally had the privilege under state law to prescribe drugs. The purpose of the CSA was partially to stop individuals from diverting controlled substances from legitimate

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162 United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975).
165 Id.
166 Id. at 272.
168 Id. at 273.
169 Id. at 271-72.
channels to the illicit market. The CSA did this by creating a closed system that regulated those with access to controlled substances, including state-licensed professionals. The court noted that “Congress could reasonably decide that in order to effectively regulate interstate commerce in drugs, it is necessary to insure that persons within legitimate distribution channels, including dispensing physicians . . ., [do] not divert drugs into the illicit market.” The court found that the provision did not encroach on states’ plenary police power.

In Rosenberg, undercover agents executed a successful sting operation in Dr. Maurice W. Rosenberg’s office for prescribing controlled substances upon the patients’ requests for such medication, without performing an examination or determining whether his patients had a legitimate medical need for such medications. A jury convicted Dr. Rosenberg of 27 counts of illegally distributing schedule II, III, and IV substances under the CSA. He appealed with a number of constitutional claims, including an assertion that, under the Tenth Amendment, only the state of California could determine whether his acts were appropriate, based on the state’s purview over medical practice. He argued that the language in the CSA provision indicated Congress’s intent that the federal government rely on a state determination. The court held that the Tenth Amendment was a truism, and that, although the state clearly has the power to regulate controlled

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170 Id.
171 Id. (citing H.R. REP. No. 91-1444, at 4566, 4571-72 (1970)).
172 Id.
173 Id. at 272-73.
174 United States v. Rosenberg, 515 F.2d 190, 191 (9th Cir. 1975).
175 Id. at 191-92.
176 Id. at 198. Dr. Rosenberg claimed that the federal government must rely on the state of California’s concept of acts within the course of professional practice, because medical practice is under the purview of the states.
substances, the federal government also has concurrent, regulatory power under both its taxing authority and the Commerce Clause.\textsuperscript{177}

More recently, objections were made on Tenth Amendment grounds to a proposed CSA Amendment, under the Pain Relief Promotion Act of 1999.\textsuperscript{178} That legislation sought to amend the CSA to prohibit the use of controlled substances for physician-assisted suicide, after the State of Oregon passed the Death with Dignity Act.\textsuperscript{179} Dissenters argued that H.R. 2260 would federalize the practice of medicine, which had always been the purview of the states.\textsuperscript{180} States would not be free to act as laboratories of democracy.\textsuperscript{181} Further, opponents argued that another potential side-effect of this legislation was the politicization of medical standards.\textsuperscript{182} Ultimately, this bill failed.

Applying the \textit{Collier} and \textit{Rosenberg} precedents, a constitutional challenge against the prescriber education requirement based upon a plenary police power does argument not hold up. Whereas the CSA provisions upheld in these cases allow the federal government to regulate local activity, the prescriber education requirement would be less invasive of states’ plenary police power to control the practice of medicine. In the face of the prescription drug epidemic, instead of reserving all discretion to the federal government, the prescriber education requirement would empower states to come up with their own professional training standards targeted to better combat the diversion of prescription drugs within the boundaries of each state.

\begin{flushleft}
\textsuperscript{177} \textit{Id.}
\textsuperscript{181} \textit{Id.}
\textsuperscript{182} \textit{Id.} at 33.
\end{flushleft}
The dissenters’ words regarding the Pain Relief Promotion Act of 1999 can be used to promote the prescriber education requirement. The 1999 congressional report stated that “because the optimal approach is often not clear, our federal system encourages States to try different approaches. With local variations, the country can discover the best course of action.”\textsuperscript{183} The prescriber education mandate would require states’ active lead to create medical standards, which would promote states’ police power over health and safety. Therefore, the requirement would respond to a national crisis, but respect each state’s jurisdiction to create and implement standards for prescriber education, fit to local concerns and preferences.

IV. Attempts and Recommendations For a Prescriber Education Requirement

Practitioner education is not only a means of reducing practitioner liability; it is also a necessary step in addressing the prescription drug abuse epidemic. This section reviews the few states that currently have legislation on prescriber education, and a recent federal attempt to require education for prescribers of controlled substances.

