


Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance

Ellen M. Weber
eweber@law.umaryland.edu

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

 Part of the [Health Law Commons](#), [Medical Education Commons](#), and the [Substance Abuse and Addiction Commons](#)

Recommended Citation

Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. Health Care L. & Pol'y 49 (2010).
Available at: <http://digitalcommons.law.umaryland.edu/jhclp/vol13/iss1/5>

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

FAILURE OF PHYSICIANS TO PRESCRIBE PHARMACOTHERAPIES FOR ADDICTION: REGULATORY RESTRICTIONS AND PHYSICIAN RESISTANCE

ELLEN M. WEBER*

INTRODUCTION

A visit to a doctor for the treatment of a chronic medical condition generally leads to a conversation about behavior changes and medications that will ameliorate the condition. The same is not true for the treatment of alcoholism and drug dependence—two of our nation’s most costly medical conditions.¹ Few pharmacotherapies exist for the treatment of alcoholism and drug dependence,² and

Copyright © 2010 by Ellen M. Weber.

* Professor of Law, University of Maryland; B.A., 1977, Dickinson College; J.D., 1980, New York University.

1. Alcoholism and drug dependence cost our nation an estimated \$300 billion annually. *Compare* Richard Saitz et al., *The Case for Chronic Disease Management for Addiction*, 2 J. ADDICTION MED. 55, 56 (2008), with NAT’L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, CTRS. FOR DISEASE CONTROL & PREVENTION, HEART DISEASE AND STROKE PREVENTION: ADDRESSING THE NATION’S LEADING KILLERS 2 (2009), available at <http://www.cdc.gov/chronicdisease/resources/publications/AAG/pdf/dhdsp.pdf> (estimating that the cost of heart diseases in 2009 totaled \$304.6 billion).

2. Three medications are currently approved and prescribed for the treatment of alcoholism: disulfiram (commonly known as Antabuse), naltrexone (in both an oral and injectable formulation), and acamprosate. CTR. FOR SUBSTANCE ABUSE TREATMENT, DEP’T OF HEALTH & HUMAN SERVS., HHS PUB. NO. 09-4380, INCORPORATING ALCOHOL PHARMACOTHERAPIES INTO MEDICAL PRACTICE: A TREATMENT IMPROVEMENT PROTOCOL (TIP) SERIES 49, at 4 (2009), available at <http://www.kap.samhsa.gov/products/manuals/tips/pdf/TIP49.pdf> [hereinafter TIP 49]. Disulfiram is an aversive agent that causes intense physical reactions if alcohol is consumed. *Id.* at 15. Naltrexone is an opioid antagonist that curbs craving and reduces the rewarding effects of drinking, thereby promoting abstinence and reducing the amount of heavy drinking. *Id.* at 28. Acamprosate is thought to normalize alcohol-related changes in brain activity, thereby reducing symptoms of protracted withdrawal that may trigger a relapse to drinking. *Id.* at 9.

Three medications—methadone, buprenorphine (in two formulations, Subutex and Suboxone) and naltrexone—have been approved as safe and effective medications for the treatment of opioid dependence. 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). Methadone, a Schedule II

remarkably few physicians prescribe those that do.³ Safe and effective medications, used in conjunction with behavioral therapies,⁴ can reduce alcohol and drug use and the morbidity associated with addiction, and shorten the period between relapse and resumed abstinence.⁵ Yet most people who suffer from addiction visit a primary

controlled substance, is a long-acting, opioid agonist that prevents withdrawal and blocks the euphoric effects of other illicit opioids. 21 U.S.C. § 812(c) (2006); 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*, at 45–46. Buprenorphine, a Schedule III controlled substance, is a partial opioid agonist that reduces craving, blocks the effect of other opioids, has a long duration of action, and reduces adverse symptoms associated with opioid withdrawal. Hendrée E. Jones, *Practical Considerations for the Clinical Use of Buprenorphine*, SCI. & PRAC. PERSP., Aug. 2004, at 4, 4–5. Naltrexone, when used for opiate addiction, blocks the effect of self-administered opiates, producing no stimulation, and seeks to *break the habit* of opiate addiction when ingested opiates fail to produce the desired effect. NAT'L INST. ON DRUG ABUSE, NAT'L INSTS. OF HEALTH, NIH PUB. NO. 99-4180, PRINCIPLES OF DRUG ADDICTION TREATMENT: A RESEARCH-BASED GUIDE 40 (2d. ed. 2009), available at <http://www.nida.nih.gov/PDF/PODAT/PODAT.pdf> [hereinafter PRINCIPLES OF DRUG ADDICTION TREATMENT]. No pharmacotherapy is available for cocaine dependence, although research suggests that disulfiram may also be an effective medication for these patients. Markus Heilig & Mark Egli, *Pharmacological Treatment of Alcohol Dependence: Target Symptoms and Target Mechanisms*, 111 PHARMACOLOGY & THERAPEUTICS 855, 859 (2006). Research has also focused on the development of vaccines to treat cocaine dependence. See COMM. ON IMMUNOTHERAPIES & SUSTAINED-RELEASE FORMULATIONS FOR TREATING DRUG ADDICTION, NAT'L RESEARCH COUNCIL, IMMUNOTHERAPIES AND SUSTAINED-RELEASE FORMULATIONS FOR TREATING DRUG ADDICTION: BEHAVIORAL, ETHICAL, LEGAL, AND SOCIAL QUESTIONS, app A-12, B-15 (Henrick J. Harwood & S Tracy G. Meyers eds., prepubl'n copy 2004) (discussing testing for depot medications targeting cocaine).

3. See Suzanne E. Thomas & Peter M. Miller, *Knowledge and Attitudes About Pharmacotherapy for Alcoholism: A Survey of Counselors and Administrators in Community-Based Addiction Treatment Centres*, 42 ALCOHOL & ALCOHOLISM 113, 113 (2007) (discussing the reasons why pharmacotherapies are not frequently used for alcoholism treatment).

4. Pharmacological and behavioral treatments are recommended to address both the neuroadaptions in the brain that result from chronic drug and alcohol misuse as well as the behavioral responses to stimuli and environment that trigger craving and can result in relapse. TIP 49, *supra* note 2, at 5. Behavioral therapy may also help patients with alcohol dependence comply with pharmacotherapy and promotes behavior change. *Id.* Pharmacotherapy and behavioral therapy are thought to operate synergistically in the treatment of alcoholism. *Id.* The same is true for treatment of opiate dependence. The National Institute on Drug Abuse has concluded that the most effective treatment for persons participating in medication-assisted treatment for opioid dependence includes individual and group counseling as well as provision of other medical, psychological, and social services. PRINCIPLES OF DRUG ADDICTION TREATMENT, *supra* note 2, at 29. Federal regulations governing office-based use of buprenorphine require physicians to demonstrate the capacity to refer patients for appropriate counseling and other ancillary services in order to receive certification to prescribe this medication. 21 U.S.C. § 823(g)(2)(B)(ii) (2006 & West Supp. 2009).

5. Raye Z. Litten et al., *Development of Medications for Alcohol Use Disorders: Recent Advances and Ongoing Challenges*, 10 EXPERT OPINION ON EMERGING DRUGS 323, 326–27 (2005); see also Andrew J. Saxon & Dennis McCarty, *Challenges in the Adoption of New Pharmacotherapeutics for Addiction to Alcohol and Other Drugs*, 108 PHARMACOLOGY & THERAPEUTICS, 119, 121 (2005) (setting out research findings, including a seventy percent abstinence rate among patients in methadone treatment programs compared to a six percent rate among untreated heroin-dependent persons; lower rates of hospitalization for life-threatening conditions among patients in methadone programs; and reduced hospitalization among HIV-infected individuals receiving drug abuse care); NAT'L INST. ON DRUG ABUSE, NAT'L INSTS. OF HEALTH, NIH PUB. NO. 99-4180, PRINCIPLES OF DRUG ADDICTION

care physician and leave without an assessment for an alcohol or drug use problem⁶ and, if appropriate, a prescription for therapeutic medications.⁷

The failure of physicians to prescribe pharmacotherapies for addiction goes to the heart of our nation's failed drug policies. Although the reasons differ for the limited prescribing practices for alcoholism and opioid dependence,⁸ they are grounded in our nation's history of regulation of medical practice related to narcotics addiction treatment; the paucity of medical training in addiction medicine; persistent stigma associated with addiction disorders; and compensation barriers to the effective treatment of this chronic medical condition.⁹ Succinctly stated, four interrelated factors—context, competence, comfort, and compensation—affect physician prescription practices in the United States.

A different picture emerges internationally. Physicians in the United Kingdom, France, and Australia play an important role in the widespread prescription of methadone and buprenorphine for the treatment of opioid dependence,¹⁰ and physicians across Europe widely prescribe acamprosate for

TREATMENT: A RESEARCH-BASED GUIDE 16 (1st ed. 1999) (“Methadone treatment has been shown to decrease criminal behavior by as much as [fifty] percent.”).

6. COMM. ON CROSSING THE QUALITY CHASM, INST. OF MED., IMPROVING THE QUALITY OF HEALTH CARE FOR MENTAL AND SUBSTANCE-USE CONDITIONS 217 (2006) (noting that less than twenty percent of general internal medicine physicians, obstetricians/gynecologists, family medicine physicians, and psychiatrists “use[] any formal [alcohol] screening tool to detect problems among those [patients] who did drink”).

7. See Thomas & Miller, *supra* note 3, at 113 (noting that, while pharmacotherapies are appropriate for alcohol use disorders, such treatments are not frequently used).

8. Naltrexone, for example, is not widely prescribed for the treatment of alcoholism, even by addiction medicine specialists, because it is perceived to have limited efficacy. Heilig & Egli, *supra* note 2, at 860. The research literature suggests that patient response to naltrexone may vary based on genetic features, and thus a lack of training in the indicated use of naltrexone (based on patient subtypes) may account for the failure to prescribe this medication. *Id.*; see also Tami L. Mark et al., *Understanding US Addiction Physicians' Low Rate of Naltrexone Prescription*, 71 DRUG & ALCOHOL DEPENDENCE 219, 221–23 (2003) (finding that physicians identified a patient's lack of compliance or willingness to take naltrexone and medication cost as affecting prescribing practices as well as concerns about efficacy and safety). Medications for the treatment of opiate dependence, on the other hand, are subject to special federal regulation that precludes physicians from dispensing methadone in an office-based practice, unless the physician is associated with an opioid treatment program, and requires additional training and certification to prescribe buprenorphine. Jerome H. Jaffe & Charles O'Keeffe, *From Morphine Clinics to Buprenorphine: Regulating Opioid Agonist Treatment of Addiction in the United States*, 70 DRUG & ALCOHOL DEPENDENCE (SUPP. 1) S3, S7 (2003). Heightened regulatory standards also perpetuate the stigma associated with opioid dependence and likely contribute to physician unwillingness and discomfort in treating persons who are opiate dependent. See *infra* Parts I.C–D.

