THE DISPARATE TREATMENT OF ADDICTION-ASSISTANCE MEDICATIONS AND OPIATE PAIN MEDICATIONS UNDER THE LAW: PERMITTING THE PROLIFERATION OF OPIATES AND LIMITING ACCESS TO TREATMENT

Melissa M. Ferrara[*]

I. INTRODUCTION

Although praised for their effectiveness in managing pain, opiate pain medications have also incited debate concerning their addictiveness.[1] Our legal system, charged with striking a balance between adequate access to pain medications and the prevention and treatment of potentially corresponding drug abuse, has severely restricted access to addiction-assistance medications while, at the same time, has placed much more relaxed limitations on access to opiate pain medications.[2] Society's view of drug addicts may explain this imbalance, but addicts may use both types of medication either to feed or to treat their addictions.

OxyContin is an opiate pain medication that is designed to treat patients with around-the-clock moderate-to-severe pain.[3] OxyContin is formulated to slowly release its active ingredient, an opioid called oxycodone, to relieve patients' pain.[4] Each tablet contains a large quantity of oxycodone, "allow[ing] patients to take their drug less often—a distinct benefit for patients who are in chronic pain."[5] In

[*] J.D., May 2012, Seton Hall University School of Law; B.A., 2004, American University; M.A., 2005, Rutgers University. The author wishes to thank the members of the Seton Hall Law Review and Kate Greenwood for their help in drafting this Comment. The author would also like to thank her first friend for motivating her to bring this issue to light.

[1] *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., SUBSTANCE ABUSE TREATMENT ADVISORY, PUB. NO. (SMA) 06-4138, OXYCONTIN: PRESCRIPTION DRUG ABUSE-2006 REVISION 2 (2006), *available at* http://kap.samhsa.gov/products/brochures/advisory/pdfs/Oxycontin-Advisory.pdf.

[2] *See infra* Part III.A–C.

[3] *OxyContin—Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Apr. 5, 2010), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm. [hereinafter *OxyContin—Questions and Answers*].

[4] *Id.*

[5] *Id.*

2009, physicians wrote 6.2 million prescriptions for OxyContin, and its retail sales reached three billion dollars.[6]

When a user breaks, cuts, or chews OxyContin pills, however, their time-release property is destroyed, and the user immediately receives the full dose of oxycodone.[7] In 2009, 584,000 people age twelve or older became "new nonmedical users" of OxyContin.[8] A 2008 study found that 2.1% of eighth graders, 3.6% of tenth graders, and 4.7% of twelfth graders had abused OxyContin for nonmedical purposes at least once in the year prior to being surveyed.[9] Between 2004 and 2008, emergency room visits for oxycodone products increased 152%.[10] Among persons age twelve and older, only marijuana use is a more prevalent form of drug abuse than that of pain relievers.[11]

The Food and Drug Administration (FDA) has approved three drugs to assist patients in combating opiate addictions: methadone, buprenorphine (in two formulations, Subutex and Suboxone), and naltrexone.[12] Naltrexone is also available in an injectable, time-release formula called Vivitrol.[13] All three drugs treat addiction to

---

[6] U.S. FOOD & DRUG ADMIN., ANNUAL U.S. OXYCONTIN PRESCRIPTIONS (MILLIONS) (2010), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM220954.pdf.

[7] *OxyContin—Questions and Answers*, *supra* note 3.

[8] U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. NO. SMA 10-4586, RESULTS FROM THE 2009 NATIONAL SURVEY ON DRUG USE AND HEALTH: VOLUME I. SUMMARY OF NATIONAL FINDINGS 58 (2010), *available at* http://www.oas.samhsa.gov/NSDUH/2k9NSDUH/2k9ResultsP.pdf.

[9] NAT'L INSTS. OF HEALTH, PRESCRIPTION AND OVER-THE-COUNTER MEDICATIONS 7 (2009), *available at* https://www.drugabuse.gov/sites/default/files/painmed09.pdf.

[10] SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., THE DAWN REPORT: TRENDS IN EMERGENCY DEPARTMENT VISITS INVOLVING NONMEDICAL USE OF NARCOTIC PAIN RELIEVERS 1 (2010), *available at* http://oas.samhsa.gov/2k10/DAWN016/OpioidEdHTML.pdf.

[11] *Id.*

[12] PHYSICIANS & LAWYERS FOR NAT'L DRUG POLICY, ALCOHOL AND OTHER DRUG PROBLEMS: A PUBLIC HEALTH AND PUBLIC SAFETY PRIORITY 40–41(2008), *available at* http://www1.spa.american.edu/justice/document.php?ID=2434; *see also* Gregory B. Collins & Mark S. McAllister, *Buprenorphine Maintenance: A New Treatment for Opioid Dependence*, 74 CLEVELAND CLINIC J. MED. 514, 514–16 (2007) (describing use of buprenorphine and methadone in treating opioid dependence); Patrick G. O'Connor & David A. Fiellin, *Pharmacologic Treatment of Heroin-Dependent Patients*, 133 ANNALS INTERNAL MED. 40, 44–47 (2000) (describing use of naltrexone in treating opioid dependence).

[13] Caleb Hellerman, *FDA OKs Drug to Fight Opiate Addiction*, CNN HEALTH CHART BLOG (Oct. 12, 2010, 6:53 PM), http://pagingdrgupta.blogs.cnn.com/2010/10/12/fda-oks-drug-to-fight-opiate-addiction/?iref=allsearch.

opiates, including heroin and prescription medications like OxyContin.[14] Methadone is a long-lasting, synthetic opioid medication that prevents withdrawal, blocks the euphoric effects of heroin and prescription opiates, and decreases cravings.[15] Methadone is an opioid agonist,[16] which means that it mimics the effects of the abused opiate.[17] "Buprenorphine is an opioid partial agonist," which means that it can produce the effects of an agonist (i.e., euphoria and respiratory depression), but its maximum agonistic effect is much less than that of a full agonist like methadone.[18] Buprenorphine also reduces cravings, blocks the effect of heroin and other opiates, reduces adverse symptoms associated with withdrawal, and has a long duration of action.[19] Unlike methadone or buprenorphine, naltrexone is an opioid antagonist, which means that it blocks receptors in the brain to prevent users from obtaining the euphoric effects of heroin and other opiates.[20] By depriving the patient of the abused opiate's effects, naltrexone works to break the habit of opiate addiction.[21]

In 2006, recognizing the need to combat opiate addiction, the World Health Organization (WHO) added methadone and buprenorphine to its Fourteenth Model List of Essential Medicines.[22] Although physicians in the United Kingdom, France, and Australia have utilized addiction-assistance medications as an effective tool to treat opiate dependence,[23] the same has not been true in the United

[14] PHYSICIANS & LAWYERS FOR NAT'L DRUG POLICY, *supra* note 12, at 39.

[15] David A. Fiellin & Patrick G. O'Connor, *New Federal Initiatives to Enhance the Medical Treatment of Opioid Dependence*, 137 ANNALS INTERNAL MED. 688, 688 (2002); O'Connor & Fiellin, *supra* note 12, at 45–46; NAT'L INSTS. OF HEALTH, NIH PUB. NO. 99-4180, PRINCIPLES OF DRUG ADDICTION TREATMENT: A RESEARCH-BASED GUIDE 37 (2d. ed. 2009), *available at* https://www.drugabuse.gov/sites/default/files/podat_0.pdf.

[16] *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., THE DASIS REPORT: PLANNED METHADONE TREATMENT FOR HEROIN ADMISSIONS 1 (2003), *available at* http://www.samhsa.gov/data/2k3/MethadoneHtx/methadoneHtx.pdf.

[17] GOODMAN AND GILMAN'S MANUAL OF PHARMACOLOGY AND THERAPEUTICS 14 (Laurence Brunton, et al. eds., 2008).