A. State Legislation Requiring Specific Controlled Substance Education for Licensure

State licensing boards determine requirements for initial professional licensing and for license renewal in each state.\textsuperscript{184} Most states require continuing practitioner education for periodic relicensure.\textsuperscript{185} A handful of states have created laws aimed at educating practitioners in controlled substance prescribing as part of licensure or re-

\textsuperscript{183} Id.
\textsuperscript{184} See infra notes 220 - Error! Bookmark not defined. for a discussion of state continuing education requirements for re-licensing.
licensure. California and Oregon require that prescribers complete a one-time pain management course.\textsuperscript{186} Michigan requires pain and symptom management training for relicensure.\textsuperscript{187} Massachusetts requires effective pain management training to obtain or renew a license.\textsuperscript{188} Tennessee requires one of 40 relicensure education hours to be in safe prescribing practices.\textsuperscript{189} Other states, including Ohio, Rhode Island, and Texas, recommend pain management training or include it as one of the options for mandatory relicensure training.\textsuperscript{190} New Mexico requires all physicians with federal controlled-substance registrations to take five hours of continuing education on pain management each year, including lessons on the pharmacology and risks of controlled substances, and information about the problems of abuse, addiction, and diversion of medicine.\textsuperscript{191}

Yet, these few states with their varying requirements fall short of mandatory training for every practitioner prescribing controlled substances. Even if more states respond to the problem by enacting legislation, only a comprehensive solution can succeed. Short of a federal mandate, illicit abusers can obtain prescription drugs from neighboring states with fewer or less specific prescriber controls.

\textsuperscript{186} \textsc{Cal. Bus. \\& Prof. Code} § 2190.5 (a-c) (Deering 2012); \textsc{Or. Rev. Stat. An.} § 677.265 (West 2012).
\textsuperscript{187} \textsc{Mich. Comp. Laws Serv.} § 333.16204 (1-2) (LexisNexis 2012).
\textsuperscript{188} \textsc{Mass. Ann. Laws} ch. 94C, § 18(e) (LexisNexis 2012).
\textsuperscript{189} \textsc{Tenn. Comp. R. \\& Regs.} 0880-2-.19(b) (2012).
\textsuperscript{190} \textsc{Ohio Admin. Code} § 4731-21-03 (2012) (encouraging practitioners who regularly treat patients with intractable pain to complete “coursework related to pharmacology, alternative methods of pain management and treatment, and addiction medicine”); \textsc{R5-37 R.I. Code R.} § 6.2.1 (LexisNexis 2012) (including pain management as one option of continuing education topics), \textsc{Tex. Occ. Code Ann.} § 156.055 (West 2012) (encouraging practitioners who treat pain patients to include continuing medical education in pain treatment).
B. The FDA Opioid REMS

Congress granted the U.S. Food and Drug Administration (“FDA”) authority to enact Risk Evaluation and Mitigation Strategies (“REMS”) as part of the Food and Drug Administration Amendments Act of 2007 (“FDAAA”). The FDAAA authorized the FDA to require pharmaceutical manufacturers to propose strategies to mitigate certain risks of drugs that have a high or suspected high risk of abuse and overdose. The FDA may impose REMS to ensure that the benefits of a drug continue to outweigh the risks.

As originally contemplated when proposed, the REMS for long-acting and extended release opioids had a stringent education requirement for prescribers. But, the resulting opioid REMS, finalized in 2012, has a much less stringent education requirement. Prior to the opioid REMS finalization, two FDA advisory committees overwhelmingly agreed that the opioid REMS cannot meet its purpose to decrease abuse, misuse, addiction, and overdose deaths from improper use of opioid medication unless it requires mandatory prescriber education regarding safe prescribing and abuse.