9. See *infra* Parts I–III.

10. Maria Patrizia Carrieri et al., *Buprenorphine Use: The International Experience*, 43 CLINICAL INFECTIOUS DISEASES (SUPP. 4) S197, S199–205 (2006) (describing France's general practitioner prescription-based model, Australia's community-based pharmacy dispensing model, Italy's specialist center model, Germany's primary physician and specialist clinic model, and Croatia's collaborative treatment center and primary care physician model); Fiellin & O'Connor, *supra* note 2, at 691 (describing opioid agonist maintenance treatment in the U.K., Australia, and France); Michael Weinrich

alcoholism.¹¹ The World Health Organization, recognizing the importance of treating opiate addiction and preventing HIV/AIDS among injection drug users, added methadone and buprenorphine to its *14th Model List of Essential Medicines* in 2006.¹² Although over-generalization may mask very real differences in the physician practices in these other countries, many have adopted a harm reduction model¹³ to address addiction, which is viewed with suspicion in the context of the United States' law enforcement and prohibitionist drug control model.¹⁴ An abstinence-based treatment philosophy continues to predominate our country's treatment approach,¹⁵ and is coupled with lingering ambivalence about whether drug addiction is a disease that should be treated or a behavior that should be punished.¹⁶ The international experience, however, demonstrates the feasibility and

& Mary Stuart, *Provision of Methadone Treatment in Primary Care Medical Practices: Review of the Scottish Experience and Implications for US Policy*, 283 JAMA 1343, 1343–44 (2000).

11. Litten et al., *supra* note 5, at 328; *see also* Mark et al., *supra* note 8, at 226 (noting that the United States has the lowest rate of prescriptions for alcoholism medications—naltrexone, acamprosate and disulfiram—per capita as compared to Australia, Canada, France, Germany, New Zealand, and the United Kingdom).

12. Carrieri et al., *supra* note 10, at S198; *see also* WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 21 (14th ed. 2005), available at http://whqlibdoc.who.int/hq/2005/a87017_eng.pdf (listing methadone and buprenorphine and noting that each should be used within an established support program).

13. *See generally* 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 (2010) (describing the harm reduction methods in England, Scotland, Ireland, Canada, and Australia). Harm reduction is a public health model that “shifts the focus away from drug use itself to the consequences or effects of addictive behavior” and offers policies and practices that are “designed to reduce the harmful consequences of addictive behavior.” G. Alan Marlatt, *Basic Principles and Strategies of Harm Reduction*, in HARM REDUCTION: PRAGMATIC STRATEGIES FOR MANAGING HIGH-RISK BEHAVIORS 49, 50 (G. Alan Marlatt ed., 1998). The use of pharmacotherapies to reduce alcohol and drug craving, prevent relapse, and treat opioid dependence falls within a harm reduction framework. *Id.* at 61–62; *see also* Carrieri et al., *supra* note 10, at S199 (describing France's acceptance of harm reduction in 1993 as a result of a notable increase in HIV infection among injection drug users).

14. Marlatt, *supra* note 13, at 49–50; Nolan, *supra* note 13, at 37, 41. For example, Congress has only recently secured sufficient votes to end a twenty-one-year ban on the use of federal funds to support needle exchange programs. Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, 123 Stat. 3034 (2009). Data have consistently demonstrated that needle exchange programs reduce HIV transmission without resulting in increased drug use, but Congress had not previously lifted the ban amidst fear of increased injection drug use. Bill Piper & Naomi Long, *Congress Gets Its Act Together: Repeals Ban on Syringe Exchange Funding, Allows D.C. to Enact Medical Marijuana Program* (Dec. 17, 2009), <http://www.alternet.org/story/144638>.

15. Marlatt, *supra* note 13, at 50; Nolan, *supra* note 13, at 36, 41; *see also* Saitz et al., *supra* note 1, at 58 (noting that pharmacotherapies are underused in the addiction system); Saxon & McCarty, *supra* note 5, at 123 (“Many of the [addiction treatment] staff members may have been trained in a self-help, total abstinence-based orientation antithetical to the use of pharmacotherapy.”).

16. *See* Richard J. Bonnie, *The Virtues of Pragmatism in Drug Policy*, 13 J. HEALTH CARE L. & POL'Y 7, 10–17 (2010) (describing various drug policy perspectives).

value of expanding physician use of pharmacotherapy for alcoholism and drug dependence.¹⁷

The enactment of the Drug Addiction Treatment Act of 2000¹⁸ (hereinafter DATA 2000) created, for the first time in nearly a century, a real opportunity to integrate pharmacotherapy addiction treatment into an office-based medical practice in the United States. Under DATA 2000, physicians who receive training and certification are permitted to prescribe buprenorphine—a Schedule III¹⁹ Controlled Substance approved by the Food and Drug Administration (FDA) in 2002 for the treatment of opioid dependence.²⁰ Since 2001, more than 24,000 physicians have been trained in the use of buprenorphine, and over 18,000 have received certification.²¹ More than one million patients have been prescribed

17. The French experience with buprenorphine and methadone has reduced the overall harm associated with untreated drug addiction, notwithstanding problems related to buprenorphine diversion. Carrieri et al., *supra* note 10, at S201. From 1996, with the expansion of methadone and introduction of buprenorphine, through 2003, the country found a five-fold reduction in the number of deaths attributable to heroin; a six-fold reduction in the number of active injection drug users; and approximately 3500 lives were saved. *Id.* at S199, S201. Croatia, which approved methadone treatment under restrictive standards in 1996, reports an HIV infection prevalence rate among drug users of under five percent. *Id.* at S204–05.

18. Children’s Health Act of 2000, Pub. L. No. 106-310, § 3502, 114 Stat. 1101, 1222–27 (2000) (codified at 21 U.S.C. § 823(g) (2006 & West Supp. 2009)).

19. Buprenorphine is a Schedule III medication because its pharmacological properties result in little physical dependence and respiratory depression, and one of the FDA-approved formulations of the medication, Suboxone, is designed to deter diversion and prevent misuse by the combination of naloxone. Jones, *supra* note 2, at 5; see also Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Buprenorphine and Buprenorphine Combination; Approved Opioid Treatment Medications Use, 74 Fed. Reg. 29,153, 29,155–56 (proposed June 19, 2009) (providing evidence demonstrating that the “scope and nature of abuse and diversion [of buprenorphine] are considerably less than that of methadone and other Schedule II opioid drug products,” and proposing modified dispensing requirements of buprenorphine in opioid treatment programs).

20. The Controlled Substances Act requires practitioners who dispense narcotic drugs to individuals for maintenance or detoxification treatment to obtain a special registration from the Drug Enforcement Administration. 21 U.S.C. § 823(g)(1). DATA 2000 waives this requirement for qualifying physicians who dispense and prescribe a Schedule III, IV, or V narcotic drug that has been approved by the FDA for use in maintenance or detoxification treatment. *Id.* § 823(g)(2)(A)–(C). A qualifying physician must have a state license and be certified in addiction medicine through subspecialty boards or medical societies. *Id.* § 823(g)(2)(G)(ii). Alternatively, a licensed physician may become qualified by participating in an eight-hour training session in the treatment and management of opioid-dependent patients. *Id.* The physician must also have the capacity to refer patients for appropriate counseling and other ancillary services. *Id.* § 823(g)(2)(B)(ii). As originally enacted, DATA 2000 limited the number of patients each physician or group practice could serve to thirty patients. Fiellin & O’Connor, *supra* note 2, at 690. Congress eliminated the group practice limitation in 2005, Pub. L. No. 109-56, § 1, 119 Stat. 591, 591 (2005), and modified the patient limitation in 2006, permitting each physician to treat up to 100 patients, upon notification, after treating thirty patients for one year. Office of National Drug Control Policy Reauthorization Act of 2006, Pub. L. No. 109-469, § 1102, 120 Stat. 3502, 3540 (2006) (codified at 21 U.S.C. § 823(g)(2)(B)(iii)). DATA 2000, as amended, does not restrict the amount of medication a physician is authorized to prescribe to a patient at any one time. 21 C.F.R. § 1301.28 (2009).

21. E-mail from Nicholas Reuter, Senior Pub. Health Analyst, Substance Abuse & Mental Health Servs. Admin., to Ellen Weber, Professor of Law, Univ. of Md. Sch. of Law (Dec. 22, 2009) (on file

buprenorphine since 2002, the majority of whom were new to substance abuse treatment and dependent on non-heroin (prescription) opioids.²²

The benefits of an office-based practice are substantial. Significantly more patients can be treated for opioid dependence through the prescription of buprenorphine in an office-based practice than in federally regulated opioid treatment programs that prescribe and dispense methadone.²³ The patients who seek office-based care tend to be younger, have fewer years of opiate dependence, and have lower rates of intravenous drug use and Hepatitis C than persons who receive treatment in methadone programs.²⁴ Patients who seek care in an office-based practice avoid both the stigma associated with obtaining care in a specialty methadone clinic, and the strict daily attendance regimen imposed on patients under federal regulations.²⁵ Finally, the co-location of addiction treatment in a primary care practice facilitates the treatment of co-occurring health conditions, such as HIV/AIDS, hepatitis, tuberculosis, and cardio-pulmonary disease, and over

with author) [hereinafter Reuter E-mail]. Physicians in all fifty states have received certification. E-mail from Anthony Tommasello, Field Med. Advisor, Reckitt Benckiser Pharm., Inc., to Ellen Weber, Professor of Law, Univ. of Md. Sch. of Law (Oct. 30, 2008) (on file with author).

22. Thomas F. Kresina et al., *United States Government Oversight and Regulation of Medication Assisted Treatment for the Treatment of Opioid Dependence*, 2 J. DRUG POL'Y ANALYSIS 1, 10 (2009).

23. Cf. Marc Auriacombe et al., *French Field Experience with Buprenorphine*, 13 AM. J. ON ADDICTIONS (SUPP. 1) S17, S18–19 (2004) (demonstrating that treatment in European methadone clinics only reached 20% to 30% of addicts because of regulations and safety concerns, but that allowing office-based physicians to prescribe buprenorphine has increased patient treatment to 43%). In 2007, approximately 265,000 individuals received medication-assisted treatment in opioid treatment programs (OTPs), 99% of whom received methadone and 1% received buprenorphine. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., DEP'T OF HEALTH & HUMAN SERVS., NATIONAL SURVEY OF SUBSTANCE ABUSE TREATMENT SERVICES (N-SSATS): 2007 DATA ON SUBSTANCE ABUSE TREATMENT FACILITIES 41 (2008), available at <http://www.dasis.samhsa.gov/07nssats/nssats2k7web.pdf> [hereinafter N-SSATS]. The number of patients in OTPs has increased slightly from 227,000 in 2003 (21% of all patients receiving treatment in specialized programs) to 265,000 in 2007 (23% of all patients). *Id.* at 26, tbl.3.2. In comparison, in 2007, over 250,000 patients received a prescription for buprenorphine, and, in 2008, more than 425,000 patients did so. Reuter E-mail, *supra* note 21. Based on historical trends, treatment capacity in OTPs will not increase significantly. The number of treatment facilities with OTPs has remained fairly constant from 2003 to 2007; roughly 1200 facilities provide medication-assisted treatment or 8% of all treatment facilities. N-SSATS at 19, tbl.2.3. The potential for increased physician participation in prescribing buprenorphine exists, as only half of the 18,000 certified physicians routinely prescribe medication. Reuter E-mail, *supra* note 21. Nothing impedes the certification of additional physicians, although it is unclear whether significantly more physicians will receive certification absent more comprehensive medical school and residency education regarding addiction treatment. See *infra* Part II. The number of physicians obtaining the required DATA 2000 training dropped sharply between 2008 and 2009, raising speculation as to whether the interest level among currently licensed physicians has reached its capacity. Reuter E-mail, *supra* note 21.