[18] *About Buprenorphine Therapy*, CSAT BUPRENORPHINE INFO. CENTER, http://buprenorphine.samhsa.gov/about.html (last visited March 12, 2012).

[19] Hendree E. Jones, *Practical Considerations for the Clinical Use of Buprenorphine*, SCI. & PRAC. PERSP., Aug. 2004, at 4, 4–5, *available at* http://www.naabt.org/documents/Practical_Conciderations%20.pdf.

[20] PHYSICIANS & LAWYERS FOR NAT'L DRUG POLICY, *supra* note 12, at 41.

[21] NAT'L INST. OF HEALTH, *supra* note 15, at 40.

[22] WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 21 (14th ed. 2005), *available at* http://whqlibdoc.who.int/hq/2005/a87017_eng.pdf.

[23] Fiellin & O'Connor, *supra* note 15, at 691 (describing opioid agonist maintenance treatment in the United Kingdom, Australia, and France).

States.[24] In the United States, an imbalanced legal structure permits the wide dissemination of highly addictive pain medications, but limits access to addiction-assistance medications. This imbalance explains the underutilization of addiction-assistance medications in the United States.

This Comment argues that the incongruent legal treatment of addiction-assistance medications in comparison to opiate pain medications is a flawed system because it increases access to opiates while limiting access to addiction assistance. This Comment will use OxyContin as an illustration of all opiate pain medications because it is so widely abused and because of the controversy surrounding the product's design.[25] Part II will explain the legal framework under which all medications fall, highlighting in particular the statutes that are applicable to this analysis. Part III will discuss the statutes and regulations that apply to OxyContin, methadone, and buprenorphine, focusing on important differences and incongruities between the two legal structures. Notably, both methadone and buprenorphine are regulated more heavily than OxyContin despite the fact that methadone is in the same controlled substance schedule as OxyContin and buprenorphine is in a less restrictive controlled substance schedule. Part IV will recommend changes that will ameliorate the disparate treatment of these medications, addressing the supply and demand sides of this problem and highlighting the Washington state model, which requires physicians to refer patients to pain specialists once their pain requires a certain dosage of an opiate pain reliever, as an example. This Comment does not advocate restricting access to pain medications for those in legitimate need, but it does question the logic of permitting the wide dissemination of drugs like OxyContin and, simultaneously, severely restricting access to methadone and buprenorphine.

[24] James L. Nolan, Jr., *Harm Reduction and the American Difference: Drug Treatment and Problem-Solving Courts in Comparative Perspective*, 13 J. HEALTH CARE L. & POL'Y 31, 36–37 (2010).

[25] *Cf.* Jennifer Corbett Dooren, *FDA Approves Reformulated OxyContin*, WALL ST. J. (Apr. 6, 2010), http://online.wsj.com/article/SB10001424052702304620304575166391268139192.html (reporting that the FDA approved a reformulated version of OxyContin on April 5, 2010, which is supposed to be more tamper resistant).

II. THE REGULATORY FRAMEWORK FOR PRESCRIPTION MEDICATIONS

Federal and state laws make up the legal framework for all medications.[26] The two pertinent federal statutes are the Food, Drug and Cosmetic Act (FDCA)[27] and the Controlled Substances Act (CSA).[28] State controls on physician licensing also contribute to the legal structure.[29] In addition, many states have adopted the Uniform Controlled Substances Act (UCSA)[30] and/or a law, like the Pain Relief Act,[31] guarding the right to pain medication.[32]

In 1938, Congress passed the FDCA.[33] The FDA administers the FDCA,[34] and it is responsible for determining the safe and effective use of prescription medications.[35] Drug research, testing, and clinical trials make up the drug approval process.[36] The process begins with the drug manufacturer conducting various laboratory and animal tests.[37] Next, the manufacturer conducts testing with humans.[38] After the tests, the manufacturer submits a New Drug Application, which includes the test results, to the Secretary of Health and Human Services.[39] The FDA's physicians and scientists review the application.[40]

---

[26] David E. Joranson & Aaron Gilson, *Controlled Substances, Medical Practice, and the Law*, *in* PSYCHIATRIC PRACTICE UNDER FIRE: THE INFLUENCE OF GOVERNMENT, THE MEDIA AND SPECIAL INTERESTS ON SOMATIC THERAPIES 173, 175–90 (Harold I. Schwartz ed., 1994).

[27] 21 U.S.C §§ 301–399d (2006).

[28] *Id.* §§ 801–971.

[29] *See generally Becoming a Physician: Medical Licensure*, AM. MED. ASSOC., http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure.shtml (last updated April 17, 2011).

[30] UNIF. CONTROLLED SUBSTANCES ACT (1994).

[31] The Pain Relief Act, 24 J. L. MED. & ETHICS 317(1996).

[32] *See generally Database of State Statutes, Regulations, and Other Official Governmental Policies*, PAIN & POL'Y STUD. GROUP, http://www.painpolicy.wisc.edu/matrix.htm (last updated Dec. 7, 2011) (containing a matrix of all state statutes, regulations, and guidelines concerning controlled substances and pain)[hereinafter *Database of State Statutes*].

[33] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

[34] 21 U.S.C. § 301 (2006).

[35] *See id.* § 355(a).

[36] Kimani Paul-Emile, *Making Sense of Drug Regulation: A Theory for Drug Control Policy*, 19 CORNELL J.L. & PUB. POL'Y 691, 698 (2010).

[37] *What Is the Approval Process for a New Prescription Drug?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194949.htm (last visited Jan. 27, 2012) [hereinafter *What Is the Approval Process for a New Prescription Drug?*].

[38] *Id.*

[39] *Id.*; § 355(b).

[40] *What Is the Approval Process for a New Prescription Drug?*, *supra* note 37.

If they determine that the drug's benefits outweigh its known risks and that the drug can be manufactured in a way that ensures a quality product, then the FDA approves the drug and the manufacturer can market it in the United States.[41] As of 2007, the FDA is authorized to require an applicant to adopt a Risk Evaluation and Mitigation Strategy (REMS) if the FDA determines that such a strategy is necessary to ensure that the drug's benefits outweigh its risks.[42]

Congress passed the Comprehensive Drug Abuse Prevention and Control Act of 1970 as the first universal drug legislation.[43] Title II of the Act is the CSA,[44] which classifies controlled substances into five schedules.[45] Schedule placement depends on a controlled substance's legitimate medical value, the risk for abuse, and its potential addictiveness.[46] A controlled substance's schedule dictates the degree of restriction with which the FDA treats each substance.[47] Schedule I controlled substances, like heroin and lysergic acid diethylamide (LSD),[48] are strictly prohibited, while Schedule V controlled substances are the least restricted and include commonly used painkillers like Codeine.[49]

The Drug Enforcement Administration (DEA), part of the United States Department of Justice, administers the CSA.[50] The DEA must consult with the FDA before scheduling a drug as a controlled substance.[51] Because the FDA's recommendations on the scientific and medical value of a drug are binding on the DEA, the DEA cannot schedule a drug if the FDA recommends otherwise.[52]

The DEA may establish total quantity and production quotas for Schedule I and Schedule II drugs.[53] When establishing quotas, the

---

[41] *Id.*

[42] 21 U.S.C. § 355-1(a) (2006).

[43] *1970-1975*, U.S. DRUG ENFORCEMENT ADMIN., http://www.justice.gov/dea/pubs/history/deahistory_01.htm (last visited Nov. 9, 2011).

[44] 21 U.S.C. §§ 801–971 (2006).

[45] § 812(a).

[46] Paul-Emile, *supra* note 36, at 698; *see* § 812(b).

[47] *See* § 812(b); Dispensing of Controlled Substances to Residents at Long Term Care Facilities, 75 Fed. Reg. 37,463, 37,464 (June 29, 2010).

[48] § 812(c).

[49] *See* Dispensing of Controlled Substances to Residents at Long Term Care Facilities, 75 Fed. Reg. 37,464 (June 29, 2010).