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192 The FDA’s Risk Evaluation and Mitigation Strategy for Extended-Release and Long-Acting Opioids is an effort to reduce risks of these drugs by introducing new safety measures. See discussion infra Part III.b.
195 Id.
196 In April 2009, the FDA published a notice for public meeting dates to discuss a REMS for certain opioid drugs, such as fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. (Federal Register Vol. 74, No. 74 April 20, 2009 pp. 17967-70.) The Federal Register announcement requested comments on the type of education that should be provided and how the certification should be administered. (Federal Register Vol. 74, No. 74 April 20, 2009 p. 17969.) The FDA conducted a lengthy process for comment—spanning three years—to elicit feedback from the public, physicians, and manufacturers on its planned opioid REMS.
detection.\textsuperscript{198} However, the final REMS compels manufacturers of long-acting and extended-release opioids to provide product warnings to patients and offer only voluntary education programs for opioid prescribers.\textsuperscript{199} The voluntary training program will most likely be carried out through manufacturer grants to recognized continuing medical education groups that will be required to obtain FDA approval of their educational materials.\textsuperscript{200} This program is consistent with the fact that FDA is not authorized to regulate prescriber behavior or professional practice. But, because of this limitation, the opioid REMS does not properly target those who must change their behaviors to stop the epidemic. Responsible prescribers, who would be most likely to participate in such voluntary training, likely already have the resources and the know-how to avoid contributing to the problem.

The REMS is still useful because, under the “learned intermediary doctrine,” when a manufacturer warns a practitioner of the risks of a drug, the practitioner then has the duty to convey the warning to patients.\textsuperscript{201} Although the REMS does not go far enough, the opioid REMS will place a heightened duty on practitioners, suggesting one further reason for practitioners to undergo training.

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\item \textsuperscript{198} John F. Peppin, et. al., Issues and Critiques of the Forthcoming Risk Evaluation and Mitigation Strategy (REMS) for Opioids in Pain Management, 27 Issues L. & Med. 91, 102-06 (2011). Even advisory committee members who voted for the proposed REMS commented that it would not be able to address the problem, saying, “I voted yes not because I think it will work but because I think it will fail and that will force a new look at this serious problem.”; “REMS is severely flawed and I agree with all the people who voted ‘No,’ but I think we need to start somewhere.” Comments from the “No” group include, “. . . we are proposing action on people not involved in the problem.”; “This group needs to send a message to congress that what they’re getting from FDA is insufficient; the DATA 2000 is a good model of what needs to be done here.” Id. at 102-03; National Prescription Drug Abuse Prevention Strategy, CENTER FOR LAWFUL ACCESS AND ABUSE DETERRENCE, 19, (2011-2012 Update ) http://www.claad.org/.
\item \textsuperscript{199} Opioid REMS; FDA Releases Final Risk Evaluation and Mitigation Strategies (REMS) for Extended Release/Long Acting Opioids Including a Prescriber Education Program, POLICY AND MEDICINE (July 09, 2012) http://www.policymed.com.
\item \textsuperscript{200} FDA Releases Final Risk Evaluation and Mitigation Strategies (REMS) for Extended Release/Long Acting Opioids Including a Prescriber Education Program, POLICY AND MEDICINE (July 09, 2012) http://www.policymed.com.
\item \textsuperscript{201} Kennedy v. Medtronic, Inc., 851 N.E.2d 778 (Ill. App. Ct. 2006).
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C. Buprenorphine as a Model for Education Requirements

The Drug Addiction Treatment Act of 2000 ("DATA 2000") specifically requires that practitioners take eight hours of state courses to prescribe certain controlled substances in the office setting.\(^{202}\) Similarly to this Article’s prescriber education proposal, except relating only to opioid addiction treatment medications rather than to all controlled substances, this currently enacted law is a viable regulation on practitioners.\(^{203}\) DATA 2000 requires education for prescribers of Schedule III, IV, and V opioid addiction treatment medications, including buprenorphine.\(^{204}\) Prescribers can waive the requirement by proving prior education through relevant certifications or other training in prescription medication abuse detection and deterrence.\(^{205}\)

Much of the justification for federal registration to prescribe buprenorphine is applicable to a general controlled substance prescriber education requirement. The DATA 2000 House report justified its authority as an exercise of the Commerce Clause.\(^{206}\) The DATA 2000 House report cited the 600,000 heroin users in need of addiction treatment and the costs of heroin addiction to families and communities.\(^{207}\) It suggested that the framework in place under the CSA should be used to further regulate certain controlled substances with risks of abuse.\(^{208}\)


\(^{203}\) See Peppin supra note 198 at 102-06 (quoting joint advisory committee (Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee) member comments at the July 22 and 23, 2010 meetings suggesting that opioid education be modeled after the buprenorphine framework); Opioid REMS Industry Working Group Meeting with Stakeholders, U.S. FOOD & DRUG ADMIN. Slide 34 (Nov. 18, 2009) http://www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm193696.pdf

\(^{204}\) 21 U.S.C. § 823(g) (2012).

