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Richard C. Boldt
rboldt@law.umaryland.edu

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INTRODUCTION: OBSTACLES TO THE DEVELOPMENT AND USE OF PHARMACOTHERAPIES FOR ADDICTION

RICHARD C. BOLDT*

More than a decade ago, Dr. Alan Leshner, then the Director of the National Institute on Drug Abuse, undertook a campaign in which he and other leaders in the addictions field sought to educate policy makers and the public generally about the significant neurophysiological components of drug use disorders. Oversimplifying, as public policy campaigns often do, Leshner asserted that “addiction is a brain disease.”¹ In fact, as Professor Richard J. Bonnie explained in his Stuart Rome Lecture, delivered on November 7, 2008 as part of a Symposium organized by the University of Maryland School of Law’s Law & Health Care Program on *Obstacles to the Development and Use of Pharmacotherapies for Addiction*, alcohol and other drug use disorders involve not only neurophysiological processes but also prominent “behavioral and contextual” features.² These behavioral and contextual components, which Bonnie characterized as “substantial,”³ are important because the conduct that makes up drug use disorders is not produced in a purely reflexive manner by the brain but instead is “mediated through consciousness.”⁴

Although the initial use of alcohol or other drugs often is voluntary, the continued ingestion of some of these substances can lead to physical dependency. An individual who is physically dependent may experience tolerance, which is the need for increasing amounts of the drug in order to achieve a consistent effect, and may suffer physical symptoms of withdrawal if administration of the drug is suspended.⁵ Most diagnostic schemes require symptoms beyond tolerance and

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* Professor of Law, University of Maryland School of Law (Baltimore, MD).

1. Alan I. Leshner, *Addiction Is a Brain Disease, and It Matters*, 278 SCI. 45 (1997).

2. Richard J. Bonnie, *The Virtues of Pragmatism in Drug Policy*, 13 J. HEALTH CARE L. & POL’Y 7, 20 (2010).

3. Indeed, Professor Bonnie suggested that the behavioral and contextual components of addiction are “much more substantial . . . than in Alzheimer’s disease, Parkinson disease, epilepsy, or schizophrenia.” *Id.*

4. *Id.* at 22.

5. A. Thomas McLellan et al., *Drug Dependence, A Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation*, 284 JAMA 1689, 1690–91 (2000); see also Editorial, *Symptoms in Chronic Morphine Induced by Withdrawal of the Drug*, 62 JAMA 1662, 1663 (1914)

withdrawal, however, in order for a substance use disorder diagnosis to be made.⁶ These additional symptoms, particularly relating to the presence of a persistent desire or craving for the substance, its continued use despite substantial social, legal, or physical costs, and the like, also have a neurobiological basis. This is because the continued heavy use of alcohol and other drugs brings about significant structural changes in areas of the brain that are critical to judgment, learning, and behavior control.⁷ As Professor Bonnie explained, “due to neurobiological processes deep in the brain over which the addict no longer has any control, he is experiencing a strong need for or desire for substance, and . . . this need is so great that it is unlikely that he will be able to resist it.”⁸ The difficulty for policy makers, however, is that these cravings are operationalized through the decision-making machinery that ordinarily marks individuals as responsible agents.

Mindful that drug use disorders are complex phenomena that involve physiological, environmental, and behavioral elements, Professor Bonnie used the occasion of his Rome Lecture to urge a middle position between, on the one hand, understanding addiction solely as willful misconduct,⁹ and, on the other, conceiving of it as entirely beyond the reach of the criminal enforcement system. Instead, he urged the development of a “stable, and essentially pragmatic, drug policy that avoids the ideologically driven positions that have for so long dominated policy discourse”¹⁰ Such a pragmatic policy, he explained, would serve to increase the use of those medications that are already available to treat drug use disorders, and, in the process, encourage the development of new pharmacotherapies for addiction.¹¹

Clinicians have long understood that alcohol and other drug use disorders are chronic relapsing conditions, and that relapse has both biological and behavioral features.¹² In light of this understanding, a number of experts have urged the development of a comprehensive treatment system to provide care across a variety

(“The sudden withdrawal of [morphine] does not result merely in negative symptoms, but often produces such intense misery and depression as to indicate actual danger.”).

6. McLellan et al., *supra* note 5, at 1690.

7. PHYSICIANS & LAWYERS FOR NAT’L DRUG POLICY, ALCOHOL AND OTHER DRUG PROBLEMS: A PUBLIC HEALTH AND PUBLIC SAFETY PRIORITY 14 (2008), *available at* <http://www1.spa.american.edu/justice/document.php?ID=2434>.