[50] Exec. Order No. 11,727, 38 Fed. Reg. 18,357 (July 6, 1973).

[51] PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 719 (3d ed. 2007).

[52] 21 U.S.C. § 811(b) (2006).

[53] *Id.* § 826; Western Fher Laboratories v. Levi, 529 F.2d 325, 327 (1st Cir. 1976).

Attorney General considers, but is not limited to, the disposal rates of the manufacturer, national trends of disposal, inventory and production cycles, the drug's stability, the availability of raw materials used in the manufacture of the drug, and emergencies, such as strikes and fires.[54]

Anyone who wishes to dispense controlled substances, such as a physician, a hospital, or a pharmacy, must register with the DEA.[55] To be eligible to obtain a registration, a practitioner must be licensed or otherwise authorized to dispense controlled substances under the laws of the state in which he or she practices.[56] DEA registration and the CSA permit the practitioner to dispense controlled substances to the extent that they are authorized under the law.[57]

The CSA also requires registrants to maintain a current and complete record of each controlled substance that they have dispensed.[58] The drug's schedule determines whether the physician may provide an oral prescription to a pharmacist or whether a written prescription is required.[59] If a practitioner violates any requirements under the CSA or if his or her license has been suspended, revoked or denied, the Attorney General can take legal action to suspend or revoke the practitioner's DEA registration.[60]

In addition to the federal statutory structure for medications, state laws and licensing requirements create the legal framework for prescribers.[61] In general, each state has a medical board charged with setting physician, hospital, and pharmacy licensing requirements and with evaluating applicants to ensure that they meet those requirements.[62] Licensure requirements vary from state to state, but they generally include meeting certain education and training requirements, passing an examination demonstrating competency to practice medicine, and a background check to verify professional competence, ethics, and character.[63]

---

[54] § 826(c).

[55] *Id.* § 822(a); 21 C.F.R. § 1301.11 (2012).

[56] *Id.* § 823(f)

[57] § 822(b).

[58] *Id.* § 827(a).

[59] *See id.* § 829.

[60] *Id.* § 824.

[61] Joranson & Gilson, *supra* note 26, at 175.

[62] Dispensing of Controlled Substances to Residents at Long Term Care Facilities, 75 Fed. Reg. 37,467 (June 29, 2010).

[63] *Id.*

Many states have adopted, in whole or in part, two model statutes in the drug-regulation area—the Uniform Controlled Substances Act (UCSA) and the Pain Relief Act.[64] The National Conference of Commissioners on Uniform State Statutes drafted the UCSA in 1994 to maintain uniformity between the laws of the states and the federal government and to provide guidance on how the federal and state laws should interact for the best use of government resources.[65] The UCSA also "provides law enforcement tools to improve investigative efforts and provides for education and training programs relating to the drug abuse problem."[66] The UCSA scheduling is identical to that contained in the CSA.[67] The UCSA provides states with discretion, including setting penalties for violations of the Act; requiring manufacturers, distributors, and dispensers of controlled substances to register with the appropriate state authority; setting the parameters for obtaining registration; and setting the grounds for suspension or revocation of registration.[68]

The Pain Relief Act is another model statute.[69] Its goals are to protect physicians who prescribe pain medications from prosecution or disciplinary or licensing actions and to protect patients' access to pain medication.[70] The Act does not protect practitioners who fail to maintain required records, write false prescriptions, or illegally divert medications for non-medical uses.[71] The Act refers to addiction and chemical dependency once, but it does so in the context of protecting access rather than expressing concern for abuse.[72] The Act provides that all patients are entitled to the same access to pain relief medication "regardless of the patient's prior or current chemical dependency or addiction."[73] The drafters, however, afford states the discretion to appoint an appropriate state body to develop standards and procedures "for the application of this Act to the care and treatment of chemically dependent individuals."[74]

---

[64] *See Database of State Statutes*, *supra* note 32.
[65] UNIF. CONTROLLED SUBSTANCES ACT Prefatory Note, at 1 (1994).
[66] *Id.* Prefatory Note, at 2.
[67] *See id.* §§ 201–212.
[68] *Id.* §§ 301–305, 401.
[69] The Pain Relief Act, 24 J. L. MED. & ETHICS 317(1996).
[70] *See id.* at 318.
[71] *Id.* (see Sec. 4.a. –d.).
[72] *Id.* (see Sec. 3.3).
[73] *Id.*
[74] *Id.*

III. COMPARING OXYCONTIN'S REGULATORY FRAMEWORK WITH THAT FOR METHADONE AND BUPRENORPHINE

Federal regulations of methadone and buprenorphine are much more stringent than those of OxyContin.[75] Although the DEA has scheduled methadone and OxyContin identically, and despite the DEA scheduling buprenorphine in a less restrictive schedule than OxyContin, the addiction-assistance medications are subject to dosage restrictions, patient limitations, and special physician registration requirements that do not apply to OxyContin and its prescribers.[76]

A. OxyContin

The FDA initially approved OxyContin on December 12, 1995.[77] In 2010, the FDA approved a new formulation of OxyContin.[78] The new pill was designed to resist efforts to circumvent its controlled-release property.[79] The effectiveness of the new design remains unknown.[80] Like methadone, OxyContin is a Schedule II drug under the CSA.[81] Although Schedule II drugs have a high potential for abuse, they also have a "currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions."[82] Severe psychological or physical dependence may result from the abuse of a Schedule II controlled substance.[83] The CSA provides that, except in emergency situations, a pharmacy may only dispense a Schedule II controlled substance pursuant to a practitioner-signed written prescription.[84]

---

[75] *See infra* Part III.A–C.

[76] *See infra* Part III.A–C.

[77] *OxyContin: Balancing Risks and Benefits: Hearing Before the S. Comm. on Health, Educ., Labor and Pensions*, 107th Cong. 14 (2002) (statement of John K. Jenkins, Dir., Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Admin.) [hereinafter Jenkins].

[78] *See* Letter from Bob A. Rappaport, Dir. Div. of Anesthesia and Analgesia Products, Center for Drug Evaluation and Research, to Craig Landau, Chief Med. Officer & Vice President, Clinical, Med. & Reg. Affairs, Purdue Pharma, (Apr. 5, 2010), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/022272s000ltr.pdf.

[79] *See id.*

[80] *See New Tamper-Resistant OxyContin Tablets to be Released August 2010*, NAT'L ASS'N BOARDS PHARMACY (Aug. 19, 2010, 11:04 AM), http://www.nabp.net/news/new-tamper-resistant-oxycontin-tablets-to-be-released-august-2010/.

[81] Jenkins, *supra* note 77.

[82] 21 U.S.C. § 812(b)(2)(A)–(C) (2006).

[83] § 812(b)(2)(C).

[84] *Id.* § 829(a).

In contrast to the addiction-assistance medications discussed below,[85] prescribers of OxyContin must comply with only one regulatory limitation.[86] It is a supply limitation, and an exception in the regulation loosens it.[87] Although the CSA prohibits the refill of prescriptions for Schedule II controlled substances,[88] the DEA has issued a regulation that allows practitioners to issue multiple prescriptions at a time, which means that a physician can provide a patient with up to three thirty-day prescriptions of OxyContin at once.[89] Despite OxyContin's and methadone's identical classification, this exception does not apply to methadone.[90]

Although methadone and OxyContin are both Schedule II substances and although buprenorphine is in a less restrictive classification than both, only the addiction-assistance medications require a practitioner to meet a special DEA registration requirement.[91] Therefore, *any* practitioner who has registered with the DEA can prescribe OxyContin, and no practitioner is under any obligation to meet any training requirements to prescribe OxyContin.