\(^{205}\) Id.


\(^{207}\) Id. at 6.

\(^{208}\) Id.
Similar to the justification for DATA 2000, the current CSA prescriber registration system can be used as the framework for a mandatory prescriber education program at a relatively low cost. Under the public interest theory of economic regulation, in the midst of a market failure due to information asymmetry, Congress should act.\textsuperscript{209} In the case of pharmaceuticals, information asymmetry occurs when manufacturers and government have more information about the appropriateness or the effectiveness of medications than prescribers and patients.\textsuperscript{210} The costs of this asymmetry in the prescription drug epidemic are enormous. Abuse of opioid pain relievers costs health insurers $72.5 billion annually in direct healthcare costs.\textsuperscript{211} If Congress were to complete a cost benefit analysis, the need for legislation similar to DATA 2000 that covers all controlled substance prescribing would be clear.

D. \textit{The Rockefeller Bill}

Realizing the need for such legislation, United States Senator Jay Rockefeller (W. Va.) introduced the Prescription Drug Abuse Prevention and Treatment Act to the Senate in March 2011.\textsuperscript{212} The bill includes a workable, mandatory prescriber education component.\textsuperscript{213} Under the prescriber education provision, the CSA would be amended to require physicians to complete 16 hours of training every three years in order to prescribe.

\textsuperscript{209} See Susan Dudley, Mercatus Policy Series: Primer on Regulation. Mercatus Center George Mason University, November 2005. p. 7-8. The public interest theory is one of many economic theories. It suggests that markets usually are efficient at allocating scarce resources, but, under certain circumstances, they may fail. The circumstances leading to market failure are externalities, overuse or under provision of public goods, monopoly power, or inadequate information. When markets fail because of these situations, politicians acting to serve the public interest should intervene and regulate. \textit{Id}.  

\textsuperscript{210} Sara Bennett, et. al., \textit{Public-Private Roles in the Pharmaceutical Sector - Implications for Equitable Access and Rational Drug Use - Health Economics and Drugs Series}, No. 005, World Health Organization, 1997 available at \url{http://apps.who.int/medicinedocs/pdf/whozip27e/whozip27e.pdf}.  


\textsuperscript{213} \textit{Id}.
methadone or other controlled substances.\textsuperscript{214} The training would be provided by an expert medical pain society\textsuperscript{215} and would specifically cover: “(i) the treatment and management of opioid-dependent patients; (ii) pain management treatment guidelines; and (iii) early detection of opioid addiction, including through such methods as Screening, Brief Intervention, and Referral to Treatment (“SBIRT”).”\textsuperscript{216} Enforcement would be funded through use of a portion of the DEA registration fee for prescribers.\textsuperscript{217}

Since its introduction, Congress has read the Rockefeller bill twice and referred it to a Committee.\textsuperscript{218} However, the bill is unlikely to pass in the 112th Congress. In the 113th Congress, the Rockefeller bill could be strengthened by focusing solely on the prescriber education component and by including specific training requirements on the risks of all controlled substances, not just opioids.\textsuperscript{219} Moreover, the current bill does not mention implementation by the states, so it would probably be administered directly through the federal government. Instead, the bill should suggest that the prescriber