24. Lynn E. Sullivan et al., *The Practice of Office-Based Buprenorphine Treatment of Opioid Dependence: Is It Associated with New Patients Entering Treatment?*, 79 DRUG & ALCOHOL DEPENDENCE 113, 114–16 (2005).

25. See Weinrich & Stuart, *supra* note 10, at 1346 (noting the avoidance of the stigma associated with attending methadone clinics as one of the advantages of receiving treatment from a primary care office); *infra* note 107 (discussing the strict pharmaceutical regime in specialty methadone clinics).

time may destigmatize addiction treatment itself.²⁶ The willingness of physicians to prescribe pharmacotherapies means that more individuals will access treatment at an earlier point in their disease and with fewer physical and mental complications.²⁷ Expansion of addiction treatment through mainstream medical treatment is essential to provide care to the more than 18 million individuals who need treatment for alcohol dependence, the 1.7 million individuals who need treatment for dependence on pain relievers, and the nearly 300,000 individuals who need treatment for heroin dependence.²⁸

The substantial human, health care, and social benefits of expanding the prescription of safe and effective pharmacotherapies for addiction treatment call for strategies to eliminate barriers to physician prescribing. An understanding of those barriers is the first step to expanding health care to millions of individuals who could benefit from effective pharmacotherapies. Part I sets out the historical and contemporary regulatory framework that has inhibited and, in some cases, prevented physicians from prescribing pharmacotherapies for addiction treatment.²⁹ Part II describes the failure of medical schools and residency programs to adequately train physicians about addiction, which deprives them of the skills, knowledge, and attitudes required to provide addiction treatment.³⁰ Part III identifies the compensation barriers that deter physicians from prescribing medications for addictions.³¹ The Article concludes with a very brief summary of systemic changes that will be required to fully recognize the promise of new medications.³²

I. THE CONTEXT: REMOVAL AND REGULATION OF PHYSICIANS IN ADDICTION TREATMENT

Federal regulation of physician prescription practices for narcotics treatment over the past century has shaped current medical practice. This regulation has essentially removed physicians from the delivery of addiction treatment, resulting

26. David A. Fiellin et al., *Methadone Maintenance in Primary Care: A Randomized Controlled Trial*, 286 JAMA 1724, 1725 (2001).

27. *See id.* (noting that pharmacotherapies plays an important role in treating those with opioid dependence and that office-based methadone maintenance would allow for greater access to treatment).

28. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., HHS PUB. NO. 09-4434, RESULTS FROM THE 2008 NATIONAL SURVEY ON DRUG USE AND HEALTH: NATIONAL FINDINGS 75 fig.7.2, 268 tbl.G.27 (2009), available at <http://oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.pdf> [hereinafter NSDUH]. In 2008, 23 million people needed treatment for an illicit drug or alcohol problem, but only 2.3 million received care in a specialized facility. *Id.* at 83.

29. *See infra* Part I.

30. *See infra* Part II.

31. *See infra* Part III.

32. *See infra* notes 176–85 and accompanying text.

in the development of specialized facilities that provide such care.³³ As the following brief history of the federal regulatory framework demonstrates, beginning around 1914 and running through most of the late-twentieth century, federal law prohibited the prescription of controlled substances for the treatment of narcotic addiction except by physicians working in highly regulated clinics.³⁴ These standards stigmatized medication-assisted treatment as well as the patients who received such care, and left generations of physicians unprepared to diagnose and treat patients with alcoholism and drug addiction.

A. Harrison Narcotics Act of 1914: Regulation of Physician Prescribing Practices

In the early twentieth century, the medical community viewed addiction as a medical problem, and physicians prescribed opioid medications for the care of addicted patients without legal restrictions.³⁵ Throughout the mid- to late-nineteenth century, physicians regularly prescribed patent medicines that contained morphine, cocaine and heroin.³⁶ Medicines used as possible “cures” for morphine, opium, and alcohol addiction also contained opiates, cocaine, and heroin,³⁷ and physicians prescribed such medications for the treatment and maintenance of addiction.³⁸ According to historian David Musto, the medical community was slow to recognize that physicians were overusing morphine, that addiction to heroin, morphine and cocaine was possible,³⁹ and that these substances should be reduced or removed from patent medicines.⁴⁰ Public health officers involved in the treatment of addiction at the turn of the century believed that physicians were indeed responsible for the majority of individuals who developed drug addictions.⁴¹

33. Fiellin & O'Connor, *supra* note 2, at 690–91. Over 13,600 specialized treatment facilities provide addiction treatment in the United States, and 8% of all facilities are OTPs that provide methadone or buprenorphine. N-SSATS, *supra* note 23, at 18–19 tbls.2.2 & 2.3. Over 80% of facilities provide outpatient treatment; 27% provide residential treatment in a non-hospital setting; and 7% provide inpatient hospital care. *Id.* at 19 tbl.2.3. Over 57% of these specialty facilities are operated by private non-profit organizations; 29% are private for-profit facilities; and approximately 12% are operated by local, state, or federal government. *Id.* at 18 tbl.2.2. Over 60% of these facilities focus primarily on substance abuse treatment services, and 29% have both substance abuse and mental health services. *Id.*

34. *See infra* Part I.A–B.

35. DAVID F. MUSTO, *THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL* 2–3 (3d ed. 1999).

36. *Id.*; *see also* *United States v. Jin Fuey Moy*, 241 U.S. 394, 402 (1916) (“[P]robably [a] very large proportion of citizens . . . have some preparation of opium in their possession . . .”).

37. MUSTO, *supra* note 35, at 3, 5.

38. *See id.* at 77–79, 97–120 (discussing early attitudes of physicians that addiction was curable, and various state and local methods of narcotics control).

39. *Id.* at 5. According to Musto, physicians themselves had one of the highest rates of addiction, and “[t]he profession was commonly believed to be one of the causes of most of the other addicts in the nation . . .” *Id.* at 64.

40. *Id.* at 5.

41. *Id.* at 98–100.

Responding to the development of a relatively large population of addicts and “a fear of addiction and addicting drugs,”⁴² Congress enacted the Harrison Narcotics Act of 1914.⁴³ The Harrison Act was a revenue bill that required physicians who prescribed preparations containing opium, cocaine, or their derivatives, to register, pay an annual tax, write prescriptions for such medicines, and maintain records of the patient and quantity of drugs dispensed.⁴⁴ The Act also established restrictions on the quantity of opiates and cocaine that could be contained in patent medicines.⁴⁵ The Act did not directly prohibit physicians from prescribing medicines containing opiates and cocaine, but it required prescriptions to be issued “in the course of his professional practice only” and limited a patient’s possession of these drugs to those that had been prescribed in “good faith” by a registered physician.⁴⁶ The primary goal of federal narcotics control officials, however, was to use the Harrison Act to stop physicians from both prescribing opiates and cocaine to individuals with addictions and maintaining such individuals on these drugs.⁴⁷

Although federal enforcement efforts to halt the prescription of narcotics to persons with addictions under the Harrison Act were rejected initially by the Supreme Court,⁴⁸ subsequent amendments to the Act strengthened the ability of the

42. *Id.* at 5.

43. Harrison Narcotics Act of 1914, Pub. L. No. 63-223, 38 Stat. 785, *repealed by* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801–971 (2006)).

44. *See, e.g.*, *United States v. Doremus*, 249 U.S. 86, 90–93 (1919) (stating the Harrison Act’s statutory requirements); *United States v. Jin Fuey Moy*, 241 U.S. 394, 399–400 (1916) (reiterating the statutory requirements).

45. MUSTO, *supra* note 35, at 60–61.

46. *Linder v. United States*, 268 U.S. 5, 13–14 (1925) (quoting the statute); *Webb v. United States*, 249 U.S. 96, 98–99 (1919) (noting the statutory requirements); *Jin Fuey Moy*, 241 U.S. at 400.

47. MUSTO, *supra* note 35, at 122–23.

48. *See Jin Fuey Moy*, 241 U.S. 394. The Supreme Court ruled that a physician could not be indicted under Section 8 of the Harrison Act for conspiring to prescribe morphine to a patient who is addicted to narcotics. *Id.* at 402. Federal officials asserted that Section 8 of the Harrison Act prohibited any individual who was not registered and did not pay the special tax to possess the prohibited substances, except to the extent the drug was prescribed “in good faith” by a registered physician. *Id.* at 399. The government further asserted that a drug prescribed to a patient addicted to opiates rather than for medicinal purposes was not prescribed “in good faith.” *Id.* The Court rejected the government’s broad assertion of police power that would “make the probably very large proportion of citizens who have some preparation of opium in their possession criminal,” and concluded that this provision only applied to the class of individuals who were required to register under the Act. *Id.* at 402. The Court also declined to interpret the parameters of “good faith” prescribing practices, ruling instead that the provision was so vague that it might have been intended to apply to persons other than the patient. *Id.*; *see also* MUSTO, *supra* note 35, at 126–27 (explaining that courts initially adopted the position that a patient could not be found to have violated the Act, as they were not subject to registration, and physicians were protected even if they prescribed for maintenance purposes as long as they had registered).

government to regulate physician practices and curtail addiction maintenance.⁴⁹ Social and cultural change, fueled by the war effort and intense nationalism following World War I, also increased public intolerance for alcohol and narcotic use and cast addiction as immoral.⁵⁰ According to Musto, by 1919, the country had denounced the maintenance of both alcoholics, via the ratification of the Eighteenth Amendment, and narcotic addicts, via robust enforcement of the Harrison Act.⁵¹

A series of Supreme Court decisions, starting in 1919, barred physicians from prescribing heroin and cocaine to patients with addictions, putting an end to medication maintenance of addiction. In *Webb v. United States*,⁵² the Supreme Court ruled that a physician's prescription for morphine that was given to "an habitual user" to "keep him comfortable by maintaining his customary use" rather than for purposes of attempting to "cure . . . the habit" was not a "prescription" within the protection of the Harrison Act.⁵³ In *United States v. Doremus*,⁵⁴ issued the same day as *Webb*, the Supreme Court upheld the indictment of a registered physician who had sold a large quantity of heroin to a patient who was addicted to narcotics without using the required prescription.⁵⁵ The Court also upheld the constitutionality of the Harrison Act as a tax measure that was intended to, among other things, prevent a non-registered patient from reselling narcotics without payment of the required tax.⁵⁶ In *United States v. Behrman*,⁵⁷ the Supreme Court ruled that a physician's prescription of large quantities of heroin, cocaine, and morphine to a patient who was known to be addicted did not fall into the physician's regular course of professional practice.⁵⁸ Although the Court recognized that physicians should be able to exercise their judgment in prescribing different doses of medication in individual cases, it concluded that the "enormous number of doses" prescribed to one patient "could only result in the gratification of a diseased appetite for these pernicious drugs or result in an unlawful parting with them to others in violation of the act"⁵⁹

As a result of these decisions, a physician was not permitted to prescribe such drugs, at least in large quantities, if drug addiction was the only disease being

49. MUSTO, *supra* note 35, at 130–31, 135–36. Among the amendments adopted in 1919 were the imposition of a tax on narcotics and requirement for stamped packages. *Id.* The latter requirement was intended to facilitate the prosecution of persons who possessed large quantities of drugs without a stamp. *Id.*

50. *Id.* at 132–34.