8. Bonnie, *supra* note 2, at 22. The sustained use of alcohol and other drugs over time alters the way that neurons communicate. PHYSICIANS & LAWYERS FOR NAT’L DRUG POLICY, *supra* note 7, at 14. Some drugs activate neurons by “mimicking” the properties of naturally occurring neural transmitters, while others function to block neural transmitters by, for example, blocking the substances that normally clear the synapses or spaces between neurons. *Id.*

9. *See Traynor v. Turnage*, 485 U.S. 535, 552 (1988) (rejecting a challenge to the characterization by the Department of Veterans Affairs of primary alcoholism as “willful misconduct”).

10. Bonnie, *supra* note 2, at 7.

11. *Id.* at 30.

12. Leshner, *supra* note 1, at 45.

of levels and through a range of different treatment modalities. Importantly, this sort of comprehensive approach to substance abuse treatment would include both behavioral and pharmacological interventions.¹³ As things now stand, the range of treatment options available to those in need often is neither comprehensive nor readily available. Although medications are used regularly during the detoxification phase of substance abuse treatment to manage the physical symptoms of tolerance and withdrawal,¹⁴ there has been resistance among some treatment providers, policy makers, actors within the legal system, and others to the further use of pharmacotherapies to manage drug craving and maintain patients in recovery. This resistance has been fueled, in part, by a perspective that emphasizes the behavioral and contextual features of addiction, and that defines recovery as freedom from all drug dependency.¹⁵

Available medications for the treatment of opioid dependency include methadone, a synthetic opioid that functions as an “agonist” to activate receptors in the brain in order to limit the effect of heroin and prescription opioids; buprenorphine, a partial agonist also used in the treatment of opioid addiction; and naltrexone, an opioid “antagonist,” that blocks receptors in the brain so as to prevent users from obtaining the euphoric effects of heroin and other opioids.¹⁶ Methadone can be used as a short-term therapy or in a long-term maintenance regime. Used alone, methadone treatment is not a cure for opioid addiction, but the evidence clearly demonstrates that it is effective in improving treatment retention, decreasing relapse, and ameliorating the other social, legal, and medical problems often associated with illicit drug misuse.¹⁷ Methadone treatment is provided in specialized treatment facilities that are closely regulated and monitored by the federal government. Buprenorphine, by contrast, is available by prescription from primary care physicians and other physicians in more decentralized clinical settings. Prescribing doctors need not be addiction medicine specialists, although they must receive some specialized training and are subject to restrictions on the number of patients they can treat.¹⁸

13. McLellan et al., *supra* note 5, at 1693. The National Institute on Drug Abuse has developed a set of principles governing the effective treatment of addiction for persons in the criminal justice system. NAT’L INST. OF DRUG ABUSE, NAT’L INSTS. OF HEALTH, NIH PUB. NO. 06-5316, PRINCIPLES OF DRUG ABUSE TREATMENT FOR CRIMINAL JUSTICE POPULATIONS: A RESEARCH-BASED GUIDE 1-5 (2007), available at http://www.nida.nih.gov/PDF/PODAT_CJ/PODAT_CJ.pdf. Among the principles is that “[m]edications are an important part of treatment for many drug abusing offenders.” *Id.* at 5.

14. PHYSICIANS & LAWYERS FOR NAT’L DRUG POLICY, *supra* note 7, at 35.

15. *Id.* at 36.

16. *Id.* at 40-41.

17. Karen L. Sees et al., *Methadone Maintenance vs 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence: A Randomized Controlled Trial*, 283 JAMA 1303, 1309 (2000).

18. PHYSICIANS & LAWYERS FOR NAT’L DRUG POLICY, *supra* note 7, at 41.

As brain science has improved, potential new therapies, including new medications to assist in the management of drug craving reactions and to respond to the problem of relapse, are on the developmental horizon.¹⁹ Unfortunately, obstacles exist at each stage of the process by which new medications are developed, tested, approved, and distributed, to limit the availability and use of potentially effective pharmacotherapies, either alone or in conjunction with other modalities of treatment. Panelists at the November 7, 2008 Law & Health Care Program Symposium explored the impediments at each of these stages including those bearing on the decision making of the pharmaceuticals industry, the FDA approval process, and clinical trials. In addition, speakers took up the question of insurance obstacles and the reluctance of physicians to prescribe medications for addiction, and a special panel was devoted to the unwillingness of many decision makers within the criminal justice system to order the use of methadone maintenance therapy and other pharmacotherapies.