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\item \textsuperscript{214} Id. at § 4.
\item \textsuperscript{215} Id. Under the proposed bill, the training would be provided by “the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, the American Academy of Pain Management, the American Pain Society, the American Academy of Pain Medicine, the American Board of Pain Medicine, the American Society of Interventional Pain Physicians, or any other organization that the Secretary determines is appropriate for purposes of this subparagraph.”
\item \textsuperscript{216} Id. SBIRT is aimed at stopping substance abuse before it becomes serious. Patients in health care venues are quickly screened to assess their alcohol and drug use. If they are deemed at risk, they receive an intervention to “rais[e] their awareness of substance abuse and motivate[e] them to change their behavior.” Rebecca A. Clay, Screening, Brief Intervention, and Referral to Treatment: New Populations, New Effectiveness Data 17 SAMSA NEWS (Nov./Dec. 2009), http://www.samhsa.gov/samhsanewsletter/Volume_17_Number_6/SBIRT.aspx.
\item \textsuperscript{218} THOMAS http://thomas.loc.gov/ (last accessed Aug. 25, 2012).
\item \textsuperscript{219} Described as “ambitious,” the bill takes on seven opioid prescribing topics. Larry H. Houck, Legislative Fixes Focus on Controlled Substance Issues, FDA LAW BLOG (Mar. 22, 2011), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/03/legislative-fixes-focus-on-controlled-substance-issues.html. Beyond the prescriber education piece, the bill includes: consumer education, a moratorium on large dose methadone hydrochloride tablets, access requirements for opioid treatment programs, clinical standards for controlled substances, state drug monitoring program requirements for answering drug enforcement information requests, and mortality reporting. S. 507, 112th Cong. (2011). Detractors of the further reach of drug enforcement would especially dislike the component requiring that state prescription monitoring programs receiving federal money in exchange for compliance with drug enforcement information requests.
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education be carried out through the existing state education framework for practitioners. Additionally, the mandatory controlled substances education should be required to occur before a practitioner can register to prescribe these substances in addition to later training.

In sum, this Part of the Article gives examples of attempts at educating prescribers in controlled substance prescribing that can be used to inform how the proposed CSA Amendment should be formulated.

V. THE NECESSARY SOLUTION: PRACTICAL COMPONENTS OF THE FEDERAL STATUTE

Under current state health systems, requirements for initial medical licensing vary by state. For medical license renewal, most states require practitioners to complete continuing medical education. The average number of state-mandated, continuing medical education credits per year range from 15 to 50 credits. Many states have further requirements for the content of these credits.

This Part first makes recommendations for the proposed Amendment. Then it uses Massachusetts, a state that already requires controlled substance education for prescribers, as a model to show how the new federal requirement would be seamless. It uses Virginia, a state that currently requires continuing medical education, but does not require education for controlled substance prescribers, as a model for how the new mandate would fit into a system that currently does not require such training. It also looks at states that have no continuing medical education requirements to see how such a mandate would work in those states.

220 The Federation of State Medical Boards (FSMB) website lists requirements for licensure by state. See State-Specific Requirements for Initial Medical Licensure FEDERATION OF STATE MEDICAL BOARDS http://www.fsmb.org/usmle_elininitial.html (last updated July 2010).
222 See id.
A. Specific Recommendations for the Prescriber Education Requirement

The prescriber education requirement could be inserted as Section 3 of 21 U.S.C. § 823(g). It could be modeled particularly after the current education component in the Rockefeller bill\(^{223}\) and the buprenorphine prescriber education requirements.\(^{224}\) Like the buprenorphine waiver,\(^{225}\) prescribers with demonstrated knowledge or training should be exempted from further requirements. Competence in an area may be demonstrated through awarded recognition or by those who have a specific medical certification, such as pain medicine or addiction medicine, or recognized specialty such as anesthesiology.

The prescriber education mandate should require controlled substance education before a prescriber can register with the DEA to prescribe controlled substances, as well as for registration renewal. Practitioners taking courses in safe controlled substance prescribing and abuse prevention while attending an accredited medical school should be deemed to meet the initial education requirement for prescribing controlled substances. When crafting the legislation, experts should determine a minimum number of course hours necessary per registration term for prescribers of controlled substances. The safe prescribing and abuse prevention courses should be integrated into education courses practitioners already must take to meet state licensing requirements, without taking more courses than they already take for licensure. State licensing boards should approve the specific content of the controlled substances education program for each class of prescribers (i.e., physicians, physician assistants, and nurse practitioners) in their state and would be able to require further hours than federally mandated, if preferred to meet state licensure or controlled substance prescribing standards.