51. *Id.*

52. 249 U.S. 96 (1919).

53. *Id.* at 99–100.

54. 249 U.S. 86 (1919).

55. *Id.* at 92, 95.

56. *Id.* at 93–95.

57. 258 U.S. 280 (1922).

58. *Id.* at 287–89.

59. *Id.* at 288–89.

treated.⁶⁰ The heightened threat of prosecution deterred most physicians from providing care to patients with addictions, even if they prescribed within the legal limits.⁶¹

B. Narcotics Clinics: Early Model of Medication-Assisted Treatment of Opioid Addiction

The model for contemporary specialized medication-assisted treatment programs also originated during the first quarter of the twentieth century.⁶² Initially sympathetic to the health concerns of persons who had developed addictions, federal and state health officials and local law enforcement,⁶³ beginning around 1912, created maintenance clinics in a dozen states that would prescribe medication in an effort to prevent suffering related to addiction and wean individuals from their drug use through the gradual reduction of dosage. In Jacksonville, Florida, for example, the City health officer established a clinic in which persons with addictions could receive free narcotics prescriptions.⁶⁴ In Tennessee, persons with addictions were registered and given refillable opiate prescriptions to minimize suffering and reduce illegal drug trafficking.⁶⁵ In New York, a series of laws and policy directives enforced between 1913 and 1920 permitted maintenance of persons with addictions by private physicians; these measures also provided for increased regulation of physician practices, patient registration requirements, and the establishment of state-run narcotics clinics for both the maintenance and treatment of addiction.⁶⁶ With a narcotics clinic system in place, state narcotic

60. *But see* *Linder v. United States*, 268 U.S. 5 (1925). The Supreme Court in *Linder* recognized the right of physicians to prescribe “moderate amounts of drugs for self-administration in order to relieve conditions incident to addiction” without violating the Harrison Act. *Id.* at 22. The Court, emphasizing the limitations of the Harrison Act as a revenue measure, acknowledged that the federal government had no authority to exercise “direct control of medical practice in the [s]tates . . .” *Id.* at 18. The Court, reversing the physician’s conviction, concluded that he did not “transcend[] the limits of . . . professional conduct” by prescribing a small dose of morphine and cocaine to a patient with narcotic addiction to relieve pain resulting from stomach cancer or an ulcer. *Id.* at 16, 22–23. The Court also painted a more sympathetic view of patients with addictions as “diseased and proper subjects for such treatment,” *id.* at 18, at least to the extent they were not involved in the diversion of narcotics, *id.* at 22.

61. MUSTO, *supra* note 35, at 184–85. In 1970, in enacting legislation to repeal the Harrison Act, Congress noted that “[t]here are relatively few practicing physicians in the U.S. today who treat narcotic addicts because of the uncertainty as to the extent to which they may prescribe narcotic drugs for addict patients.” INST. OF MED., FEDERAL REGULATION OF METHADONE TREATMENT 123 (Richard A. Rettig & Adam Yarmolinsky eds., 1995) [hereinafter FEDERAL REGULATION OF METHADONE TREATMENT].

62. *See* MUSTO, *supra* note 35, at 97–98 (describing the innovation of the city drug clinic in Jacksonville, Florida in 1912).

63. *Id.* at 97–98, 151. Law enforcement recognized that maintenance clinics were effective in reducing crime. *Id.* at 168 (indicating that the clinic in Shreveport, Louisiana was supported by the federal District Court Judge, chief of police, and sheriff); *id.* at 177 (noting that clinics in New Haven, Connecticut were under the supervision of police surgeons who were paid for by the police department).

64. *Id.* at 97.

65. *Id.* at 100.

66. *Id.* at 102–20.

control officials intended to revoke the prescribing authority of physicians who refused to adhere to prescription limitations or dosages deemed to be consistent with “curing” addiction.⁶⁷ Federal and State officials also promoted institutionalized care to help patients withdraw from drugs,⁶⁸ even though that care proved relatively ineffective as patients could resume use by attending a narcotics clinic.⁶⁹

By 1920, federal officials had resolved to close maintenance clinics. The operation of clinics by local health departments was a continuing source of “legal” drug maintenance, which, by this time, was unlawful under *Webb* and *Doremus*.⁷⁰ Maintenance clinics also made enforcement of the Harrison Act against private physicians who abused prescription standards difficult, since both provided essentially the same care.⁷¹ Discouraged by the failure of maintenance clinics and hospitals to cure addiction, some public health officials had come to believe that elimination of drug availability was the best hope of a successful cure.⁷² Although not supported by evidence from the treatment provided in hospitals, some of the most ardent supporters of a medical model began to endorse abrupt withdrawal from narcotics.⁷³ The American Medical Association issued a resolution in 1920 opposing ambulatory maintenance clinics and condemning the use of heroin,⁷⁴ which sanctioned the further prosecution of physicians who continued to prescribe maintenance medication.⁷⁵

Federal and state initiatives to address addiction as a disease ended by the mid-1920s. All maintenance clinics were shuttered by 1925,⁷⁶ and the federal government adopted a supply-side strategy to eliminate drug addiction through strict law enforcement and international treaties.⁷⁷ Opiate and cocaine dependence

67. *Id.* at 116.

68. *Id.* at 141–42. Treasury Department officials envisioned a nationwide system of hospitals that would provide treatment to persons who would suffer from the abrupt denial of drugs through the increasingly strict enforcement of the Harrison Act. *Id.* at 141–43. Federal legislation was introduced in 1919 that would have provided federal matching funds to states that would establish and maintain hospitals. *Id.* at 143–44. The legislation, dependent on a hefty appropriation at a time of economic recession, failed to pass. *Id.* at 144, 155.

69. *Id.* at 119.

70. *Id.* at 119–20 (concluding that *Webb* and *Doremus* “essentially outlawed the maintenance of addiction and even the reduction method and ambulatory treatment”).

71. *Id.* at 149.

72. *Id.* at 144–46, 149, 162.

73. *Id.*

74. *Id.* at 148; Jaffe & O’Keeffe, *supra* note 8, at S3 (noting that by 1920 the AMA condemned prescribing opioids to addicts).

75. Jaffe & O’Keeffe, *supra* note 8, at S3.

76. MUSTO, *supra* note 35, at 173, 177.

77. *Id.* at 181–82.

were no longer considered a medical problem but rather a criminal justice issue.⁷⁸ This history “became part of the ‘lore’ that affected medical practice and research for almost 50 years and had a profound influence on government officials when the issue of narcotic maintenance again emerged in relation to methadone.”⁷⁹

C. Regulation of Methadone Maintenance Treatment: Resurrection of a Clinic-Based Model of Care to Prevent Drug Diversion

1. Physicians Barred from Prescribing Methadone for Treatment of Addiction in Office-Based Practice

The current regulatory scheme for medications that are approved to treat opiate addiction⁸⁰ continues to restrict physician practice and impose federal oversight that is unprecedented for the prescription of FDA-approved medications, including Schedule II drugs.⁸¹ The regulatory framework dates back to the 1960s when research conducted by Drs. Vincent Dole and Marie Nyswander determined that methadone, a synthetic opiate that had been used in the late 1950s for

78. Federal prisons became so overcrowded with drug-addicted prisoners by the 1920s that Congress enacted legislation that led to the establishment, in the mid-1930s, of two prisons in Lexington, Kentucky, and Fort Worth, Texas for the incarceration of narcotic addicts. *Id.* at 204–06. These prisons were run by the Public Health Services, with oversight by both the Justice Department and Federal Bureau of Narcotics, and were eventually turned into hospitals at which addiction treatment research was conducted. *Id.* at 205–06. Foreshadowing the importance of medications to treat opiate dependence, some of the initial studies concluded that less than ten percent of persons with chronic addictions were able to maintain abstinence after discharge from long-term treatment that offered only psychiatric care and counseling. FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 38.

79. FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 121.

80. The Harrison Act was repealed in 1970 with the enactment of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236. The 1970 Act addressed the “research, treatment, and prevention of drug abuse and dependence” as well as “drug abuse law enforcement authority.” See FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 123. One purpose of the Act was “to clarify for the medical profession . . . the extent to which they may safely go in treating narcotic addicts as patients.” *Id.* Title II of the Act was the Controlled Substances Act, which classified all substances under five schedules based on their abuse potential, psychological and physical effects, and medical uses. Tit. II, 84 Stat. at 1242–84 (codified at 21 U.S.C. §§ 801–971).

81. See Jaffe & O’Keeffe, *supra* note 8, at S5 (noting that clinicians have criticized federal regulations as “a burdensome interference with the practice of medicine”). Three layers of federal regulatory oversight by the FDA, Drug Enforcement Administration (DEA), and Department of Health and Human Services (formerly the Department of Health, Education and Welfare) governed the use of methadone for detoxification and maintenance treatment of opiate addiction for over 30 years. FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 135. As of 2001, the FDA transferred its oversight responsibility to the Substance Abuse and Mental Health Administration within the Department of Health and Human Services. Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. 4076, 4076 (Jan. 17, 2001) (codified at 42 C.F.R. pt 8). DEA’s oversight and registration requirements for physicians who seek to use methadone for the treatment of addiction remain in place. See *infra* note 95 (detailing registration and competency requirements for physicians who desire to dispense narcotic drugs in connection with addiction treatment).

detoxification treatment for heroin dependence,⁸² could be used as a maintenance medication to effectively treat heroin dependence.⁸³ Treatment centers, operating under Investigational New Drug applications issued by the FDA, began prescribing methadone for addiction treatment under the guise of research⁸⁴ and claimed exemption from the Federal Bureau of Narcotics' policies that still rendered the dispensing of opioids to addicts illegal.⁸⁵ In 1972, in response to the dramatic expansion of methadone treatment and concerns about the abuse and diversion of this medication, the FDA, in collaboration with the Special Action Office for Drug Abuse Prevention and the Bureau of Narcotics and Dangerous Drugs (the predecessor to the DEA), promulgated regulations⁸⁶ that authorized the use of methadone maintenance treatment under strict and close control to ensure safe distribution, administration, and dispensing.⁸⁷

The regulatory framework itself was antithetical to the integration of addiction treatment into mainstream medical practice: it restricted the availability of methadone to approved programs and hospital pharmacies,⁸⁸ and precluded private physicians from prescribing medication for addiction treatment unless they were approved as a "program" and met all requirements of the regulation including

82. FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 39. Methadone was also used in the late 1940s by the Lexington, Kentucky narcotic hospital as a treatment for opiate withdrawal syndrome, *id.* at 125–26, and had been approved by the FDA in 1947 for the treatment of pain, *id.* at 10.

83. *Id.* at 126.

84. *Id.* at 128.

85. Jaffe & O'Keeffe, *supra* note 8, at S4.

86. Approved New Drugs Requiring Continuation of Long-Term Studies, Records, and Reports; Listing of Methadone with Special Requirements for Use, 37 Fed. Reg. 26,790, 26,790 (Dec. 15, 1972) (codified at 21 C.F.R. pt. 130) (repealed by Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. at 4076).

87. FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 123, 132.

88. 21 C.F.R. § 130.44(b)(1)(i), (iii) (1973); FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 130. According to Dr. Jerome Jaffe, the Director of the Special Action Office for Drug Abuse Prevention in 1972, the drafters of these regulations did not "intend for medication dispensing to be forever limited to a few large clinics. Although they recognized that access to treatment by individual physicians might temporarily be limited, they believed that the regulations would be revised as knowledge expanded and as opioid maintenance treatment became less controversial." Jaffe & O'Keeffe, *supra* note 8, at S5. The future model would be one in which individual practitioners would be linked to pharmacies and other sites that would be authorized to dispense drugs for the treatment of addiction. *Id.* This model has never been realized in the United States, albeit implemented effectively in research settings. Fiellin et al., *supra* note 26, at 1725–26, 1729. It is also a well-established model of care in the United Kingdom and other countries. See Phillip O. Coffin et al., *Support for Buprenorphine and Methadone Prescription to Heroin-Dependent Patients Among New York City Physicians*, 32 AM. J. DRUG & ALCOHOL ABUSE 1, 5 (2006) (describing pharmacy practices to dispense methadone in Scotland and Australia); Jennifer McNeely et al., *Office-Based Methadone Prescribing: Acceptance by Inner-City Practitioners in New York*, 77 J. URB. HEALTH 96, 101 (2000) (describing the "shared care" system of care in the United Kingdom in which addiction specialists support a network of primary care physicians caring for methadone patients).

staffing requirements.⁸⁹ The regulations also dictated who would be eligible for methadone treatment (based on an individual's age and duration of drug dependence), maximum initial doses, minimum amount of counseling, urinalysis testing, and the factors used to determine a patient's eligibility for non-supervised administration of ("take-home") medication.⁹⁰ These standards not only usurped individualized medical determinations for patient care but also institutionalized a stigma surrounding patients in methadone treatment. Patients were required to obtain care in separate, free-standing programs and to take their medication on a daily basis under directly observed administration for substantial periods of time.⁹¹ States were also authorized to impose additional restrictions on patients who participated in methadone treatment.⁹²

Two years later, Congress enacted the Narcotic Addict Treatment Act of 1974,⁹³ which was intended to complement the FDA regulations and clamp down further on what Congress considered to be inappropriate prescribing practices by physicians.⁹⁴ This Act amended the Controlled Substances Act to require annual registration of practitioners and treatment sites with the Drug Enforcement Administration (DEA)⁹⁵ and authorized the DEA to regulate the storage and security of drugs used to treat addiction.⁹⁶

89. § 130.44(b)(1)(iv), (d)(4) (requiring one physician, two nurses, and four counselors for every 300 patients). Under the regulations, a methadone treatment "program" was required to provide comprehensive services including counseling, rehabilitation, and other social services, such as vocational and educational guidance and employment placement in addition to dispensing methadone. *Id.* § 130.44(b)(1)(ii); see FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 130. A program was required to obtain approval from the FDA and a state-based authority, § 130.44(c)(4), and approval was contingent on DEA approval of the physical site at which the medication would be dispensed and certification of compliance with the Controlled Substances Act. *Id.* § 130.44(c)(5); FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 130. These standards effectively precluded physicians not affiliated with a treatment program from prescribing the medication.

90. § 130.44(d); Jaffe & O'Keeffe, *supra* note 8, at S4.

91. § 130.44(d)(7)(i). Patients were required to take medication under direct observation for at least six days a week for a three-month period; those who demonstrated substantial progress in rehabilitation and could demonstrate that daily attendance interfered with employment, education, or home-making responsibilities were eligible for a two-day, take-home supply of medication. *Id.* A three-day, take-home supply was not offered until the patient had participated successfully in treatment for two years. *Id.* No patient was afforded a week's supply of take-home medication until he or she had participated successfully in treatment for three years. Fiellin et al., *supra* note 26, at 1726.

92. Jaffe & O'Keeffe, *supra* note 8, at S5. Four states—Montana, Wyoming, South Dakota, and North Dakota—have no certified opioid treatment programs. U.S. GOV'T ACCOUNTABILITY OFFICE, Pub. No. GAO-09-341, METHADONE-ASSOCIATED OVERDOSE DEATHS: FACTORS CONTRIBUTING TO INCREASED DEATHS AND EFFORTS TO PREVENT THEM 6 n.13 (2009) [hereinafter METHADONE-ASSOCIATED OVERDOSE DEATHS]. Five other states—Idaho, Mississippi, New Hampshire, Vermont, and West Virginia—have instituted programs since 2001. Saxon & McCarty, *supra* note 5, at 122.

93. Pub. L. No. 93-281, 88 Stat. 124 (1974) (codified as amended at 21 U.S.C. § 823(g)(1) (2006 & West Supp. 2009)).

94. FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 134–35.

95. *Id.* Under the Controlled Substance Act, a physician who seeks to dispense narcotic drugs for maintenance treatment or detoxification must obtain a separate DEA registration for such purpose.

2. Regulatory Revision But Rejection of Opportunities for Physician Office-Based Practice

This federal regulatory framework for methadone maintenance treatment remained in place for thirty years, notwithstanding recommendations to dramatically revamp the standards so that patients would have greater access to this effective medication for opiate addiction. In 1995, the Institute of Medicine (IOM) concluded that “no compelling *medical* reason [exists] for regulating the therapeutic use of methadone differently from any other Schedule II controlled substance.”⁹⁷ It found that the regulations had deprived society of reaping the full benefit of methadone as an effective treatment for addiction and preventative measure for other public health problems and crime.⁹⁸ According to the IOM, the extraordinary regulatory controls had prevented some individuals from obtaining treatment tailored to their needs; prevented doctors from exercising professional judgment in treating patients; and resulted in the isolation of treatment programs from mainstream medical practice.⁹⁹ The IOM recommended, among other things, that the regulations be reduced in scope, supplemented by clinical practice guidelines that shift responsibility for treatment decisions from regulators to clinicians,¹⁰⁰ and provide for maintenance treatment outside of a licensed treatment program.¹⁰¹

Long-overdue revisions to the federal methadone regulations, promulgated in 2001, have moved in the direction of a clinical practice model by instituting an accreditation and certification scheme for programs,¹⁰² but do little to encourage or enable physicians to establish an office-based model for dispensing methadone. The Department of Health and Human Services (HHS) rejected recommendations to develop standards that would permit physicians to prescribe methadone in office-

§ 823(g)(1). Registration is contingent upon an HHS finding that the physician is qualified under its regulatory standards; the DEA determining that the physician will comply with security standards for storing narcotic drugs and record-keeping requirements; and HHS finding that the physician will comply with standards related to the amount of narcotic permitted to be given to a patient for unsupervised use (i.e. take-home medication). *Id.*

96. Jaffe & O’Keeffe, *supra* note 8, at S5.

97. FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 219.

98. *Id.* at 30–31.

99. *Id.* at 31.

100. *Id.* at 221, 204. The IOM was particularly critical of the arbitrary restrictions on physician and clinical practice in the context of dictating the length of treatment and limiting take-home medication for the sole purpose of controlling diversion. *Id.* at 220.

101. *Id.* at 204.

102. Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, 66 Fed. Reg. 4076, 4076 (Jan. 17, 2001) (codified at 42 C.F.R. pt. 8). OTPs are required to obtain accreditation from a national body that evaluates the program’s compliance with federal opioid treatment standards, 42 C.F.R. § 8.4(a) (2009), and certification from the Substance Abuse and Mental Health Services Administration. *Id.* § 8.11(a)(2). Certification is based on the OTP obtaining accreditation and demonstrating compliance with programmatic standards and any other conditions. *Id.*

based settings without affiliation with an opioid treatment program (OTP), citing “the lack of trained and experienced practitioners to diagnose, admit, and treat opiate addicts who are not sufficiently stabilized without the support of an OTP.”¹⁰³ Although a physician could theoretically seek accreditation and certification for an office-based practice, the cost associated with satisfying these requirements make it impractical for a physician who is not associated with an existing program to do so.¹⁰⁴ The regulations instead seek to gradually increase treatment capacity in office-based practices by authorizing “medical maintenance” of stabilized patients who, after two years of continuous treatment, may be permitted to have a one-month supply of medication¹⁰⁵ and may be referred to physicians who maintain formal arrangements with OTPs.¹⁰⁶ Apart from this limited expansion, the current regulations reduce, albeit not substantially, the restrictions on patient attendance requirements and take-home (unsupervised) medication privileges.¹⁰⁷ The federal regulations continue to weight the risk of diversion¹⁰⁸ as more salient than clinical judgment, individualized patient care, and strategies to encourage patients to enter treatment earlier in the course of their addiction.¹⁰⁹

Nearly a decade later, modification of federal regulatory standards to reduce barriers to office-based methadone practice seems unlikely. A sharp increase in methadone-related overdose deaths, dating from 2002, linked to the increased availability of methadone for pain management from private physicians,¹¹⁰ has

103. 66 Fed. Reg. at 4079. The Department also cited the current DEA regulations, which do not permit registrants to prescribe narcotics for addiction treatment, as a regulatory standard that barred this model. *Id.*

104. Jaffe & O’Keeffe, *supra* note 8, at S7; *see also* 66 Fed. Reg. at 4079 (noting comments that accreditation and certification would be “prohibitively expensive for individual physicians”).

105. § 8.12(i)(3)(vi).

106. 66 Fed. Reg. at 4079; § 8.11(h) (setting out a process whereby the OTP may seek an exemption from any programmatic standard, including permitting a private physician to treat a limited number of patients without satisfying certain staffing and service standards).

107. Patients are allowed a single take-home dose for a day the clinic is closed and must demonstrate compliance with treatment, stability in home environment, and an absence of criminal activity and drug and alcohol use to be eligible for additional take-home medication. § 8.12(i)(1)–(2). Patients deemed eligible for unsupervised administration of medication are restricted to one additional take-home dose during the first ninety days of treatment; two additional doses per week for the next three months; three additional doses per week for up to nine months; and a maximum six-day supply for the remainder of the first year in treatment. *Id.* § 8.12(i)(3). Patients must participate in treatment continuously for one year before receiving a two-week, take-home supply of medication. *Id.* The IOM recommended a far more generous take-home schedule after the first three months of treatment, with medical maintenance beginning after one year in treatment. FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 199–200.

108. § 8.12(i) (stating that “take-home” standards are designed “[t]o limit the potential for diversion of opioid agonist treatment medications to the illicit market”).

109. *See* FEDERAL REGULATION OF METHADONE TREATMENT, *supra* note 61, at 200 (outlining the therapeutic value of a more flexible take-home medication policy).