The OxyContin REMS requires that the manufacturer send training materials, including information on patient selection, dosing, risks, and addiction, to healthcare professionals.[92] The training packet includes an OxyContin Education Confirmation Form.[93] The manufacturer maintains a list of the prescribers who submit the form.[94] While a prescriber's signature on the form confirms that he or she "read the REMS Education Materials for OxyContin and understand[s] the major risks associated with OxyContin and how to appropriately select and educate patients to whom OxyContin is prescribed," failure to complete the form does not affect a physician's ability to prescribe the drug.[95] The OxyContin REMS also requires the drug manufacturer to provide prescribing information and a medication guide with each bottle of the drug and imposes labeling

[85] *See infra* Part III.B–C.

[86] *See* 21 C.F.R. § 1306.12 (2012).

[87] *See id.*

[88] § 829(a).

[89] § 1306.12.

[90] *See id.*

[91] 21 U.S.C. § 823(g)(1) (2006).

[92] PURDUE PHARMA, OXYCONTIN RISK EVALUATION MITIGATION STRATEGY 2 (2010), http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf.

[93] *Id.* at 3.

[94] *Id.*

[95] *Id.* at 35.

requirements.[96] The REMS also advises prescribing physicians to inform patients to flush unused tablets down the toilet.[97] Patients also receive this information in the eight-page medication guide.[98] Accordingly, unlike addiction-assistance medications, any physician can prescribe OxyContin without meeting any training or DEA registration requirements and without ever certifying that he or she read the training materials that the REMS obligates the manufacturer to provide.

The only other limitation placed on OxyContin relates to the DEA's quota powers for Schedule I and II controlled substances.[99] Oxycodone is the opiate pain reliever that OxyContin contains.[100] Until 2011, the DEA had increased the quota for oxycodone every year since 2002[101] with the exception of 2008, when the quota remained unchanged from 2007.[102] In 2010, the quota for oxycodone available for sale was 105,500,000 grams.[103] In 2002, the quota for oxycodone available for sale was 34,482,000 grams, which means that over that eight-year period, the DEA permitted a 206% increase in the oxycodone quota.[104] The DEA decreased the quota to 98,000,000 grams in 2011.[105] OxyContin is available in seven dosage strengths, ranging from ten milligram to eighty milligram tablets.[106] Although oxycodone is used in other medications, if one assumes, for illustrative purposes, that OxyContin was the only medication manufactured from oxycodone, the 2010 quota would permit the production of between 15,050,000,000 (for ten milligram tablets) and 1,881,250,000

[96] *Id.* at 1–2; *see also* PURDUE PHARMA, MEDICATION GUIDE (2010), http://www.fda.gov/downloads/Drugs/DrugSafety/UCM208530.pdf.

[97] PURDUE PHARMA, *supra* note 96.

[98] *Id.*

[99] *See* 21 C.F.R. § 1315.30 (2012).

[100] *OxyContin—Questions and Answers*, *supra* note 3.

[101] *See Federal Register Notices*, OFFICE DIVERSION CONTROL, http://www.deadiversion.usdoj.gov/fed_regs/index.html (last visited, Jan. 26, 2012) (listing the quotas for each year under a separate link).

[102] *Compare* Controlled Substances: Final Revised Aggregate Production Quotas for 2007, 72 Fed. Reg. 48,616, 48,618 (Aug. 24, 2007), *with* Controlled Substances: Final Revised Aggregate Production Quotas for 2008, 73 Fed. Reg. 66,939, 66,941 (Nov. 12, 2008).

[103] Controlled Substances: Final Revised Aggregate Production Quotas for 2010, 75 Fed. Reg. 55,828, 55,830 (Sept. 14, 2010).

[104] Controlled Substances: Final Revised Aggregate Production Quotas for 2002, 67 Fed. Reg. 59,313, 59,315 (Sept. 20, 2002).

[105] Controlled Substances: Final Revised Aggregate Production Quotas for 2011, 76 Fed. Reg. 77,016, 77,019 (Dec. 9, 2011).

[106] PURDUE PHARMA, *supra* note 92, at 29.

(for eighty milligram tablets) tablets of OxyContin. Although the DEA has the power to limit OxyContin production through its quota authority, the DEA has dramatically increased the availability of oxycodone over the last eight years. While this may be warranted for legitimate users, the increase remains in stark contrast to the limited availability of addiction-assistance medications.[107] Additionally, while the rate of marijuana dependence or abuse has remained steady over the last eight years, the number of people suffering from pain-reliever dependence or abuse has increased from 1.5 million to 1.9 million over the same period of time.[108]

B. Methadone

The FDA approved methadone in late 1972 to treat opiate addiction.[109] "Methadone is to an addict what insulin is to a diabetic, for both drugs enable an otherwise ill individual to function as a healthy, normal human being contributing his part to society."[110] Although not a cure for opiate addiction, when used as a short-term therapy or in a "long-term maintenance treatment program,"[111] methadone "improve[s] treatment retention, decreas[es] relapse, and ameliorat[es] the other social, legal, and medical problems often associated with illicit drug misuse."[112]

Despite the identical controlled substance classification of OxyContin and methadone,[113] the regulatory and statutory treatment of methadone is far more restrictive than OxyContin's, particularly in regards to patients' access.[114] The patients each drug is designed to serve—drug addicts versus pain sufferers—may explain this disparity. In light of the rates of OxyContin abuse,[115] however, some portion of

---

[107] *See infra* Part.III.B.–C.

[108] U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 8, at 6.

[109] INST. OF MED., FEDERAL REGULATION OF METHADONE TREATMENT 1 (Richard A. Rettig & Adam Yarmolinsky eds.,1995).

[110] Andrew G. Bucaro & Mary Williams Cazalas, *Methadone: Treatment and Control of Narcotic Addiction*, 44 TUL. L. REV. 14, 31 (1969).

[111] 21 U.S.C. § 802(29) (2006) ("The term 'maintenance treatment' means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.").

[112] Richard C. Boldt, *Introduction: Obstacles to the Development and Use of Pharmacotherapies for Addiction*, 13 J. HEALTH CARE L. & POL'Y 1, 3 (2010) (citing Karen L. Sees et al., *Methadone Maintenance vs 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence: A Randomized Controlled Trial*, 283 JAMA 1303, 1309 (2000)).

[113] *See* 21 U.S.C. § 812(c) (2006).

[114] *See infra* Part.III.B.–C.

[115] *See supra* text accompanying notes 7–11.

OxyContin prescriptions are, in fact, provided to drug addicts. Accordingly, a distinction based on patient needs alone fails to fully justify the radical disparities.

The Narcotic Addiction Treatment Act of 1974 and the Drug Addiction Treatment Act of 2000 amended the CSA, updating approval and licensing procedures for practitioners who treat opiate addiction with medication.[116] On January 21, 2001, the Substance Abuse and Mental Health Services Administration (SAMHSA) of the Department of Health and Human Services promulgated regulations concerning the treatment of opiate dependence with addiction-assistance medications.[117] The regulations define the registration requirements for practitioners and the accreditation and certification-based system for facilities that dispense methadone, referred to as Opioid Treatment Programs (OTPs), which SAMHSA oversees.[118] The Administrator of SAMHSA has delegated some oversight responsibilities to its Center for Substance Abuse Treatment (CSAT) and, within CSAT, to the Division of Pharmacologic Therapies.[119] The regulations did not disturb the states' authority to regulate OTPs.[120] Accordingly, a tripartite system of oversight between the states, SAMHSA, and the DEA remained in place after the amendments.[121]

1. Opioid Treatment Programs

Unlike OxyContin, which is available from any doctor's office, methadone is only available from OTPs, which are subject to heavy federal regulation and frequent local zoning controversies.[122] The process to qualify as an OTP consists of two parts—accreditation and certification.[123] Accreditation is a peer-review process.[124] Reviewers evaluate the OTP's pending application pursuant to SAMHSA's OTP

[116] JOSEPH T. RANNAZZISI & MARK W. CAVERLY, DRUG ENFORCEMENT ADMIN., PRACTITIONER'S MANUAL 23 (2006), *available at* http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf; *see* Narcotic Addiction Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124; 21 U.S.C. § 823(g) (2006).