\(^{223}\) See supra Part III.d.
\(^{224}\) See supra Part III.c.
\(^{225}\) Id.
The prescriber education legislation should also add a section under 21 U.S.C. § 843 of the CSA on prohibited acts, which would prohibit misstatement of facts to the DEA regarding prescriber controlled substance education. The penalties currently in force in that section would then apply.\footnote{The penalties for a first-time offender include imprisonment for up to four years, a fine, or both. 21 U.S.C. § 841(d) (2012).} As with most actions under the CSA against prescribers, the DEA would investigate controlled substance prescribers’ compliance based on tips or complaints that usually emanate from the state.\footnote{See H.R. REP. NO. 106-378, pt. 1, at 4 (1999) (stating that civil actions revoking a practitioner’s license are hardly ever initiated by the DEA. Usually, state action precipitates the DEA’s initiation of a civil action).} In investigating complaints, the DEA should work with the relevant state medical board to determine whether the federal documentation requirements for controlled substance education were met. For instance, in Virginia, pursuant to an investigation request, the process for obtaining the physician’s documentation of training could be similar to what is now utilized for the random auditing process for continuing medical education.\footnote{See 18 VA. ADMIN. CODE § C85-20-235 (D) (2012).} As included in the Rockefeller bill, funding for enforcement could be drawn from a portion of the prescriber registration fees or it could be drawn through funding currently available for DEA enforcement.

B. Massachusetts as a Model

In Massachusetts, prescribers must take 100 credits of continuing professional development every two years with at least 40 hours in Category 1, which are courses accredited by certain medical organizations listed in the Massachusetts statute.\footnote{243 MASS. CODE REGS. 2.06(6) (2012).} Massachusetts also has various stipulations on the content of the continuing education. At least 51 of the credits must be in the practitioner’s primary areas of practice, with
additional requirements of ten hours in risk management, two hours focusing on the board’s regulations, and two hours in end-of-life-care issues.\footnote{Id.}

Moreover, Massachusetts is one of the few states that already requires pain management and opioid education before practitioners initially receive or renew their professional license. Three education hours must encompass “(i) effective pain management; (ii) identification of patients at high risk for substance abuse; and (iii) counseling patients about the side effects, addictive nature, and proper storage and disposal of prescription medications.”\footnote{Id.} The law directs each related licensing board to develop appropriate standards for such training.\footnote{Id.} Massachusetts offers a free online course that meets the statutory education requirement.\footnote{SAFE AND EFFECTIVE OPIOID PRESCRIBING FOR CHRONIC PAIN, www.opioidprescribing.com (last visited Sept. 3, 2012).}

Enactment of a new federal education requirement would likely fit seamlessly into Massachusetts’ current education scheme because Massachusetts has robust prescriber education requirements. If the federal requirements were more stringent or required further hours of controlled substance education on average per year, Massachusetts practitioners would need to meet the further federal requirements that go beyond the current state scheme.

C. **Virginia as a Model**

The Virginia Board of Medicine requires 60 hours of “continued competency requirements” every two years.\footnote{18 VA. ADMIN. CODE § C85-20-235 (A) (2012) (entitled “Continued competency requirements for renewal of an active license”).} Practitioners are free to determine the contents of the
curriculum, with the following few restrictions. The Board requires at least 30 “Type 1” hours in “activities or courses offered by an accredited sponsor or organization sanctioned by the profession.” The rest of the Virginia credits may be “Type 2,” which are “chosen by the licensee to address such areas as ethics, standards of care, patient safety, new medical technology, and patient communication.” These may be earned through self study, medical publications, attending professional meetings, learning new procedures, sitting on medical ethics panels, and so forth. Newly licensed physicians are exempted from the 60 hour requirement.