110. METHADONE-ASSOCIATED OVERDOSE DEATHS, *supra* note 92, at 18–24 (finding that a “[l]ack of knowledge about [methadone’s] unique pharmacological properties among practitioners” who

resulted in a call by some in Congress for increased regulation of prescription practices for methadone.¹¹¹ Addiction treatment experts, undoubtedly wary of a backlash to advances in office-based care for individuals with histories of opiate dependence,¹¹² have urged caution in imposing new regulations, which would deter the use of beneficial medications.¹¹³ They instead recommend that private physicians follow patient-centered practices that include understanding a patient's history of alcohol and drug use, adjusting care management for patients with substance use histories, and implementing practices to ensure that patients store medications securely, use prescribed medications appropriately, and are monitored for diversion.¹¹⁴

D. Federal Regulation of Buprenorphine: Opportunity to Provide Addiction Treatment in Office-Based Settings

The enactment of DATA 2000 and the FDA's approval of buprenorphine for office-based practices in 2002 have increased access to opioid addiction treatment in a range of health care settings.¹¹⁵ Keenly aware of the history regarding addiction maintenance in the 1920s, the limited scope of medical education related to addiction treatment, and the regulatory strictures and stigma associated with methadone maintenance treatment, the federal government and the manufacturer of buprenorphine have taken important steps to ensure appropriate prescription practices while expanding access to office-based care. They have developed

prescribe methadone for pain "and [their] patients as well as abuse of diverted methadone . . . have contributed to" the rise of methadone-associated deaths; and reporting that the increase in deaths tracked to the increase in methadone used for pain managements rather than its use in OTPs); see also Aron J. Hall et al., *Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities*, 300 JAMA 2613, 2616–17 (2008) (in study of overdose pharmaceutical deaths in West Virginia, 56% of decedents had not been prescribed the drugs; 63% of deaths associated with pharmaceutical diversion; and 21% with "doctor-shopping").

111. See Methadone Treatment and Protection Act of 2009, S. 754, 111th Cong. (2009) (calling for increased federal oversight of methadone as used in treatment of pain and addiction, including amendment of the Controlled Substances Act to require a sixteen-hour training program for practitioners to be registered to prescribe methadone or other opioids; establishment of dosing standards for pain management and addiction treatment and benchmark standards for reduction of methadone abuse; and elimination of unsupervised take-home medication for patients when OTP is closed for business).

112. METHADONE-ASSOCIATED OVERDOSE DEATHS, *supra* note 92, at 25. S. 754 would impose additional restrictions on methadone treatment programs, even though the GAO, in its report requested by the sponsor of the bill, found virtually no relationship between the increase of methadone-associated deaths and OTP prescription and security practices. *Id.* at 19–20, 22–23.

113. A. Thomas McLellan & Barbara Turner, *Prescription Opioids, Overdose Deaths, and Physician Responsibility*, 300 JAMA 2672, 2672 (2008) (responding to Hall and colleagues, *supra* note 110, prior to McLellan becoming the current Deputy Director for Demand Reduction, Office of National Drug Control Policy).

114. *Id.* at 2673.

115. See *supra* notes 18–28 and accompanying text.

clinical practice guidelines,¹¹⁶ risk management strategies,¹¹⁷ and physician education and on-going clinical support¹¹⁸ with a cadre of physician-leaders.¹¹⁹ Anticipating reluctance among physicians to prescribe buprenorphine for addiction treatment out of fear of disciplinary actions, the federal government has encouraged the Federation of State Medical Boards to develop a model policy guideline that recommends physicians assess all patients for substance abuse and sets out guidelines for prescribing buprenorphine consistent with legitimate medical purposes.¹²⁰ The federal government publicizes the growing number of certified physicians and maintains a web-based physician locator to aid individuals who are seeking care.¹²¹ It has also funded a range of demonstration projects to evaluate best practices in providing office-based care.¹²² Finally, whenever evidence of diversion of buprenorphine has emerged, federal and state officials have responded quickly¹²³ to prevent the most drastic of regulatory solutions—rescheduling

116. *E.g.*, CTR. FOR SUBSTANCE ABUSE TREATMENT, U.S. DEP'T OF HEALTH & HUMAN SERVS., DHHS PUB. NO. 04-3939, CLINICAL GUIDELINES FOR THE USE OF BUPRENORPHINE IN THE TREATMENT OF OPIOID ADDICTION: A TREATMENT IMPROVEMENT PROTOCOL (TIP) SERIES 40 (2004), *available at* http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf [hereinafter TIP 40].

117. *See, e.g.*, Letter from H. Westley Clark, Dir., Ctr. for Substance Abuse Treatment (Apr. 3, 2006), *available at* <http://buprenorphine.samhsa.gov/CompoundingandSellingBuprenorphine.pdf> (indicating that Reckitt-Benckiser Pharmaceuticals, Inc. administers a comprehensive Risk Management Program designed to reduce the risks and consequences of the diversion of buprenorphine).

118. *See, e.g.*, Letter from H. Westley Clark, Dir., Ctr. for Substance Abuse Treatment (Jan. 13, 2006), *available at* <http://buprenorphine.samhsa.gov/LocatorDisclosureRequest.pdf> (describing a Physician Clinical Support System, established under the Center for Substance Abuse Treatment, to provide a national mentoring network for physicians treating opioid dependence).

119. *See infra* Part II for a discussion of the importance of leaders within the medical profession to encourage adoption of new medical practices and pharmacotherapies.

120. FED'N. OF STATE MED. BDS. OF THE U.S., INC., MODEL POLICY GUIDELINES FOR OPIOID ADDICTION TREATMENT IN THE MEDICAL OFFICE (April 2002), *available at* http://www.fsmb.org/pdf/2002_grpo_Opioid_Addiction_Treatment.pdf ("Qualified physicians need not fear disciplinary action from the Board or other state regulatory or enforcement agency for appropriate prescribing, dispensing or administering approved opioid drugs in Schedules III, IV, or V, or combinations thereof, for a legitimate medical purpose in the usual course of opioid addiction treatment.").

121. Substance Abuse & Mental Health Servs. Admin., U.S. Dep't of Health & Human Servs., Buprenorphine Physician and Treatment Program Locator, http://buprenorphine.samhsa.gov/bwns_locator/index.html (last visited Feb. 19, 2010).

122. *See, e.g.*, Kresina et al., *supra* note 22, at 16 (identifying the conclusion of a five-year project by the Health Services and Resources Administration to study the integration of buprenorphine treatment into HIV primary care).

123. For example, in 2006, the Substance Abuse and Mental Services Administration responded to reports of diversion and abuse of buprenorphine by commissioning an independent assessment of the problem. *See* JBS INT'L, INC., DIVERSION AND ABUSE OF BUPRENORPHINE: A BRIEF ASSESSMENT OF EMERGING INDICATORS (Nov. 30, 2006), *available at* http://buprenorphine.samhsa.gov/Buprenorphine_FinalReport_12.6.06.pdf. The report concluded that diversion and abuse were concentrated in certain geographic regions and primarily involved attempts to self-medicate with buprenorphine when formal treatment was not available as well as some illegal importation from outside the United States. *Id.* at 1. Maryland's health department responded to a highly critical newspaper series on buprenorphine, which highlighted medication diversion, *see, e.g.*, Fred Schulte & Doug Donovan,

buprenorphine as a Schedule II controlled substance—that would reverse the gains that have been achieved through office-based practice.¹²⁴

Regulatory¹²⁵ and non-regulatory obstacles—some of which are the collateral consequences of the past century’s restrictions on medical practice—continue to limit access to buprenorphine in an office-based practice. In late 2009, speculation surfaced about the DEA’s desire to suppress the number of physicians who prescribe buprenorphine when the enforcement agency informed DATA 2000 waiver practitioners of its plans to inspect their practices.¹²⁶ For many, the DEA’s action reflected its “reputation among some doctors for choosing heavy-handed enforcement over patient needs—along with a perceived hostility toward buprenorphine and other opiate-replacement therapies”¹²⁷ Treatment experts observed that DEA’s actions could have a chilling effect on family practitioners and internal medicine specialists who have been encouraged to embrace the treatment, but may grow tired of “all of the challenges one needs to surmount to prescribe buprenorphine.”¹²⁸

Although the buprenorphine experience is promising, it may be too early to tell whether the “use of buprenorphine in office based settings will . . . lead the United States to a more pragmatic attitude towards dealing with the consequences of heroin addiction—and [whether] that . . . pragmatism will be long lasting

The “Bupe” Fix, BALT. SUN, Dec. 16, 2007, at 1A, available at http://articles.baltimoresun.com/2007-12-16/news/0712160063_1_heroin-abuse-addicts, by requiring local jurisdictions to implement diversion control plans. STATE OF MD. DEP’T OF HEALTH & MENTAL HYGIENE, STATEWIDE BUPRENORPHINE INITIATIVE: DIVERSION CONTROL PLAN (Jan. 2, 2008), available at http://www.maryland-adaa.org/content_documents/BupInitiativeWeb/BupGuidelines.pdf.

124. See Jaffe & O’Keeffe, *supra* note 8, at S10–11. If rescheduled as a Schedule II controlled substance, buprenorphine would be subject to the same restrictions as methadone, limiting its availability to OTPs. *Id.* One field director for Reckitt Benckiser regularly warns that “[t]he future of buprenorphine for the treatment of opioid addiction rests in the hands of current prescribers.” E-mail from Anthony Tommasello, Field Med. Advisor, Reckitt Benckiser Pharm., Inc., to Ellen Weber, Professor of Law, Univ. of Md. Sch. of Law (Dec. 21, 2009) (on file with author).

125. For example, under DATA 2000, physicians are the only “practitioners” authorized to prescribe buprenorphine. 21 U.S.C. § 823(g)(2)(A), (B)(i) (2006 & West Supp. 2009). Permitting mid-level practitioners who are otherwise authorized to prescribe medications, such as physician assistants and nurse practitioners, to prescribe buprenorphine under supervision could expand care generally and facilitate integrated treatment for HIV and opioid dependence. See Kresina et al., *supra* note 22, at 16 (noting the potential benefit of expanded prescribing capabilities); Bruce R. Schackman et al., *Overcoming Policy and Financing Barriers to Integrated Buprenorphine and HIV Primary Care*, 43 CLINICAL INFECTIOUS DISEASES (SUPP. 4) S247, S252 (2006) (calling for the creation of demonstration projects to evaluate supervised distribution by mid-level practitioners).

126. Bob Curley, *DEA Letter Sparks Fears About Intimidation of Buprenorphine Docs*, JOIN TOGETHER, Oct. 1, 2009, <http://www.jointogether.org/news/features/2009/dea-letter-sparks-fears-about.html>.

127. *Id.* (reporting that DEA officials have denied that they are discouraging the use of buprenorphine and claim the inspections are merely intended to carry out their regulatory responsibilities).

128. *Id.* (reporting that the July 24, 2009 letter informed practitioners that they could exit the DATA 2000 program by filling out a form and, thereby, avoid inspection).

...¹²⁹ An examination of the three other obstacles to physician prescribing practices may shed more light on those prospects and the work that remains to be done to reap the full benefits of pharmacotherapies for addiction treatment.