[117] 42 C.F.R. §§ 8.1–8.34 (2011).

[118] § 8.11.

[119] *Opioid Treatment Regulation*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., http://www.dpt.samhsa.gov/regulations/regindex.aspx (last visited Mar. 12, 2012) [hereinafter *Opioid Treatment Regulation*]; *see also* § 8.11(f)(2) (providing discretion to certain entities).

[120] *See* § 8.11(f).

[121] *See* § 8.11(f)(2).

[122] PHYSICIANS & LAWYERS FOR NAT'L DRUG POLICY, *supra* note 12, at 40.

[123] 42 C.F.R. § 8.4 (2011).

[124] *Id.*

standards and visit the facility to verify that it meets accreditation requirements.[125] After accreditation, "SAMHSA uses the accreditation results along with other data to determine whether the program is qualified to carry out treatment under the standards in the regulations."[126] SAMHSA then certifies the programs that qualify, at which time these programs can dispense methadone.[127]

In addition to the federally-required accreditation and certification process, an OTP must comply with local zoning restrictions.[128] Zoning is an exercise of the state's police power.[129] A relatively recent line of cases in Pennsylvania illustrates the tension between local zoning initiatives and anti-discrimination laws.[130] In *New Directions Treatment Services v. City of Reading*, the Third Circuit invalidated a zoning statute that provided specific limitations on methadone facilities, finding that the statute violated the Americans with Disabilities Act (ADA) and the Rehabilitation Act.[131] The Pennsylvania statute[132] at issue in *New Directions* restricted the location of the methadone facility, specifically its proximity to residential housing, schools, parks, playgrounds, churches or other establishments of regular religious worship, and child-care facilities.[133] The statute also provided that a local governing body could opt out of the proximity restriction by majority vote, allowing a methadone facility to operate closer to a restricted building than provided in the statute.[134] The City of Reading (the "City") did not opt out of the proximity requirements and denied a permit to New Directions Treatment Services ("New Directions"), a methadone treatment facility.[135] New Directions appealed the denial.[136] The district court granted the City's motion for summary judgment.[137]

---

[125] *Id.*

[126] *Opioid Treatment Regulation*, *supra* note 119.

[127] *Id.*

[128] *See* New Directions Treatment Servs. v. City of Reading, 490 F.3d 293, 298 (3d Cir. 2007).

[129] *See* Village of Euclid v. Ambler Realty Co., 272 U.S. 365, 387 (1926).

[130] *See New Directions*, 490 F.3d 293; *see also* Freedom Healthcare Servs. v. Zoning Hearing Bd. of New Castle, 983 A.2d 1286 (Pa. Commw. Ct. 2009).

[131] *New Directions*, 490 F.3d 293.

[132] 53 PA. CONS. STAT ANN. § 10621 (West 1999).

[133] *New Directions*, 490 F.3d at 299.

[134] *Id.*

[135] *Id.* at 299.

[136] *Id.* at 300.

[137] *Id.*

New Directions then appealed to the Third Circuit, which held that providing local governments the ability to waive the proximity restrictions did not mitigate the fact that the law singled out methadone facilities—and therefore methadone patients—and that this rendered the statute facially discriminatory under the ADA and the Rehabilitation Act.[138] If, however, the methadone facility posed a significant risk to the population, the ADA and the Rehabilitation Act would not prohibit the zoning restrictions.[139] Relying on objective evidence, like links between crime rates and methadone clinics, the United States Court of Appeals for the Third Circuit found no evidence to support the safety concerns that the City and its residents raised; the court found that the denial more closely resembled "deprivations based on prejudice, stereotypes, or unfounded fear."[140] Accordingly, the significant risk doctrine did not validate the zoning statute.[141]

The Third Circuit also evaluated whether the City violated the Fourteenth Amendment's guarantee of equal protection in its application of the statute.[142] The court remanded the claim, instructing the district court to apply the rational basis test and to determine: (1) whether the issues raised that were unrelated to the nature of the facility or its clientele, such as loitering, noise, or parking, differentiated this facility from other permitted uses, and (2) whether such a distinction would permit denying the permit or whether the purported legitimate reasons for the denial were pretextual.[143]

Two years later in *Freedom Healthcare Services v. Zoning Hearing Board of the City of New Castle*, the Pennsylvania Commonwealth Court relied on *New Directions* to find that a zoning board had improperly denied a zoning permit to a methadone facility.[144] Here, the board based the denial on the lack of parking; the danger to the health, safety, and welfare of the neighborhood that the facility would present because of the applicant's "noticeable inexperience" in running a methadone facility; the increase in traffic; and the presence of chil-

[138] *Id.* at 305.

[139] *New Directions*, 490 F.3d at 305.

[140] *Id.* at 307 (citing School Bd. of Nassau Cnty. v. Arline, 480 U.S. 273, 287 (1987)).

[141] *Id.*

[142] *Id.* at 310.

[143] *Id.* at 312.

[144] Freedom Healthcare Servs. v. Zoning Hearing Bd. of New Castle, 983 A.2d 1286 (Pa. Commw. Ct. 2009).

dren in the area of the facility.[145] Freedom Healthcare Services argued that the board improperly applied the zoning ordinance and that the zoning permit application met all parking requirements.[146] The board asserted that Freedom Healthcare Services had the burden of producing sufficient evidence to demonstrate that it would not harm the health and safety of the community based on the facility's hours, patients, and the traffic it would produce.[147] Although the court found these concerns valid, it held that the ordinance did not place restrictions on the hours or number of patients of a medical clinic and it would, therefore, be inappropriate to apply them to this zoning permit application.[148]

While courts have found that zoning statutes cannot discriminate against methadone facilities, facility locations remain controversial. In Salem, Massachusetts, the zoning board rewrote its zoning ordinance to tighten its definition of "medical facility" and attempted to add language imposing additional restrictions on drug-dispensing facilities while leaving other medical offices unaffected all based on rumors of a pending methadone treatment facility application.[149] Potential and current neighbors of methadone facilities have raised objections to the location of treatment centers from Boise, Idaho,[150] to Somers Point, New Jersey,[151] to Columbia, Tennessee,[152] voicing concerns over crime rates, parking, traffic, and exposing children to addicts.[153]

2. Physician and Dosage Requirements

In addition to the facility restrictions, practitioners who wish to dispense methadone must meet special DEA registration require-

[145] *Id.* at 1289–90, 1292.

[146] *Id.* at 1290.

[147] *Id.* at 1291.

[148] *Id.* at 1292.

[149] Bella Travaglini, *Salem Clinic Proposal Prompts Rewrite of Zoning Amendment*, BOSTON.COM (June 29, 2010, 12:05 PM), http://www.boston.com/yourtown/news/salem/2010/06/salem_ordinance.html.

[150] Kiersten Throndsen, *Methadone Clinic Has Some Upset Over Location*, KBOI2.COM (Nov. 17, 2009, 10:55 PM), http://www.kboi2.com/news/70345467.html.

[151] Shaun Smith, *Narrow Street, Methadone Clinic Raise Safety Concerns for West Cedar Avenue*, SHORE NEWS TODAY (Sept. 15, 2010), http://www.shorenewstoday.com/index.php/mainland-/mainland/4305-narrow-street-methadone-clinic-raise-safety-concerns-for-west-cedar-avenue.html.

[152] Carley Gordon, *Neighborhood Outraged over Proposed Clinic*, WSMV (Oct. 27, 2011, 3:19 PM), http://www.wsmv.com/story/15894787/neighborhood-outraged-over-proposed-clinic.