In Virginia, physicians who are not trained in prescribing controlled substances while in medical school can still obtain their medical licenses. No further medical education is required for licensure until completing the requirements for re-licensure by the fourth year of practice. Under the prescriber education requirement, Virginia practitioners desiring to prescribe controlled substances would need to complete an education course designed or recognized by Virginia. The Virginia Board of Medicine would need to ensure that Virginia’s available courses meet the educational standard for registration under the CSA. The training would need to occur before initial controlled substance registration and as part of a practitioner’s required 60 hours of training every two years. Prescribers who have taken a qualifying class in medical school before initial licensure or who are otherwise specifically recognized, certified, or of a qualifying specialty, would be deemed to satisfy the requirement.

239 18 VA. ADMIN. CODE § C85-20-235 (B) (2012).
D. States without Continuing Medical Education Requirements

Some states do not currently require continuing medical education at all. Colorado, Indiana, Montana, New York, South Dakota, and Vermont have no requirement, although Vermont has new legislation that will go into effect in 2014.²⁴⁰ Although state-specific education efforts targeting the local environment are preferable, the prescriber education requirement could include stipulations under which prescribers in states without education requirements could substitute a program from a nationally accredited program recognized under the federal law. Like the Rockefeller bill, the CSA amendment could defer to the judgment of credible medical organizations, such as the American Medical Association, the American Society of Anesthesiologists, and the American Society of Addiction Medicine, in defining the programs in addition to those that are state approved.

VI. Benefits of the Proposed Prescriber Education Requirement: Education to Empower Physicians to Prescribe Appropriately, Improve Patient Treatment, and Reduce Liability

An education requirement, through the longstanding, stable state-regulated health systems, recognizes the importance of protecting states’ rights to govern the practice of medicine and other professions. The epidemic status of the prescription drug abuse problem suggests that swift, coordinated action among government authorities is necessary.

Opponents of an education mandate suggest that such a requirement would make prescribers fearful of criminal liability, and that it would cause many practitioners to

eliminate controlled substance prescribing from their practices. The resulting reduction in numbers of prescribers, in turn, is claimed to limit access to medications for patients suffering with pain or other conditions for which controlled substances are prescribed. On the contrary, educated physicians can make healthier prescribing decisions for patients and will counsel patients on proper use of controlled substances. Rather than reducing access to controlled substances, practitioners will be empowered through training to prescribe drugs without fear. Those unwilling to obtain education in safe prescribing pose a threat to patients and should not be prescribing controlled substances.

Controlled substance prescribers who follow their state-based training can take comfort in learning medical board investigation practices and negligence case law, which protect practitioners who implement reasonable precautions to prevent diversion, misuse, and abuse. Accordingly, practitioners who complete training programs and follow state guidance should have a strong defense if they ever face an investigation or a prescribing liability case.

Opponents of practitioner education suggest agreement on controlled substance prescribing standards is impossible because of the varying opinions in the medical

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242 Id.
243 See discussion supra note 44.
community.\textsuperscript{244} Physicians do face uncertainty when even experts cannot agree. But, not acting will not solve the problem for patients, practitioners, or the public. The reasonable care standard for physicians is defined as the standard recognized by other professionals in the community.\textsuperscript{245} State-based education programs present an opportunity to develop appropriate standards for different locales and situations.\textsuperscript{246} It is important that prescribers take steps to educate themselves so that they can stay abreast of evolving standards and shield themselves from liability.

Without a workable solution to the prescription drug abuse epidemic, patients, prescribers, and manufacturers may face even tighter controls that could further threaten the availability and marketability of medications that have potential for diversion, misuse, and abuse. With proper training, physicians will be able to prescribe (or not prescribe) with confidence. Greater education and certainty will increase access to medications for legitimate patients, equip physicians to better educate those patients, and reduce physicians’ chances of liability for inappropriate prescribing.

Conclusion

The federal government must take action aimed directly at the reducing the diversion of prescription medications. Enacting a mandatory prescriber education requirement under the CSA that respects states’ plenary police powers and that is consistent with the federal government’s authority under the Commerce Clause and Necessary and Proper Clause can properly address this epidemic at the first point of


\textsuperscript{245} See supra note 39.

\textsuperscript{246} See supra notes 180 - 183.
failure: where a physician improperly writes a prescription for a controlled substance because he does not know any better.