II. COMPETENCE AND COMFORT: THE EFFECT OF LIMITED MEDICAL SCHOOL EDUCATION AND CLINICAL TRAINING IN ADDICTION MEDICINE

The historical failure of medical schools and residency programs to provide adequate instruction in addiction and training in addiction medicine¹³⁰—a direct consequence of the Harrison Act—undermines the capacity and willingness of physicians to prescribe pharmacotherapies.¹³¹ The exposure many medical students and residents get to individuals with drug dependence, particularly in urban teaching hospitals, is to those with active addiction rather than persons successfully participating in treatment.¹³² Seeing these individuals at their worst reinforces perceptions that these patients do not do well and are unmotivated to recover,¹³³ and does little to promote positive attitudes about caring for this population.¹³⁴ Medical education in addiction is further handicapped by the limited number of physician role models across clinical disciplines with expertise in addiction who

129. Jaffe & O’Keeffe, *supra* note 8, at S11.

130. Norman S. Miller et al., *Why Physicians Are Unprepared to Treat Patients Who Have Alcohol- and Drug-Related Disorders*, 76 ACAD. MED. 410, 410, 413 (2001) (reporting that the average four-year medical school devoted a total of twelve hours of curricular time to alcohol and drug use disorders); Saxon & McCarty, *supra* note 5, at 122 (noting that, after the 1920s, physicians were discouraged from treating heroin-dependent persons and medical school curricula provided no training in this area); Schackman et al., *supra* note 125, at S248 (attributing the limited education and clinical experience in addiction medicine to the separation of medical and substance abuse treatment); Joyce C. West et al., *Challenges in Increasing Access to Buprenorphine Treatment for Opiate Addiction*, 13 AM. J. ON ADDICTIONS S8, S13 (2004) (“[M]ost medical residency training programs have historically not included training related to the treatment of opiate addiction . . .”).

131. See *supra* discussion accompanying notes 103 (lack of trained physicians cited by HHS as rationale for rejecting office-based prescribing of methadone), 110 (failure of practitioners to understand pharmacotherapy of methadone has contributed to overdose deaths among patients prescribed the drug for pain management), and 114 (advising physicians prescribing pain medications to identify patients with histories of alcohol and drug problems).

132. Interview with Dr. Christopher Welsh, Assoc. Prof. of Psychiatry, Univ. of Md. Sch. of Med., in Baltimore, Md. (Oct. 27, 2008) [hereinafter Welsh Interview].

133. John N. Chappel, *Medical Education in Substance Abuse: The Acquisition of Knowledge, Attitudes, and Skills*, in SUBSTANCE ABUSE: A COMPREHENSIVE TEXTBOOK, 1269, 1276 (Joyce H. Lowinson et al. eds., 4th ed. 2005).

134. *Id.* at 1276–78 (discussing the complex basis of negative attitudes about patients with alcohol and drug use disorders, and concluding that “the best results, in terms of positive attitudes and skills, occur when residents rotate through addiction treatment units and are supervised by experts in addiction medicine . . .”); see also Schackman et al., *supra* note 125, at S248 (describing Seattle’s methadone medical maintenance treatment program in which generalist physicians were trained to provide methadone treatment to stable patients and given expert clinical support as questions arose, and noting that training resulted in physician satisfaction and more positive attitudes toward methadone treatment).

can ensure that future generations of physicians develop the requisite attitudes, skill, and knowledge needed to treat patients with addictive diseases.¹³⁵

As a result, many physicians do not understand the biological underpinning of addiction, which would promote the prescribing of effective medications,¹³⁶ or consider addiction a treatable medical condition¹³⁷ or, at least, one that they should address.¹³⁸ Others view addiction pharmacotherapies as more difficult to prescribe than other medications they routinely prescribe and manage for patients.¹³⁹ The stereotypical views of addicts that permeate society generally also affect physicians who respond by not wanting patients with addictions in their offices.¹⁴⁰

135. Miller et al., *supra* note 130, at 410; *see also* Chappel, *supra* note 133, at 1278, 1283–84 (indicating that role models from the student or physician’s clinical discipline have the greatest impact on attitudes); D. Dwayne Simpson, *A Conceptual Framework for Transferring Research to Practice*, 22 J. SUBSTANCE ABUSE TREATMENT 171, 173 (2002) (noting the importance of organizational leadership in adopting new technologies); Weinrich & Stuart, *supra* note 10, at 1346–47 (concluding that the physician leadership in Scotland has been critical to expanding office-based methadone treatment).

136. *See, e.g.*, Mark et al., *supra* note 8, at 225 (“Physicians who had read more about naltrexone and were more confident in their knowledge of [the medication] . . . prescribed it more often.”).

137. TIP 49, *supra* note 2, at 45; *see also* West et al., *supra* note 130, at S14 fig.1 (identifying physician values and beliefs that affect diffusion of buprenorphine treatment, including stigma and negative attitudes towards opiate addiction and its treatability; negative attitudes towards pharmacological treatment of addiction; lack of training in addiction; and perception of addiction as a medical problem).

138. *See* Chinazo O. Cunningham et al., *Attending Physicians’ and Residents’ Attitudes and Beliefs About Prescribing Buprenorphine at an Urban Teaching Hospital*, 38 FAM. MED. 336, 337 (2006). A study of primary care/social medicine residents and attending physicians at six ambulatory clinics associated with an urban university teaching hospital revealed that 83% cared for patients who use heroin or misuse opioid prescriptions, but only 74% were comfortable discussing illicit drug use and only half were comfortable discussing drug treatment. *Id.* The majority reported caring for patients with substance use disorders by referring them to social workers, counselors, or drug treatment programs. *Id.* Only 38% believed primary care physicians should prescribe buprenorphine, and 36% reported interest in prescribing. *Id.* A survey of New York City physicians immediately prior to FDA approval of buprenorphine, found that 36% would consider prescribing methadone and 26% would consider prescribing buprenorphine if the medications were picked up at a pharmacy. Coffin et al., *supra* note 88, at 3–4. The survey also revealed that 45% of respondents would not prescribe methadone and 42% would not prescribe buprenorphine. *Id.* In a post-DATA 2000 study of psychiatrists to assess comfort in prescribing buprenorphine, over 80% reported they *would not* be comfortable participating in office-based treatment, even though this specialty has a greater proportion of patients who suffer from opiate addiction. West et al., *supra* note 130, at S9–10.

139. Saxon & McCarty, *supra* note 5, at 126. *Contra* TIP 49, *supra* note 2, at 45–46 (discussing treatment experts view that initiating pharmacotherapy for alcoholism is no more difficult than beginning to prescribe an anti-depressant or anti-hypertensive medication, and that monitoring these medications is less difficult than medication regimens for diabetes and coronary disease).

140. YNGVILD OLSEN ET AL., TREATING OPIOID ADDICTION IN OFFICE BASED SETTINGS: FINDINGS FROM A PHYSICIAN SURVEY 10–11 (2004), *available at* <http://www.healthmaryland.org/pdf/2004%20Physician%20Survey.pdf> (reporting in a survey of Maryland physicians that half of the physicians who were unwilling to prescribe buprenorphine “believed that opioid addiction treatment is beyond the scope of practice for an office-based physician,” that patients with addiction do not want to change their habit, and that having opiate addicted patients in their offices is undesirable); Saxon & McCarty, *supra* note 5, at 123 (citing physician perceptions of addiction patients as “drug seeking, demanding, manipulative, irresponsible, and respond[ing] poorly to

A second “comfort” factor related to patient medical characteristics emerges among physicians who are willing to prescribe pharmacotherapies for persons with opiate addictions. This patient population often presents multiple medical and psychosocial needs that make their care more difficult than that of the average patient.¹⁴¹ Maryland physicians engaged in office-based buprenorphine treatment report that patient care requires increased time and attention to address the patient’s psychosocial and behavioral issues as well as third-party payer reimbursement obstacles.¹⁴² Patients often present with a need for immediate treatment because they are in withdrawal and the detoxification process affects office staff and other patients.¹⁴³ Patients with co-occurring, psychiatric disorders may not be appropriate for primary care practices and may require care from a psychiatrist.¹⁴⁴

Physician resistance and negative attitudes are not intractable, however. Physicians in the United States have shown that they can treat other complex and stigmatized disorders, such as depression and HIV, with appropriate training, clinical experience, guidance, and effective pharmacotherapies.¹⁴⁵ The same is true in the addiction context. Research has shown that physicians who have experience providing primary care to patients who were known to participate in methadone treatment express a far greater willingness to prescribe medication in an office-based setting.¹⁴⁶ Other studies have concluded that substantial majorities of primary care physicians are willing to prescribe buprenorphine if provided appropriate training and support.¹⁴⁷

treatment”); West et al., *supra* note 130, at S14 fig. 1 (identifying perceived risks that affect physician adoption of buprenorphine, including desirability and complexity of population and concerns about patients in office not responding to the medication).

141. McNeely et al., *supra* note 88, at 100–01; *see also* CTR. FOR A HEALTHY MD., INC. & MEDCHI, MD. STATE MED. SOC’Y, IMPROVING PATIENT ACCESS TO BUPRENORPHINE TREATMENT THROUGH PHYSICIANS OFFICES IN MARYLAND: SUMMARY OF FINDINGS, RECOMMENDATIONS, AND ACTION STEPS 4 (2007), available at <http://www.healthymaryland.org/pdf/Improving%20Patient%20Access%20for%20Bup%20Treatment.pdf> (summarizing that physicians certified to prescribe buprenorphine reported that the behavioral and psychosocial factors associated with addiction make addiction treatment different from other diseases) [hereinafter CTR. FOR A HEALTHY MD.].

142. *Id.* at 4–5; *see also infra* Part III (discussing the cost of care in office-based practice).

143. CTR. FOR A HEALTHY MD., *supra* note 141, at 4, 6.

144. *See, e.g.*, Nat’l Guideline Clearinghouse, Mental Health Disorders Among Substance-Using HIV-Infected Patients 6, 8 (2008), http://www.guideline.gov/summary/pdf.aspx?doc_id=12276.

145. Fiellin & O’Connor, *supra* note 2, at 691.

146. *See* OLSEN ET AL., *supra* note 140, at 8 (indicating that 36% of physicians were willing to prescribe buprenorphine to an established patient with opioid dependence compared to 28% of physicians willing to prescribe to a new patient); McNeely et al., *supra* note 88, at 99 tbls. II, III (reporting that among a sample of physicians, 99% of whom had provided care to a patient who participated in a methadone treatment program, 70% were comfortable managing the care of a drug user and 66% would prescribe medication if given proper training and support).

147. Cunningham et al., *supra* note 138, at 337–38 (finding that 72% of resident and attending physicians ambulatory clinics in New York would be willing to prescribe buprenorphine if given appropriate training and support, and citing similar results in studies of directors of primary care and HIV clinics and pharmacists).

The federal government has stepped in to provide a short-term antidote to inadequate medical school training and physician role models. The Substance Abuse and Mental Health Services Administration has published detailed treatment guidelines on the diagnosis of alcoholism and drug dependence and use of pharmacotherapies,¹⁴⁸ and Congress has mandated education in the case of buprenorphine.¹⁴⁹ As part of a pre-DATA 2000 study, the National Institute on Drug Abuse funded a team of expert physicians to recruit and train physicians in several states to prescribe buprenorphine in an office-based practice and demonstrated feasibility and physician satisfaction.¹⁵⁰ A federally-funded Physician Clinical Support System now exists to provide mentoring in the use of pharmacotherapies.¹⁵¹ Nonetheless, the long-term solution for adequate training is for “the medical education system . . . to support mechanisms that develop appropriate practice patterns by physicians and allow for increased training and experience in caring for . . . [alcohol and drug dependent] patients.”¹⁵²

International models offer possible strategies that would assist physicians in treating patients who present greater psychosocial and behavioral needs. The United Kingdom has implemented a “shared care” model that links general practitioners with drug counselors and public health workers who consult on difficult patients, review practices, and help resolve problems.¹⁵³ Physicians are already required, under DATA 2000, to have the capacity to refer patients for appropriate counseling and other ancillary services,¹⁵⁴ but office-based physicians may also require assistance internally.¹⁵⁵ Overcoming the historical separation between the primary care and specialty treatment systems and creating functional relationships between the two (as opposed to a one-way referral system) will be essential under a shared care model.