[153] *See* sources cited *supra* notes 149–52.

ments beyond those required for OxyContin,[154] despite the fact that both are Schedule II controlled substances. In addition to the normal registration requirements,[155] a practitioner who wishes to dispense methadone must obtain an additional, separate registration number from the DEA.[156] The practitioner must also obtain the approval of and register with both the CSAT and the appropriate state methadone authority.[157]

Methadone patients also face dosage and other types of restrictions that are much more severe than the ninety-day supply restriction on OxyContin, including limits on when patients can take methadone home and how much can be prescribed during the course of their treatment.[158] A practitioner cannot prescribe more than thirty milligrams of methadone as an initial dose and more than forty milligrams on the first day of treatment, unless the practitioner documents that forty milligrams did not suppress withdrawal symptoms.[159] A *single* take-home dose of methadone is permitted for the time when the methadone clinic is closed.[160] In addition, the regulations list criteria that help physicians evaluate patients for unsupervised methadone use.[161] If a patient meets the criteria, the regulations permit the patient to take a single dose per week outside the clinic during the first ninety days of treatment.[162] During the second ninety days of treatment, the patient is permitted to take two doses per week for use outside the clinic.[163] In the third ninety days, this quantity increases to three doses per week.[164] The patient is permitted a maximum supply of six take-home doses per week for the remainder of the first year of treatment.[165] After the first year of continuous treatment, the patient may receive a two-week supply at a time.[166] After the second year of continuous treatment, the patient may reach the max-

[154] 21 U.S.C. § 823(g)(1) (2006).

[155] For a detailed discussion of the normal registration requirements, see *supra* Part II.

[156] § 823(g)(1).

[157] RANNAZZISI & CAVERLY, *supra* note 116, at 23.

[158] 42 C.F.R. § 8.12(h) (2011).

[159] § 8.12(h)(3)(ii).

[160] § 8.12(h)(4).

[161] *Id.*

[162] *Id.*

[163] *Id.*

[164] *Id.*

[165] 42 C.F.R. § 8.12(h)(4) (2011).

[166] *Id.*

imum take-home amount—a one-month supply.[167] The patient must continue to make monthly visits.[168] If a patient requires an exception to the take-home structure, for example, because of employment, disability, or transportation hardships, the physician must submit to SAMHSA and (where applicable) to the state methadone authority an "exception request" for approval to deviate from these restrictions.[169]

In sum, localities create targeted zoning restrictions that are discriminatory and not based on empirical evidence to impede methadone facilities, governing agencies proffer no evidence of special skills or complexities in methadone treatment to substantiate additional physician registration requirements, and methadone dosage restrictions are draconian. In contrast to the rigid regulatory structure for methadone, the OxyContin regulations do not require practitioners to prescribe the medication from a federally-certified facility separate from their offices but does require them to comply with just one dosing limitation, which has an exception that permits a practitioner to provide three prescriptions at once.[170] In light of the similarities between the chemical compositions of these two drugs, their incongruent treatment under the law seems unfounded. Furthermore, in light of the increase in opiate prescription abuse, the regulations appear to encourage the continued use of opiate pain medications while vigorously limiting access to methadone, which treats the very addiction that the OxyContin regulations facilitate.

C. Buprenorphine

Physicians in the United States have used low doses of buprenorphine since 1985 for the treatment of pain.[171] In October 2002, the FDA approved two buprenorphine products containing high doses of the drug—Suboxone and Subutex—for the treatment of opiate addiction.[172] In its higher dosage, buprenorphine reduces craving, blocks the effect of heroin and other opiates, reduces adverse symptoms associated with withdrawal, and remains active for a longer duration.[173]

---

[167] *Id.*

[168] *Id.*

[169] 42 C.F.R. § 8.11(h) (2011).

[170] *See supra* Part III.A.

[171] *See* DRUG ENFORCEMENT ADMIN., BUPRENORPHINE (2011), *available at* http://www.deadiversion.usdoj.gov/drugs_concern/buprenorphine.pdf.

[172] *Id.*

[173] Jones, *supra* note 19, at 4–5.

Following the recommendation of the Department of Health and Human Services, the DEA classified buprenorphine and the products containing the drug as Schedule III controlled substances.[174] Schedule III drugs have a lower potential for abuse than Schedule I or II drugs, have a currently accepted medical use, and abuse of these drugs "may lead to moderate or low physical dependence or high psychological dependence."[175]

Unlike methadone and similarly to OxyContin, practitioners can prescribe Suboxone and Subutex outside the heavily regulated OTP environment.[176] Unlike OxyContin and similarly to methadone, however, to prescribe buprenorphine, practitioners must meet special registration criteria and the number of patients they can treat is limited.[177] As with methadone, a practitioner who wishes to prescribe buprenorphine must obtain an additional registration with the DEA on an annual basis.[178] Because buprenorphine is a Schedule III controlled substance rather than a Schedule II controlled substance, however, the CSA permits practitioners to waive the additional registration requirement if they are able to meet certain criteria.[179]

A practitioner who seeks waiver must first submit a written notification of intent to the Secretary of the DHHS.[180] The written notification must include the practitioner's DEA registration number and a certification that the practitioner meets two of the following criteria: is licensed under state law *and* (1) is board certified in addiction psychiatry from the American Board of Medical Specialties, *or* (2) has an addiction certification from the American Society of Addiction Medicine, *or* (3) is board certified in addiction medicine from the American Osteopathic Association, *or* (4) has other specialized training either through coursework or participation in clinical trials of the drug.[181] The practitioner must also certify that he or she has the capacity to refer addiction treatment patients for other appropriate counseling and services and that he or she will not exceed the regulated patient limits.[182] Practitioners are limited to treating thirty pa-

---

[174] *Id.* at 4; *see also* 21 U.S.C. § 812(c) shed. III (2006).

[175] § 812(b)(3)(A)–(C).

[176] PHYSICIANS & LAWYERS FOR NAT'L DRUG POLICY, *supra* note 12, at 41.

[177] *See id.*

[178] *See* 21 U.S.C. § 823(g)(2) (2006).

[179] *Id.*

[180] § 823(g)(2)(B)–(D).

[181] §§ 823(g)(2)(B)(i), 823(g)(2)(G)(ii).

[182] § 823(g)(2)(B)(ii).

tients in the first year, with a maximum of one hundred patients thereafter.[183]

The CSAT then evaluates whether the practitioner meets the waiver requirements. If so, the CSAT refers the waiver request to the DEA.[184] If the DEA approves the practitioner's request, the practitioner receives a Unique Identification Number.[185] At this time, the practitioner may dispense buprenorphine.[186] Over a two-year period, the practitioner must meet stringent record-keeping requirements, including keeping records of receipt, storage, and distribution,[187] none of which are required to dispense OxyContin.[188]

Practitioners may dispense Schedule III controlled substances with a written or oral prescription.[189] In contrast to every other Schedule III medication, only physicians can prescribe buprenorphine.[190] The physician must include his or her regular DEA registration number and Unique Identification Number on each prescription.[191] The physician must also maintain a record of each prescription for a period of at least two years.[192] As of June 2009, the SAMHSA and the DEA had approved nearly 15,700 physicians to provide office-based buprenorphine treatment, about 13,150 to treat up to thirty patients, and about 2500 to treat up to one hundred patients.[193]

The rules provide for an exception to the registration or registration waiver requirement to permit a practitioner to administer, but not prescribe, buprenorphine in an emergency situation in which a patient is experiencing acute withdrawal symptoms and in which it would be impractical to require a practitioner to meet the registration requirement.[194] Under the so-called "three-day rule," a practitioner may administer three daily doses of the medication to last for a single seventy-two-hour period, permitting the practitioner a period

[183] § 823(g)(2)(B)(iii).

[184] RANNAZZISI & CAVERLY, *supra* note 116, at 23.

[185] *Id.*

[186] *Id.*

[187] *Id.*

[188] *See supra* Part III.A.

[189] 21 U.S.C. § 829(b) (2006).

[190] Robert J. Roose et al., *Nurse Practitioner and Physician Assistant Interest in Prescribing Buprenorphine*, 34 J. SUBSTANCE ABUSE TREATMENT 456, 458 (2008).