In addition to Professor Bonnie's Rome Lecture, two additional papers from the Symposium are included in this issue of the *Journal of Health Care Law & Policy*. The article by Professor James L. Nolan, Jr.,²⁰ draws upon ethnographic material he collected in preparing his recent book on problem-solving courts in the U.S., Scotland, Ireland, Canada, Australia, and England.²¹ Nolan reports that drug courts in each of the jurisdictions that he studied, other than the United States, rely on methadone maintenance as a "main staple" of the drug abuse treatment they provide.²² In the United States, by contrast, the majority of drug courts do not make use of methadone maintenance treatment or other pharmacotherapies.²³ In the case of the U.K., Nolan explains, the reliance on methadone and other pharmacotherapies is due to Britain's longstanding practice of according a leading role to physicians in the setting of drug policy and is consistent with the tradition of English doctors providing maintenance drugs for "stable addicts."²⁴ More broadly, he suggests that the different disposition toward the use of medications to manage addictions is due to a fundamental difference of perspective between those who direct drug courts in the U.S. and elsewhere. "The goal of most U.S. drug courts is 'total abstinence,' or what some have referred to as 'demand reduction.'"²⁵ In all of

19. See *Medications Development at NIDA*, TOPICS IN BRIEF (Nat'l Inst. on Drug Abuse, Nat'l Insts. of Health), July 2008, available at <http://www.nida.nih.gov/pdf/tib/MedicationsDev.pdf> (discussing research efforts at the National Institute on Drug Abuse to develop new addiction medications).

20. 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).

21. JAMES L. NOLAN JR., LEGAL ACCENTS, LEGAL BORROWING: THE INTERNATIONAL PROBLEM-SOLVING COURT MOVEMENT (2009).

22. Nolan, *supra* note 20, at 39.

23. *Id.* at 36–37.

24. *Id.* at 39–40.

25. *Id.* at 36.

the other jurisdictions he examined, Nolan reports that the abstinence model has given way to a harm minimization approach. Under this approach the goals of the program are defined in terms of the reduced use of substances of abuse and reduced criminal offending, and treatment interventions are selected accordingly.²⁶

The article by Professor Ellen Weber²⁷ focuses on the failure of physicians in the United States to prescribe pharmacotherapies for the treatment of alcohol and other drug use disorders. Professor Weber asserts that this failure “goes to the heart of our nation’s failed drug policies.”²⁸ She catalogues the different reasons for the underutilization of medication-based therapies in the treatment of alcoholism and opioid dependence, stressing inadequacies in the medical training that physicians receive, the persistent stigma associated with those who suffer from addictions disorders, and the compensation barriers to the provision of effective treatment.²⁹ Professor Weber also discusses the tradition in the U.S. of providing alcohol and other drug abuse treatment services outside of primary care settings.³⁰ This failure to mainstream addictions diagnosis and treatment, which is exemplified by the highly segregated setting within which methadone treatment is made available, has served as an obstacle to the development of new therapies and has contributed to the underutilization of those medications that are available. “Succinctly stated,” states Professor Weber, “four interrelated factors—context, competence, comfort, and compensation—affect physician prescription practices in the United States.”³¹

The abuse of alcohol and other drugs is a serious health problem throughout the United States. An estimated 22.6 million Americans abuse alcohol and other drugs on a regular basis.³² The costs to individuals, families, and communities are enormous.³³ Neuroscientists have learned a great deal about how alcohol and other drugs of abuse work to “produce pleasure by activating a specific network of neurons called the brain reward system.”³⁴ Researchers have also gained new insights into how neurophysiology interacts with genetic susceptibility and environmental factors in the case of individuals with drug use disorders.³⁵ Given this understanding, it is clear that the use of medications—those already available and new pharmacotherapies that are only on the bench or in clinical trial—must be

26. *Id.* at 36, 38.

27. 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).

28. *Id.* at 51.

29. *Id.* at 69–75.

30. *Id.* at 55–66.

31. *Id.* at 51.

32. PHYSICIANS & LAWYERS FOR NAT’L DRUG POLICY, *supra* note 7, at 9.

33. *Id.* at 12.

34. SOC’Y FOR NEUROSCIENCE, BRAIN FACTS: A PRIMER ON THE BRAIN AND NERVOUS SYSTEM 36 (2008), available at http://www.sfn.org/skins/main/pdf/brainfacts/2008/brain_facts.pdf.

35. *Id.* at 37.

included in any effective and comprehensive response to this public health problem.