148. See, e.g., TIP 49, *supra* note 2, at xii (stating that the goal of TIP 49 is to “provide[] the basic information, evidence- and consensus-based guidelines . . . necessary to help health-care practitioners treat patients with [alcohol use disorders]”); TIP 40, *supra* note 116, at viii (“The goal of this TIP [40] is to provide information that physicians can use to make practical and informed decisions about the use of buprenorphine to treat opioid addiction.”).

149. See *supra* note 21. Physicians must first have the motivation to obtain the training and apply for certification to prescribe buprenorphine.

150. Saxon & McCarty, *supra* note 5, at 124–25.

151. See *supra* note 118.

152. Fiellin & O’Connor, *supra* note 2, at 691; see also Welsh Interview, *supra* note 132 (noting that residents will gain exposure to office-based buprenorphine only through physicians who are certified to prescribe).

153. McNeely et al., *supra* note 88, at 101 (describing the United Kingdom’s experience); Weinrich & Stuart, *supra* note 10, at 1346 (describing Scotland’s experience).

154. 21 U.S.C. § 823(g)(2)(B)(ii) (2006 & West Supp. 2009).

155. See Alexander Y. Walley et al., *Office-Based Management of Opioid Dependence with Buprenorphine: Clinical Practices and Barriers*, 23 J. GENERAL INTERNAL MED. 1393, 1396 (2008) (“[P]roviders adding [office-based opioid treatment] with buprenorphine to one’s practice require[] increased administrative and clinical resources.”).

III. COMPENSATION: BARRIERS TO COVERING THE COST OF CARE IN AN OFFICE-BASED PRACTICE

Physicians must be assured of adequate compensation if they are to offer medication-assisted treatment in their office-based practice.¹⁵⁶ Unlike the French health insurance program, which completely subsidizes office-based buprenorphine treatment,¹⁵⁷ physicians in the United States must contend with a wide range of commercial and public (i.e., Medicaid and Medicare) insurance plans that restrict patient access to care and physician reimbursement.¹⁵⁸ Compensation issues affect the willingness to offer this service even among those physicians who are inclined to prescribe pharmacotherapy for persons with addictions.¹⁵⁹

Addiction treatment in the United States has suffered historically from a lack of parity in insurance coverage.¹⁶⁰ Insurance plans routinely impose treatment limitations and financial requirements on addiction benefits that are not only different from the coverage for other medical conditions but also fail to recognize that addiction is a chronic medical condition.¹⁶¹ Thus, plans restrict the number and frequency of office visits and increase the amount of patient co-payments as treatment is extended.¹⁶² These underwriting practices impede the delivery of office-based care that requires a longer (and perhaps indefinite) duration of treatment for optimal outcomes and more intensive services at various times to

156. Saxon & McCarty, *supra* note 5, at 126 (observing that physicians are unlikely to actively seek addiction patients unless they receive financial incentives equal to those for other patients); Interview of Dr. Jerome Jaffe, Clinical Professor, Univ. of Md. Sch. of Med., in Baltimore, Md. (Oct. 27, 2008) (explaining that the treatment of patients with addictions must add value to a physician's practice and that reimbursement is not adequate for care of patients with buprenorphine).

157. Carrieri, *supra* note 10, at S199.

158. See Saxon & McCarty, *supra* note 5, at 123 (discussing the “[s]ocial, economic, and political forces . . . [that] work against more widespread use and delivery of addiction treatments,” including limited government and private funding sources).

159. OLSEN ET AL., *supra* note 140, at 9, 17 tbl.3 (reporting that among physicians willing to prescribe buprenorphine, adequate reimbursement ranked as item of greatest need).

160. Saxon & McCarty, *supra* note 5, at 123. The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), effective October 2009, may begin to address some insurance barriers. Pub. L. No. 110-343, § 512, 122 Stat. 3881 (codified as amended in scattered sections of 26, 29, 42 U.S.C.). The MHPAEA prohibits different or separate treatment limitations and financial requirements for substance use and medical/surgical benefits in most commercial and Medicaid managed care policies. 26 U.S.C.A. § 9812(a)(3)(A) (West Supp. 2009); 29 U.S.C.A. § 1185a(a)(3)(A) (West Supp. 2009); 42 U.S.C.A. § 300gg-5(a)(3)(A) (West Supp. 2009). The MHPAEA does not require health insurance plans to provide coverage for addiction treatment or medications, and parity requirements only apply to the extent the policy offers coverage for substance use disorders. *E.g.*, 26 U.S.C.A. § 9812(a)(1)(A), (2)(A).

161. A. Thomas McLellan et al., *Drug Dependence, A Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation*, 284 JAMA 1689, 1694 (2000); see also Heilig & Egli, *supra* note 2, at 856 (discussing alcohol dependence as a chronic relapsing disease); Saitz et al., *supra* note 1, at 55 (discussing drug and alcohol dependence from a chronic disease management perspective).

162. *Cf.* A. Thomas McLellan et al., *supra* note 161, at 1693–94 (supporting insurance parity initiatives that do not limit the number and frequency of office visits covered).

address relapse. In addition, reimbursement rates often do not compensate adequately for the intensity of the service that must be provided to patients who require counseling for their psychosocial needs.¹⁶³

Insurance coverage for medication is a separate and often complicated issue. Insurance plans may or may not include medications for alcoholism and opioid dependence in their formularies,¹⁶⁴ and those that do may impose restrictions on the long-term use of costly medications like buprenorphine and naltrexone.¹⁶⁵ A patient's ability to cover the cost of these medications out-of-pocket over the long term can be cost-prohibitive, can lead to patient compliance problems,¹⁶⁶ and has been identified as a factor that affects physician prescribing decisions.¹⁶⁷

Some insurance plans also impose prior authorization requirements for medication reimbursement—a common insurance practice, but one that is uniquely incompatible with the need to deliver immediate care to a patient in the throes of opioid withdrawal in the doctor's office.¹⁶⁸ Any delay in the delivery of medications can result in patient distress and the risk of adverse medical outcomes, or the patient being lost to treatment.¹⁶⁹ Satisfying preauthorization requirements for current patients who need to refill prescriptions can also consume substantial time.¹⁷⁰ Private physicians, who already contend with reimbursement restrictions and high patient volume under managed care contracts, must have adequate administrative staff to address these insurance issues alone.¹⁷¹

A physician's reluctance to provide medication-assisted treatment in the highly variable insurance context is understandable, particularly when balancing the needs of this patient population against the physician's existing patients.¹⁷² Some physicians attempt to work around low reimbursement rates and other insurance barriers by requiring patients to pay directly for physician services instead of billing the patient's insurance plan.¹⁷³ This administrative solution clearly excludes or inappropriately shortens the length of care for those without

163. CTR. FOR A HEALTHY MD., *supra* note 141, at 9.

164. Schackman et al., *supra* note 125, at S249 (reporting that every state Medicaid program but two include buprenorphine in their formularies, although state Medicaid programs may impose separate restrictions, and that, as of 2006, buprenorphine was not listed on model guidelines for Medicare prescription drug benefits).

165. CTR. FOR A HEALTHY MD., *supra* note 141, at 5.

166. *Id.*

167. Mark et al., *supra* note 8, at 226 (“Physicians ranked cost [of naltrexone] as the second most common reason . . . [for] not prescrib[ing] . . . to more patients.”).

168. CTR. FOR A HEALTHY MD., *supra* note 141, at 5.

169. *Id.*

170. *Id.*

171. Welsh Interview, *supra* note 132.

172. See CTR. FOR A HEALTHY MD., *supra* note 141, at 5–6 (noting that physicians are required to make practice management decisions regarding buprenorphine because of the substantial burden imposed on the health care provider by patients and insurers).

173. *Id.* at 5.

adequate resources.¹⁷⁴ These administrative burdens and reimbursement barriers may also result in physicians limiting the number of patients with opioid dependence who they are willing to treat.¹⁷⁵

National health care reform, if enacted, may begin to address some of the systemic compensation barriers. Both the Senate- and House-passed bills would require the coverage of substance use disorders in the essential benefit package and require enforcement of the current Mental Health Parity and Addiction Equity Act standards in individual, small group, and large group plans.¹⁷⁶ Equitable health care coverage is necessary to address an obstacle that will restrict office-based practice even if physician training improves.

CONCLUSION

The continuing role of law enforcement in shaping the public's perception of persons with alcohol and drug addiction, and the addiction treatment system itself, will undoubtedly result in slow and cautious advances in the use of pharmacotherapies for addiction.¹⁷⁷ The diffusion of addiction medications in physician office-based practices will depend upon ongoing research that documents the safe and effective use of medications outside of heavily regulated or specialty care settings and satisfaction by both physicians and patients.¹⁷⁸ Evidence-based research may be the most effective response to overly aggressive enforcement efforts that deem diversion the primary harm to be addressed.

Progress must also occur simultaneously on several different health care fronts. Medical schools and residency programs must do more to educate all physicians about addiction, the need for universal screening of alcohol and drug use disorders, and the evidence-based options for managing this chronic disease.¹⁷⁹ The medical profession and specialty addiction treatment system must develop more seamless relationships so that physicians can obtain timely and effective support when caring for patients with addiction.¹⁸⁰ Health insurance plans must structure benefit coverage for substance use disorders in a way that will facilitate treatment under a chronic disease model and reimburse physicians adequately for labor-

174. *See id.* (noting the concern of physicians that patients' inability to pay will cause them to decrease dosages before they are ready).

175. *See id.* at 6 (indicating that a number of physicians "were unsure if they would increase the number of patients [that] they treat" due to "[t]he intensity of demand on physicians from both patients and payers . . .").

176. Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 222 (2009) (benefit); § 214(b) (parity); Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. § 1302 (2009) (benefit); § 1311(j) (parity).

177. *See supra* Part I.

178. *See supra* notes 18–28 and accompanying text.

179. *See supra* Part II.

180. *See supra* notes 151–55 and accompanying text.

intensive, office-based services.¹⁸¹ Persons with substance use disorders and their families must advocate for more accessible, readily available, and less stigmatizing treatment options.¹⁸² Finally, policymakers must begin to incorporate harm reduction strategies in our drug policies, just as we use various tools to reduce the harmful consequences of smoking, alcohol use, and other public health problems.¹⁸³ Medication use in office-based practices is an important harm reduction strategy that will likely increase access to treatment in the United States and “demonstrate what can be achieved by easier and less stigmatizing access” to care.¹⁸⁴ Although these efforts all involve paradigm shifts, they are long over-due and are necessary to reduce the toll of addiction in the United States.¹⁸⁵

181. *See supra* Part III.

182. *See supra* notes 25–26 and accompanying text.

183. *See supra* notes 10–17 and accompanying text.

184. Jaffe & O’Keeffe, *supra* note 8, at S11.

185. *See supra* note 28 and accompanying text.