[191] 21 C.F.R. § 1306.05(a)–(b) (2011).

[192] § 1304.04(a).

[193] DRUG ENFORCEMENT ADMIN., *supra* note 171.

[194] 21 C.F.R. § 1306.07(b) (2012).

to arrange for the patient's treatment in a detoxification[195] or maintenance program.[196] The practitioner may not renew or extend the seventy-two hour period.[197]

In sum, addiction-assistance medications' regulations require special DEA registration, and practitioner training and impose facility restrictions, dosage limits, and patient limits. These restrictions stand in stark contrast to the controls imposed on OxyContin—a drug that is abused and classified in a schedule above buprenorphine, yet is limited only through a quota that has steadily increased over an eight-year period and through restrictions on prescription refills.

IV. RECOMMENDED REFORMS

The results of the SAMHSA 2009 annual survey on national drug use highlight two reforms that are required to address OxyContin abuse—proper medication disposal and physician oversight and/or training.[198] The survey breaks down the reported sources of prescription pain relievers based on the users' most recent non-medical uses and found that 70.2% of users obtained the drug from a friend or relative, 17.6% obtained the drug from one doctor, 4.8% obtained the drug from a drug dealer or stranger, and 0.4% bought the drug on the Internet.[199] Additionally, eighty percent of the friends or relatives who provided the drug to the users obtained the drug from just one doctor.[200] These statistics highlight two issues on the supply side of this equation: (1) the need to appropriately advise patients on how to dispose of their medications; and (2) the need for heightened requirements on practitioners who prescribe opiate pain medications.

---

[195] *See* 21 U.S.C. § 802(30) (2006) ("The term 'detoxification treatment' means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.").

[196] *Questions & Answers*, DRUG ENFORCEMENT ADMIN., http://www.deadiversion.usdoj.gov/drugreg/faq.htm (last visited, Feb. 17, 2012).

[197] *Id.*

[198] *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. NO. SMA 10-4586, RESULTS FROM THE 2009 NATIONAL SURVEY ON DRUG USE AND HEALTH: VOLUME I. SUMMARY OF NATIONAL FINDINGS 28 (2010), *available at* http://www.oas.samhsa.gov/NSDUH/2k9NSDUH/2k9ResultsP.pdf.

[199] *Id.*

[200] *Id.*

A. OxyContin Supply Reforms

1. Disposal

The OxyContin REMS provides that prescribing physicians should advise patients to flush unused tablets down the toilet.[201] As noted earlier in this Comment, the REMS is not binding on a physician and is not used to police physician or patient practices.[202] The REMS should be updated to impose more stringent labeling requirements, particularly advising patients of the appropriate disposal method for unused pills. Currently, the appropriate disposal method is contained in an eight-page medication guide provided to OxyContin patients.[203] The disposal instructions should not be buried in such a long, dense document, but rather should be prominently placed on the label. There are, however, many concerns about contamination of the water supply with prescription medications.[204] Therefore, patients should be encouraged to also use drug take-back programs to dispose of unused OxyContin.

On October 12, 2010, President Obama signed the Secure and Responsible Drug Disposal Act into law.[205] The Act amends the CSA to extend to states and private entities the ability to create drug take-back programs, which could provide an additional outlet for the safe disposal of old or unwanted medication.[206] Prior to this law, only law enforcement authorities could lawfully collect controlled substances.[207] On September 25, 2010, the DEA conducted a nationwide drug take-back day, collecting more than 121 tons of medicine at over 4,000 collection sites.[208] The new law will permit exploration of these programs.[209] Perhaps doctors' offices, hospitals, and pharmacies should also have a receptacle for medication disposal, which would

[201] PURDUE PHARMA, *supra* note 92, at 33.

[202] *Id.*

[203] PURDUE PHARMA, *supra* note 96.

[204] *See* MAE WU ET. AL., DOSED WITHOUT PRESCRIPTION: PREVENTING PHARMACEUTICAL CONTAMINATION OF OUR NATION'S DRINKING WATER 3 (2009), *available at* http://docs.nrdc.org/health/files/hea_10012001a.pdf.

[205] Pub. L. No. 111-273, 124 Stat. 2858 (2010).

[206] Carol M. Ostrom & Lauren C. Williams, *New State Pain-Medication Law Has Doctors and Patients Nervous*, SEATTLE TIMES (Sept. 11, 2010, 12:04 PM), http://seattletimes.nwsource.com/html/localnews/2012873602_drugs12m.html.

[207] *Id.*

[208] Alicia A. Caldwell, *DEA Drug Take-Back Nets 121 Tons of Unwanted Drugs*, ASSOCIATED PRESS, Oct. 5, 2010, *available at* http://www.msnbc.msn.com/id/39526659/ns/health-more_health_news/.

[209] *See* H.B. 1121, 2011 Leg., 1st Reg. Sess. (Ind. 2011).

enable a patient to access a proper disposal location without substantially deviating from his or her normal routine or waiting for a drug take-back program day.[210] New Jersey is also exploring secure receptacles, such as refurbished, locked mailboxes at municipal police stations.[211]

2. Physician Training

The legal treatment of methadone and buprenorphine emphasizes the importance of practitioner training for the proper dispensing of these drugs. OxyContin prescribers should be required to meet similar training standards. The OxyContin REMS is insufficient to ensure that practitioners are properly trained. Although information that the manufacturer provides to practitioners contains useful guidelines, there is no requirement that practitioners follow the guidelines, or even read the materials before prescribing the medication.[212] At a minimum, practitioners should have to return the certification form currently enclosed in the REMS materials to be eligible to prescribe OxyContin. Perhaps a DEA registration-and-waiver structure similar to that applicable to buprenorphine should also apply to OxyContin. This would allow practitioners with particularized training in pain management to prescribe OxyContin, and encourage pain-management patients to pursue care with a practitioner with expertise in relieving pain. This system may help ensure that legitimate pain sufferers access appropriate care from physicians who meet particularized training requirements. Furthermore, it may be easier for practitioners who deal with pain patients on a regular basis to differentiate the illegitimate users from the legitimate users.

Finally, health insurers, both private and public, should refuse to cover prescriptions of OxyContin for ailments other than chronic or long-term pain. OxyContin was specifically designed to treat patients with around-the-clock moderate-to-severe pain.[213] Accordingly, doctors should not treat patients suffering from short-term conditions that require pain suppressing medications with OxyContin.

---

[210] *See Bill Would Let Indiana Pharmacies Collect Old Meds*, ASSOCIATED PRESS, Jan. 10, 2011, *available at* http://www.ibj.com/bill-would-let-indiana-pharmacies-collect-old-meds/PARAMS/article/24511.

[211] S. 541, 214th Leg., 2010 Sess. (N.J. 2010).

[212] *See* PURDUE PHARMA, *supra* note 92, at 35(noting that the completion of the Education Confirmation Form does not affect a practitioner's ability to prescribe OxyContin).

[213] *OxyContin—Questions and Answers*, *supra* note 3.

3. State Legislatures and the Washington State Model

State legislatures should act to limit the prescribing of OxyContin to patients in chronic or long-term pain, for which the drug is designed. Washington state's efforts represent one example of such an initiative. At the beginning of 2010, the Washington State Legislature introduced, and quickly passed, a bill aimed at curbing the disparate legal treatment of pain relief medications.[214] Statistics finding that more Washington residents died from prescription overdoses than car accidents prompted quick action.[215] Governor Christine Gregoire signed the bill into law on March 25, 2010; it became effective on June 10, 2010.[216]

The first of its kind in the nation, the law requires the state's appropriate rulemaking agencies to determine a painmedication dosage level at which practitioners would need to refer patients to pain specialists.[217] Although the law does not create specific penalties for failing to adhere to the forthcoming rules, state officials have represented a practitioner who violates the rules will face sanctions from the state licensing boards that could include losing the right to practice medicine.[218] The state adopted voluntary guidelines for practitioners three years ago, but a 2009 survey found that about half of doctors were unaware of them and many were simply not following them.[219] To strike a balance between facilitating pain relief and creating addiction controls, the law exempts patients with cancer, acute injury or surgery, or who are in end-of-life care from the new restrictions.[220] More states should consider initiatives like Washington's and attempt to balance access to pain medication while minimizing the diversion of pain medication for illicit uses.

B. Reforming the Demand for Addiction-Assistance Medications

In addition to the reforms on the supply side of the issue, reforms must also address the demand side by providing addicts the

[214] WASH. REV. CODE § 18.32.785 (2010).

[215] Ostrom & Williams, *supra* note 206.

[216] H.R. 2876, 61st .Leg., Reg. Sess. (Wa. 2010).

[217] WASH. REV. CODE § 18.32.785 (2010).

[218] Barry Meier, *Move to Restrict Pain Killers Puts Onus on Doctors*, N.Y. TIMES, July 29, 2010, at B1.

[219] *Id.*

[220] Ostrom & Williams, *supra* note 206.

opportunity to obtain medication to treat their disease. According to post-marketing surveillance by buprenorphine's manufacturer, fifty percent of physicians who are eligible to treat patients with buprenorphine reported that patients who are waiting to get into treatment utilize diverted buprenorphine to treat themselves.[221] The surveyed physicians attributed this fact to the insufficient number of physicians who are eligible to prescribe buprenorphine and to the fact that those physicians are not evenly distributed throughout the country.[222] Accordingly, the patient limit should be eliminated.[223] The patient limitations were designed to prevent hundreds of patients from waiting outside doctors' offices for treatment.[224] Despite patient demand that outweighs resources, methadone facilities do not suffer from such a problem.[225] Therefore, it seems overly precautionary to limit the number of buprenorphine patients. Additionally, practitioners prescribing buprenorphine need to first demonstrate their training in the treatment of addiction or obtain a special DEA registration.[226] A physician who chooses to develop expertise in this area should be allowed to treat as many patients as he or she is capable of treating. Just as pain-management patients deserve access to their medications and should consult practitioners with expertise in their ailment, so too should addicts. Furthermore, nurse practitioners and physician assistants should be able to prescribe buprenorphine.[227] The policy reason for restricting nurse practitioners and physician assistants from prescribing buprenorphine is unclear in light of the fact that they can prescribe other Schedule III drugs.[228] As the role of non-physician providers has dramatically increased in the last decade, this unexplained restriction may further unnecessarily limit access to buprenorphine.[229]

With regard to methadone, despite findings that demonstrate the effectiveness of maintenance treatment, less than twenty percent

---

[221] *Off-Label Use of Buprenorphine for Pain Worries Officials*, ALCOHOLISM & DRUG ABUSE WKLY., Jan. 11, 2010, at 2.

[222] *Id.*

[223] For a discussion of patient limits, see *supra* notes 182–83.

[224] Laurie Barclay, *New Legislation Increases Number of Patients Allowed for Treatment with Buprenorphine*, MEDSCAPE MED. NEWS (Dec. 20, 2006), http://www.medscape.com/viewarticle/549706.

[225] *See* Ruth Schubert, *Wait for Methadone Puts Hundreds of Lives on Hold*, SEATTLE POST-INTELLIGENCER, Mar. 17, 2003, at A1.

[226] *See supra* text accompanying notes 178–82.

[227] *See* Roose, *supra* note 190, at 458.

[228] *Id.* at 456.

[229] *Id.* at 456, 459.

of the heroin addicts in the United States use the treatment.[230] Heroin addicts who use maintenance treatment decrease their weekly heroin intake by sixty-nine percent, their criminal activity by fifty-two percent, and increase their full-time employment by twenty-four percent.[231] Therefore, the legal structure for methadone should reflect its positive effects, encouraging use and increasing the availability of this treatment. Instead, because addicts can only receive this treatment at stand-alone facilities, which are often the subject of local controversy, clinic locations and hours of operation can be inconvenient, and addicts using the facility may be subject to the negative reactions by the surrounding community.[232] This "can create powerful feelings of mistrust and alienation and a strong reluctance to seek out or participate in programs."[233] Furthermore, two states, North Dakota and Wyoming, simply do not have methadone treatment facilities.[234] The number of facilities in other states varies from one, in Mississippi, to almost 150, in New York and California respectively.[235] Additional barriers to access include fees, forms to fill out, referral requirements, and waiting lists.[236] The law should reflect methadone's positive effects rather than discourage physicians and addicts from using it in addiction recovery.

V. CONCLUSION

The legal structure for OxyContin enables a patient to obtain his or her drug of choice with relative ease because the patient can obtain it through any practitioner at any healthcare facility. But, should that patient become addicted to OxyContin, he or she will have to find a practitioner and/or facility that has jumped through several regulatory hoops to have the power to prescribe a drug to help him or her combat this addiction.

---

[230] Robert Mathias, *NIH Panel Calls for Expanded Methadone Treatment for Heroin Addiction*, NAT'L INST. DRUG ABUSE NOTES (Nov./Dec. 1997), http://archives.drugabuse.gov/NIDA_Notes/NNVol12N6/NIHPanel.html.

[231] *Id.*

[232] *See* CTRS. FOR DISEASE CONTROL AND PREVENTION, SUBSTANCE ABUSE TREATMENT FOR INJECTION DRUG USERS: A STRATEGY WITH MANY BENEFITS 3 (2002), *available at* http://www.cdc.gov/idu/facts/TreatmentFin.pdf.

[233] *Id.*

[234] *See Opioid Treatment Program Directory*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., http://dpt2.samhsa.gov/treatment/directory.aspx (last visisted, Jan. 27, 2012) (select "North Dakota" and "Wyoming from" drop down menu).

[235] *Id.* To view the statistics for each state, select "Mississippi", "New York", and "California" from the drop down menu.

[236] CTRS. FOR DISEASE CONTROL AND PREVENTION, *supra* note 232.

Drug addicts are not a beloved part of society.[237] One need not search beyond the transcripts from zoning board hearings or newspaper articles regarding methadone clinics to appreciate this.[238] The courts have played a role in protecting addicts from discrimination by invalidating discriminatory zoning actions, but only Congress and the relevant state and federal agencies can change a legal structure for medications that discriminates against addicts. This structure has created a recipe for abusing OxyContin by failing to ensure that physicians are properly trained to dispense OxyContin and by failing to educate the public on how to properly dispose of pain medications. But paradoxically, this structure also seems to punish addicts by denying them access to medications proven to assist them in combating their addiction.

A fear that addicts will abuse drugs, even those designed to help them, may explain the more stringent regulation of methadone and buprenorphine. But OxyContin is abused every day. The drug's time release properties, the amount of oxycodone contained in the pills, and the ease with which the pills can be tampered creates a perfect storm for abuse. The legal structure for OxyContin should reflect this, and the disparities between the regulations for addiction-assistance medications and OxyContin should be rectified through the creation of more stringent prescription guidelines, better disposal instructions, and increased physician training.

---

[237] *See Americans Want Insurance to Cover Addiction; Unsure if it Does*, HAZELDON FOUND. (Feb. 3, 2009), http://www.hazelden.org/web/public/pr090209 healthinsurance.page.

> Although 78 percent of Americans recognize that addiction is a chronic disease rather than a moral failing, the words used by those surveyed when asked to describe people who have problems with drugs or alcohol included: "sinner," "irresponsible," "selfish," "stupid," "uncaring," "loser," "undisciplined," "pitiful," "pathetic," "weak," "criminal," "derelict," "washed up" and "crazy." The single highest negative consequence reported of having a family member with a drug problem was "embarrassment/social stigma."

Id.

[238] *See supra* note 140, 149–52 and accompanying text.